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Methodological framework for the systemic integration of environmental sustainability in the pharmaceutical industry

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« Science sans conscience n’est que ruine de l’âme. »

“Science without consciousness is nothing but the ruin of the soul.”

— François Rabelais

ABSTRACT

Environmental sustainability has become essential for the pharmaceutical industry, whose mission to improve human health increasingly conflicts with its environmental impacts. However, despite growing attention, sustainability efforts remain scattered, difficult to scale, and weakly embedded in product and process development. The research addresses this challenge by analyzing current approaches, identifying structural and organizational limitations, and clarifying the need for sector-specific frameworks. The central question focuses on how to structure the systemic integration of environmental sustainability in the pharmaceutical industry. Two hypotheses are formulated: first, that a structured Circular Economy strategy can enable the emergence and reinforcement of circular practices; and second, that systemic integration requires consolidating validated initiatives into repeatable practices and building organizational capabilities that support long-term adoption. The work follows the Design Research Methodology and combines literature review, empirical investigations, and experimental studies carried out within Sanofi. The results include a Circular Economy Integration Model and a sector-adapted strategy, evaluated through several collaborative projects. Building on these findings, a transition framework is developed to transform isolated environmental initiatives into systemic practices, demonstrated through applications such as a portfolio-level Life Cycle Assessment of insulin products and a methodology for developing environmental manufacturing guidelines. A capability model is then proposed to support the institutionalization of sustainability across functions, exemplified by the integration of eco-design practices into technology standards. Overall, the thesis provides a coherent set of models, methods, and integration pathways that address both strategic and operational dimensions of environmental sustainability. It shows how fragmented initiatives can evolve into systemic organizational capabilities and supports the broader transition toward more sustainable pharmaceutical development.

Keywords: Environmental sustainability; pharmaceutical industry; Circular Economy; systemic integration; Life Cycle Assessment; Eco-design; Capabilities; sustainability transition; manufacturing processes.

La soutenabilité environnementale constitue un enjeu stratégique pour l'industrie pharmaceutique, dont la mission de protection de la santé humaine entre en tension croissante avec ses impacts environnementaux. Malgré des avancées récentes, les initiatives demeurent souvent ponctuelles, difficiles à étendre et insuffisamment intégrées aux processus de développement des produits et des procédés. L'analyse des pratiques actuelles met en évidence des limites structurelles et organisationnelles, ainsi que la nécessité de cadres adaptés aux spécificités du secteur. La recherche s'articule autour d'une question centrale : comment structurer l'intégration systémique de la soutenabilité environnementale dans l'industrie pharmaceutique ? Deux hypothèses orientent le travail : (1) une stratégie d'Économie Circulaire structurée peut favoriser l'émergence et la consolidation d'initiatives circulaires ; (2) l'intégration systémique requiert la transformation d'initiatives éprouvées en pratiques reproductibles et le développement de capacités organisationnelles pérennes. La démarche suit la Design Research Methodology et combine revue de littérature, investigations empiriques et études expérimentales menées au sein de Sanofi. Les résultats incluent un modèle d'intégration de l'Économie Circulaire et une stratégie sectorielle évaluée à travers plusieurs projets collaboratifs. Un cadre de transition est ensuite proposé pour faire évoluer des initiatives isolées vers des pratiques systémiques, illustré notamment par une Analyse de Cycle de Vie à l'échelle d'un portefeuille d'insulines et par une méthodologie de développement de recommandations environnementales pour les procédés de fabrication. Enfin, un modèle de capacités organisationnelles est développé pour soutenir l'institutionnalisation de la soutenabilité, comme en témoigne l'intégration de l'éco-conception dans des standards technologiques. Cette thèse propose ainsi un ensemble cohérent de modèles, méthodes et leviers d'intégration permettant de transformer des actions fragmentées en véritables capacités organisationnelles, au service d'un développement pharmaceutique plus durable.

Mots clés : Soutenabilité environnementale ; industrie pharmaceutique ; économie circulaire ; intégration systémique ; analyse de cycle de vie ; éco-conception ; capacités ; transition ; processus et produits.

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LIST OF ACRONYMS

AI	Artificial Intelligence
ANSM	Agence Nationale de Sécurité du Médicament et des Produits de Santé
API	Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical
ATMP	Advanced Therapy Medicinal Product
BU	Business Unit
CDMO	Contract Development Manufacturing Organisations
CE	Circular Economy
CEIM	Circular Economy Integration Model
CHC	Consumer Healthcare
CMM	Capability Maturity Model
CIP	Cleaning In Place
CoP	Community of Practice
CSB	Corporate Sustainability Benefits
CSR	Corporate Social Responsibility
CTF	Circular Transition Framework
DfS	Design for Sustainability
DfX	Design for X
DR	Design Requirement
DRM	Design Research Methodology
DS-I	Descriptive Study I
DS-II	Descriptive Study II
DTM	Design Theories and Methodologies
EcoM2	Ecodesign Maturity Model
ED	Eco-design
EF	Environmental Footprint
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EMF	Ellen MacArthur Foundation
ES	Environmental Sustainability
ESG	Environmental, Social and Governance
FDA	Food and Drug Administration
FSSD	Framework for Strategic Sustainable Development
GBU	Global Business Unit
GDT	General Design Theory
GHG	Greenhouse Gas
GMP	Good Manufacturing Practices
HC	Healthcare
HCP	Healthcare Professional
ICH	International Council for Harmonization
IND	Investigational New Drug
IPCC	Intergovernmental Panel on Climate Change
ISO	International Organization for Standardization
KM	Knowledge Management
KPI	Key Performance Indicator
LCA	Life Cycle Assessment
LCM	Life Cycle Management
MCDM	Multi-Criteria Decision-Making
MCI	Material Circularity Indicator
MFA	Material flow Analysis
NAS	Novel Active Substance
NPD	New Product Development

OCM	Organizational Change Management
OCMS	Organizational change management for sustainability
OCS	Organizational Capabilities for Sustainability
OECD	Organization for Economic Co-operation and Development
OL	Organizational Learning
OPM3	Organizational Project Management Maturity Model
PCP	Patient Care Pathway
PDP	Product Development Process
PEF	Product Environmental Footprint
PLM	Product Lifecycle Management
PM9R	Pharmaceutical Manufacturing 9R
PMI	Process Mass Intensity
PS	Prescriptive Study
R&D	Research & Development
RC	Research Clarification
SbD	Sustainable by Design
SBT	Science Based Target
SC4CCM	Supply Chain for Community Case Management
SDG	Sustainable Development Goal
SIP	Sterilizing In Place
SLR	Systematic Literature Review
SME	Subject Matter Expert
SMI	Sustainable Markets Initiative
SOP	Standard Operating Procedure
SPD	Sustainable Product Development
SRQ	Sub-Research Question
TA	Therapeutic Area
TBL	Triple Bottom Line
UDT	Universal Design Theory
UN	United Nations
VSM	Value Stream Mapping
WHO	World Health Organization

GENERAL INTRODUCTION

Human activities are placing growing pressure on ecosystems and the global environment. These environmental burdens have been extensively documented through various scientific frameworks and are now considered among the most critical challenges of the 21st century(UNEP, 2012). At the core of this degradation lie unsustainable modes of production and consumption, underscoring the urgent need to transition toward cleaner production systems and more responsible consumption patterns, an imperative formalized in the United Nations' Sustainable Development Goals (SDGs), established in 2015 (e.g., SDG 12) (UN, 2015a).
Manufacturing industries play a central role in delivering value to societies worldwide. Yet, while they contribute to economic development and social well-being, they are also responsible for considerable environmental impacts (Mgbemene et al., 2016; Parry et al., 2025; Siekmann et al., 2023; Yuhuan et al., 2024). The severity of these impacts has been emphasized by the concept of planetary boundaries, six of the nine thresholds that define a safe operating space for humanity have now been exceeded (Richardson et al., 2023). Simultaneously, demographic projections from the United Nations anticipate continued global population growth: from 8.2 billion in 2024 to a peak of 10.3 billion in the 2080s (UN, 2024). These trends suggest that environmental pressures will only intensify in the coming decades.
Within this broader context, the pharmaceutical industry faces a fundamental paradox. Its primary mission is to improve human health through the development of medicines, vaccines, and therapeutic solutions, yet it also contributes significantly to environmental degradation (Moermond et al., 2025). The healthcare sector accounts for approximately 4.5% of global greenhouse gas (GHG) emissions (Eckelman et al., 2020), with pharmaceuticals responsible for around 15% of this footprint. Moreover, the pharmaceutical sector's emission intensity is estimated to be 55% higher than that of the automotive industry (Belkhir and Elmeligi, 2019). Environmental impacts go beyond GHG emissions: they include substantial ecosystem degradation (Aib et al., 2025; Wilkinson et al., 2022), rising waste generation (Kenny and Priyadarshini, 2021), and the increasing recognition of links between environmental pollution and public health risks (Ogden and Gachon, 2019).

This paradox, preserving both human health and the environment, presents a complex and urgent challenge for the sector (Mackenzie and Jeggo, 2019). The growing global population, highlighted by the UN (UN, 2024) , underscores the future difficulty of meeting healthcare needs, a challenge already made visible during the COVID-19 crisis. To ensure the continuity of pharmaceutical innovation and production, the sector must transition to more sustainable practices (K.L. Ang et al., 2021; SMI, 2025; Vilochani et al., 2025). Integrating environmental sustainability across the product lifecycle, from R&D to commercialization, is essential. Each medicine or vaccine carries an environmental burden, making it critical to act early in the development process.
For companies such as Sanofi, this implies embedding environmental considerations directly into how products are designed, developed, and manufactured. However, adoption of such practices remains limited. This is partly due to sector-specific challenges: high regulatory constraints, complex products and product development processes, and the involvement of numerous internal and external stakeholders (Moermond et al., 2025). As emphasized by Belkhir and Elmeligi (2019), integrating sustainability into the pharmaceutical sector is not only urgent but unavoidable, particularly as aging populations in developed countries drive increasing healthcare demands in the coming decades (Belkhir and Elmeligi, 2019).

In light of the environmental crisis, it is now widely accepted that our production and consumption systems are unsustainable. For the pharmaceutical industry, this creates a dual responsibility: it must continue to protect human health while actively reducing its environmental footprint. Sustainability is no longer optional, it is a prerequisite for ensuring operational resilience, maintaining access to resources, and fulfilling the industry's long-term mission. Aligning health objectives with planetary boundaries is not simply a strategic opportunity, it is an environmental necessity. This perspective aligns with the One Health principle that protecting human health requires safeguarding the environmental systems on which it depends (Brown et al., 2024).

To address their environmental impacts, pharmaceutical companies have progressively adopted various assessment and mitigation strategies. Early efforts focused on evaluating specific risks, notably through Environmental Risk Assessments (ERA), designed to assess the fate and effects of active pharmaceutical ingredients (APIs) in ecosystems (Luu, 2023a). In parallel, the emergence of products carbon footprint provided a first quantitative insight into climate-related impacts.

From the 1990s onward, the field of Green Chemistry emerged as a major lever for minimizing the environmental burdens of chemical synthesis. It laid the foundation for more proactive approaches in process design (Marco et al., 2019) . Yet, these methods often remain limited to specific stages of development or isolated production steps (Becker et al., 2022).
In recent years, more holistic approaches have gradually gained traction, offering a comprehensive lifecycle perspective. Concepts such as eco-design, with environmental Life Cycle Assessment (LCA), and Circular Economy (CE) have emerged as promising approaches or concepts for evaluating and improving the environmental performance of pharmaceuticals throughout their entire life cycle (K.L. Ang et al., 2021; Chen et al., 2024) . Among them, Design for Sustainability (DfS), which includes eco-design, highlights the pivotal role of product and process design in the broader sustainability transition (Ceschin and Gaziulusoy, 2016).

Despite the use of LCA and eco-design practices becoming more frequent in the pharmaceutical sector, their application remains largely limited and performed on an ad hoc basis (Chen et al., 2024; Emara et al., 2019; Jiménez-González and Overcash, 2014) . Most initiatives are isolated, with project-specific efforts, with limited cross-functional understanding or integration of life cycle thinking across the organization (Boscherini et al., 2010; Zils et al., 2023) . As a result, several challenges persist: (1) environmental sustainability is not yet systemically integrated within pharmaceutical organizations and their development processes (Klein et al., 2022; Lozano, 2008) ; (2) existing tools and methods are not always adapted to the complexity and constraints of pharmaceutical products and processes (EFPIA, 2020; Luu, 2023a); (3) operationalizing sustainability at scale remains difficult due to a lack of clear organizational pathways and shared frameworks (Pigosso et al., 2013; Uhrenholt et al., 2022; Vilochani et al., 2024) . These limitations form the foundation of this research. The purpose of this doctoral thesis is to support the integration of environmental sustainability practices into pharmaceutical product and process development, enabling a reduction in environmental impacts without compromising product safety, efficacy, or long-term value creation.

To address the challenges and stakes identified, this doctoral research is positioned at the intersection of multiple disciplines: engineering design, environmental sustainability, and pharmaceutical science. The work adopts both an interdisciplinary and transdisciplinary approach, recognizing the need to bridge technical, environmental, and industrial knowledge disciplines to enable actionable change. It was conducted through a collaborative partnership between Sanofi, a global pharmaceutical company, and the Laboratory of Product Design and Innovation (LCPI) at the Arts et Métiers Institute of Technology in Paris.

In this context, this doctoral thesis takes place within a research axis focused on integrating sustainability and environmental approaches into organizations. Based on the state of the art conducted on these scientific fields, the key challenges related to the integration of environmental sustainability include the fragmentation of existing approaches and initiatives, the limited scalability of efforts across the company, the absence of robust organizational mechanisms to embed sustainability into decision-making, and the need to develop capabilities that are aligned with both regulatory requirements and industrial constraints. Hence, this research aims to answer the following research question: *"How to structure the systemic integration of environmental sustainability in the pharmaceutical industry?".* The term systemic is used here in its general meaning, relating to the whole rather than to isolated parts, to emphasize that sustainability must be embedded across the overall organizational system.

Two hypotheses have been formalized to guide and support this research question.

The first focuses on the Circular Economy, which is increasingly recognized as a key approach for operationalizing sustainability by decoupling value creation from the consumption of finite resources (EMF, 2013a). CE has also gained momentum in the pharmaceutical sector as a lever for improving resource efficiency, reducing waste, and enabling new forms of collaboration across supply chains. The hypothesis suggests that a structured Circular Economy strategy, enabling internal and external collaboration and alignment, can foster the emergence and reinforcement of circular initiatives in the pharmaceutical sector, ultimately contributing to the reduction of environmental impacts across the organization.

To support this first hypothesis, two sub-research questions have been formulated based on the gaps identified:

- *SRQ1.1: What are the key elements of a Circular Economy strategy in the pharmaceutical sector, and how can they be effectively implemented?*

- *SRQ1.2: To what extent can a CE strategy be effectively applied in pharmaceutical contexts, and how do collaboration mechanisms influence its implementation and outcomes?*

The second hypothesis builds upon the first, extending beyond Circular Economy alone to address the broader challenge of systemic integration of environmental sustainability. It posits that integration can be achieved by consolidating validated environmental projects into systemic practices and by institutionalizing the sustainability strategy as enduring organizational capabilities. In doing so, the hypothesis highlights the need for mechanisms that transform fragmented initiatives into systemic practices, and for capability-building processes that embed sustainability durably across organizational functions.

Here again, two sub-research questions have been developed to support this hypothesis:

- *SRQ2.1: How can validated environmental projects be consolidated and standardized into practices that support systemic integration across pharmaceutical product and process development?*
- *SRQ2.2: How can the environmental sustainability strategy and its components be institutionalized across organizational functions to develop durable capabilities?*

These two hypotheses are explored through a combination of literature review, empirical data collection, and experimental work conducted within Sanofi. The research led to both theoretical and practical contributions. These aim to support the systemic integration of environmental sustainability in the pharmaceutical sector. The work follows the Design Research Methodology (DRM) (Blessing and Chakrabarti, 2009a), progressing through iterative phases of problem analysis, solution development, and validation.

In line with the DRM (Blessing and Chakrabarti, 2009a), the research begins by characterizing the context and identifying gaps through interviews, internal documentation analysis, and scientific literature review. This stage led to the definition of a CE integration model and a structured Circular Economy (CE) strategy adapted to the pharmaceutical context. The strategy includes dedicated performance indicators and a roadmap for implementation. These prescriptive elements were then confronted with real-world collaborative projects, such as take-back systems and recycling initiatives, enabling reflection on enablers and barriers to implementation and validation of the proposed strategic framework (supporting H1).
Building on these findings, further work was conducted to improve the positive impacts of existing projects and move from isolated projects to systemic practices. This includes a portfolio-level Life Cycle Assessment (LCA) of insulin products and the development of a practical methodology for environmental guidelines development for manufacturing processes. These initiatives, along with previous eco-design integration efforts, formed the foundation for deeper systemic integration. This was achieved through the development of a capability framework for environmental sustainability across key functions. As a direct result, and concrete example, of this systemic integration, eco-design practices were successfully embedded into manufacturing process development through their integration into “Technology Standards” through transdisciplinary collaboration (supporting H2).

Across these research phases, the work combines descriptive and prescriptive elements to propose actionable frameworks and integration pathways adapted to the specificities of pharmaceutical development. These results are presented in the following chapters and discussed in light of the research questions and broader scientific context.

The work conducted in the frame of this thesis is organized in four main phases:

- **Phase 1**: Presentation of the context, stakes, state of the art
- **Phase 2**: Problem formalization - Formalization of the Problematic from the findings from the literature and empirical data
- **Phase 3**: Experimental work – description of the work performed during the thesis, to test and validate the hypotheses.
- **Phase 4:** Discussion and contributions – synthesis of the contributions, limitations, and perspectives

These four phases are structured into seven chapters allowing for a better understanding of the reasoning followed during this thesis.

Chapter 1: Context, positioning and stakes of the work (Phase 1)
This chapter introduces the overall motivation and relevance of the thesis. It presents the environmental challenges associated with current production and consumption models, the paradox faced by the pharmaceutical industry, between preserving human health and contributing to environmental degradation, and the pressing need to align health objectives with sustainability imperatives. It then situates the research within its industrial (Sanofi), scientific (LCPI), regulatory, and socio-technical contexts, and concludes with a synthesis of the stakes that justify structured research on the systemic integration of environmental sustainability.

Chapter 2: State of the art (Phase 1)
This chapter reviews the relevant academic literature and theoretical frameworks. It introduces key concepts such as Design Science & Engineering, Design for Sustainability, or Circular Economy. It also analyzes how these concepts have been adopted, and sometimes overlooked, in the pharmaceutical sector and highlights structural, organizational, and methodological limitations. Particular attention is paid to the challenges of integrating environmental approaches within organizations and to systemic change. The chapter concludes with a gap analysis, which lays the groundwork for the formalization of the research problem.

Chapter 3: Research question, hypotheses and methodology (Phase 2)
The findings from the state of the art are synthesized into chapter 3 which formalizes the main research question structuring the doctoral thesis. Two hypotheses and their associated sub-research questions are introduced to address key challenges identified earlier. The chapter also presents the methodological approach used and details the research activities conducted throughout the thesis.

Chapter 4: Circular Economy Strategy and Collaborative Initiatives (Phase 3)
This chapter provides a response to Hypothesis 1 and addresses sub-RQs 1.1 and 1.2.

- Part A develops a structured Circular Economy strategy tailored to the pharmaceutical context. It presents a CE integration model (CEIM), performance indicators, and a roadmap. The work is grounded in interviews, literature, and internal documentation.
- Part B explores real-world collaborative projects (e.g., take-back systems, Single-Use Technologies remanufacturing, solvent recycling), using a case study approach. It analyzes their implementation, barriers, and alignment with the strategic model.

The synthesis compares theory and practice, outlining strengths and limitations, and stresses the need to move beyond isolated initiatives toward systemic integration.

Chapter 5: Systemic integration of Environmental Sustainability (Phase 3)
This chapter addresses Hypothesis 2 and sub-RQs 2.1 and 2.2.

- Part A presents two empirical projects that evolved from isolated efforts into systemic initiatives: a portfolio-level LCA for insulin products offering high-level insights across therapeutic platforms, and a methodology translating LCA results into environmental manufacturing guidelines.
- Part B focuses on embedding sustainability within the organization: It introduces a capability framework to evaluate and support systemic integration. As an outcome, a four-step process for integrating eco-design practices into technology standards is proposed and tested.

The synthesis shows how both case-based and organizational efforts jointly contribute to systemic change and validate H2.

Chapter 6: Contributions & Limits (Phase 4)
This chapter consolidates the results presented in Chapters 4 and 5 and revisits the main research question and hypotheses. It highlights the key contributions of the thesis from both industrial and academic perspectives. These contributions are discussed alongside their limitations, and the chapter provides a detailed synthesis of the formalization and evaluation work conducted.

Chapter 7: Conclusion and Perspectives (Phase 4)
Chapter 7 synthesizes the thesis results and recontextualizes them to highlight their contribution to the systemic integration of environmental sustainability. It also identifies open questions and research avenues that remain to be explored, aiming to further advance scientific understanding and industrial application in this field.

Résumé en français - Introduction générale

L'industrie pharmaceutique est confrontée à un paradoxe majeur : sa mission est d'améliorer la santé humaine, tout en générant des impacts environnementaux significatifs. Dans un contexte de dépassement des limites planétaires, de croissance démographique et d'augmentation des besoins en santé, elle doit concilier innovation thérapeutique et réduction de son empreinte environnementale. Cette transition est d'autant plus nécessaire que les enjeux environnementaux conditionnent désormais la résilience des systèmes de santé et la capacité du secteur à remplir durablement sa mission.

Au cours des dernières décennies, différentes approches ont été développées pour réduire ces impacts, telles que les évaluations des risques environnementaux, la chimie verte, l'éco-conception ou encore l'économie circulaire. Malgré ces avancées, leur mise en œuvre dans l'industrie pharmaceutique demeure souvent ponctuelle, limitée à certains projets ou étapes du développement, sans réelle intégration au sein des organisations. Les contraintes réglementaires, la complexité des produits et des procédés, ainsi que le manque de cadres organisationnels adaptés freinent leur déploiement à grande échelle.

Cette thèse s'inscrit à l'interface des sciences de l'ingénieur, de la soutenabilité environnementale et des sciences pharmaceutiques. Réalisée en partenariat entre Sanofi et le laboratoire LCPI des Arts et Métiers, elle vise à répondre à la question suivante : *comment structurer l'intégration systémique de la soutenabilité environnementale dans l'industrie pharmaceutique ?*

La recherche repose sur deux hypothèses complémentaires. La première étudie le rôle d'une stratégie d'économie circulaire structurée et collaborative comme levier de transformation. La seconde s'intéresse à la manière de transformer des initiatives environnementales isolées en pratiques organisationnelles pérennes, intégrées aux processus et aux capacités de l'entreprise.

S'appuyant sur la Design Research Methodology (DRM), cette recherche combine revue de littérature, études empiriques et expérimentations industrielles menées chez Sanofi. Elle aboutit au développement de modèles, méthodes et cadres d'intégration permettant de soutenir la transition de l'industrie pharmaceutique vers un développement plus durable, en conciliant exigences environnementales, industrielles et réglementaires.

La thèse s'organise en quatre phases décomposées en sept chapitres : le contexte et l'état de l'art (Chapitres 1-2), la formalisation de la problématique et de la méthodologie (Chapitre 3), le travail expérimental testant les deux hypothèses (Chapitres 4-5), et enfin la synthèse des contributions, limites et perspectives (Chapitres 6-7).

Chapter 1. Context & Motivations

Transitioning toward environmental sustainability is increasingly recognized as a key priority at global, industrial, and scientific levels. In the face of escalating environmental pressures, rising societal expectations, and expanding regulatory frameworks, organizations are being pushed to rethink how they create value, revisiting their strategies, processes, and products.

This chapter aims to position the present research within this broader context. It begins by introducing the main environmental challenges and existing conceptual frameworks shaping current debates on sustainable development. It then narrows the focus to the industrial context in which this thesis was conducted, highlighting the specificities of the pharmaceutical sector, and in particular, Sanofi, the industrial partner of this research.

The scientific context is then introduced, drawing on key principles from design sciences and sustainability research. The institutional environment in which the thesis was carried out is also presented. Finally, the chapter concludes by clarifying the main societal, industrial, and academic stakes of the research. The articulation of this multi-layered context provides the foundation for understanding the relevance, scope, and intended contributions of the work.

1.1. ENVIRONMENTAL CONTEXT

1.1.1. Human activities and environmental impacts

From early agriculture to urbanization and the industrial revolution, human development has profoundly transformed natural ecosystems at a planetary scale. Over time, human activities have become a dominant force of environmental change. These transformations take multiple forms, such as deforestation, land conversion, or infrastructure expansion, and generate widespread environmental impacts, including biodiversity loss, resource depletion, and climate change (Goudie, 2013). Today, there is no longer any ambiguity regarding the role of anthropogenic activities in environmental degradation (Markham, 2019; Takala, 1991). Human-induced pressures are responsible for the pollution of air, water, and soil, and are driving systemic disruptions such as climate change. These impacts are not isolated: they interact and accumulate, undermining ecosystem integrity and posing direct risks to public health (Edo et al., 2024).

In its most recent assessment, the Intergovernmental Panel on Climate Change (IPCC) presents a clear conclusion: human activities, primarily through greenhouse gas (GHG) emissions, have unequivocally caused global warming (Basu et al., 2023; Gaber et al., 2023; IPCC, 2023). These emissions stem from unsustainable energy and land use, as well as production and consumption patterns, across and within countries and socioeconomic groups (Sutherland et al., 2020). The result has been widespread adverse impacts on both nature and people, with escalating losses and damages (IPCC, 2023).
Although efforts to adapt have made some progress, they remain insufficient to offset the magnitude of current and projected impacts. Without transformative change, GHG emissions will continue to rise, leading to increasingly severe, and in some cases irreversible, consequences. Climate change and broader environmental degradation now pose critical threats to both human well-being and planetary health. Accelerated, equitable mitigation and adaptation efforts are therefore essential for sustainable development. As highlighted more than a decade ago, environmental pressures resulting from human activities remain among the most pressing challenges of the 21st century (UNEP, 2012).

Beyond unsustainable production and consumption patterns, demographic dynamics also play a crucial role in shaping environmental pressures. Global population growth, while uneven across regions, has significant implications for sustainable development. As the total population increases, so does aggregate demand for food, housing, infrastructure, healthcare, and other essential services, further intensifying the strain on natural resources and ecosystems (UN, 2023a). Although the global population is expected to peak around 10.3 billion by the mid-2080s before gradually declining (UN, 2024), many countries already experiencing rapid population growth face compounded economic, social, and environmental challenges. These include poverty, malnutrition, inadequate access to education and healthcare, and increasing vulnerability to climate change.

Rapid demographic expansion in these contexts amplifies environmental impacts and makes transitions to sustainable development pathways more difficult (UN, 2023b, 2021). This amplification occurs through increased aggregate demand for food, energy, housing, and infrastructure, which accelerates land use change, resource depletion, and pollution. These effects are especially pronounced in low-income regions with limited adaptive capacity. Additionally, research has shown that population growth interacts with other factors such as affluence and technology to intensify environmental burdens (Dietz and Rosa, 1994) , and that rising population density often correlates with greater environmental stress, particularly in developing nations (Pimentel and Pimentel, 2006). In fact, population growth tends to intensify the environmental consequences of economic activity. Higher living standards often correlate with increased energy use, resource extraction, and waste generation, making it even more critical to decouple development from environmental degradation. In this light, minimizing the environmental footprint of future population growth is a central challenge for global sustainability efforts.

1.1.2. Key frameworks for understanding environmental impacts

The major environmental challenges outlined in the previous section underscore the urgent need for prevention, mitigation, and systemic change to preserve a livable planet. Over the past decades, several conceptual frameworks have emerged to help scientists, policymakers, and citizens better understand the extent of human impacts on the Earth system and the pathways to sustainability. This section introduces a selection of key concepts that are particularly relevant to this thesis. While not exhaustive, they provide a useful overview of the environmental thinking and frameworks that currently shape our understanding of sustainability challenges and guide strategic responses.

One of the most influential among them is the Planetary Boundaries framework. Introduced by Rockström et al. (2009), it identifies nine critical Earth system processes, such as climate regulation, biodiversity, and biogeochemical flows, that are essential for maintaining the stability and resilience of the planet (Rockström et al., 2009). Each boundary represents a threshold beyond which the risk of irreversible and large-scale environmental change becomes significantly higher. This framework is grounded in the recognition that we have entered the Anthropocene, a new geological era where human activities have become the dominant force of planetary change. The Planetary Boundaries concept therefore aims to define a safe operating space for humanity, within which development can occur without destabilizing the Earth system (Rockström et al., 2009).
Since its introduction, the framework has been updated multiple times (Figure 1) (Persson et al., 2022; Richardson et al., 2023; Steffen et al., 2015). The most recent update in 2023 provided, for the first time, a full quantification of all nine boundaries, and revealed that six out of nine boundaries have now been transgressed, with increasing human pressure across most dimensions (Richardson et al., 2023; Rockström et al., 2024).

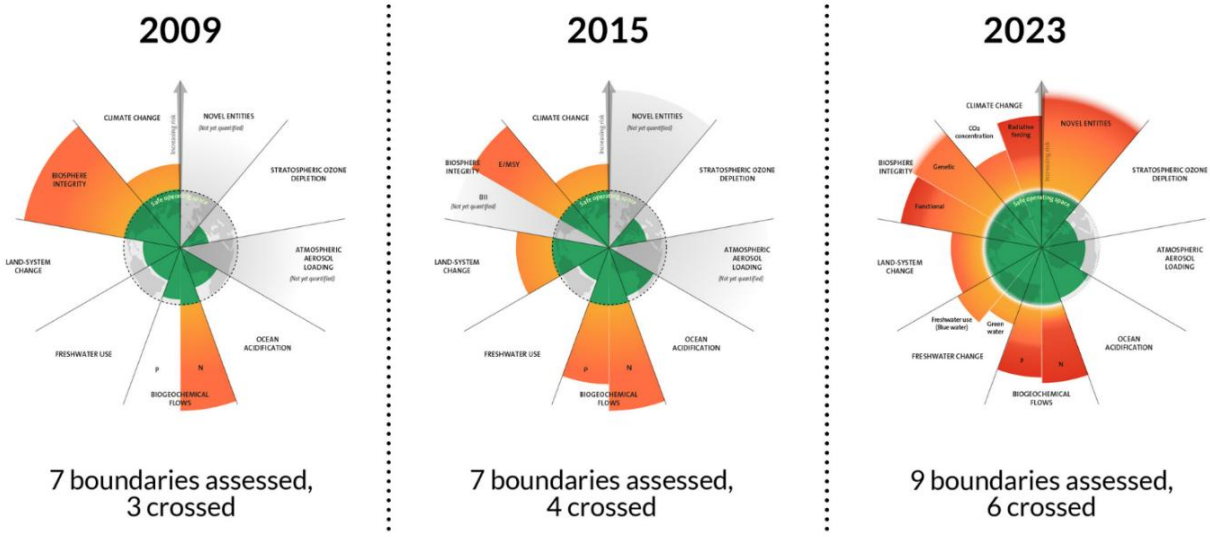

Figure 1. Evolution of the planetary boundaries framework (Credit: Azote for Stockholm Resilience Centre, Stockholm University. Based on Richardson et al. 2023, Steffen et al. 2015, and Rockström et al. 2009)

Additionally, beyond its role in diagnosing the current state of the Earth system, the Planetary Boundaries framework is increasingly used to explore potential development pathways that remain within the earth limits (Vuuren et al., 2025). In this context, the notion of "absolute sustainability" has emerged, reflecting a shift from relative to absolute metrics for impact assessment based on the planet's carrying capacity (Bjørn and Hauschild, 2013). This evolution has given rise to new methodologies such as the Absolute Environmental Sustainability Assessment (AESA), which aims to quantify environmental impacts in relation to defined planetary limits rather than to incremental improvements alone (Hauschild et al., 2020).

Another key concept developed to raise awareness of unsustainable consumption patterns is the Country Overshoot Days (Global Footprint Network, 2025). This indicator, updated annually, marks the calendar date on which humanity would exhaust the Earth's yearly biocapacity budget if everyone on the planet lived like the residents of a given country. In 2025, France's overshoot day falls on April 16th, meaning that if the global population adopted French consumption patterns, we would deplete the Earth's annual regenerative capacity within just over three months. Put differently, three planets would be needed to sustain such a level of resource use. This concept offers a simple yet powerful illustration of the magnitude of ecological overshoot and the inequalities in consumption that exist between nations. However, while highly effective for awareness-raising, it remains limited analytically, as it focuses primarily on resource consumption and does not capture the full complexity of environmental pressures.
In line with the previous concepts, the Circularity Gap is an indicator developed to track our progress toward more sustainable resource use. Since 2019, the Circle Economy Foundation has published the Circularity Gap Report, providing an annual analysis of the global state of circularity (Circle Economy, 2025). Circular economy is increasingly acknowledged as a means to deliver human wellbeing while staying within planetary boundaries. The circularity gap measures the proportion of materials re-entering the economy versus those extracted anew, offering a global benchmark to understand trends and progress over time. Despite growing interest in circular economy principles and an increase in supportive policies, the latest findings are sobering. According to the 2025 report, global circularity has declined to just 6.9%, down from 9.1% in 2018 and 7.2% in 2023 (Circle Economy, 2025, 2023).

Finally, at the intersection of environmental imperatives and business strategy lies the Triple Bottom Line (TBL) concept, which encourages companies to consider not only financial performance but also their social and environmental impacts. Introduced by John Elkington in the 1990s, it urges organizations to evaluate their performance through the three pillars of sustainable development: People, Planet, and Profit (Elkington, 1998). The TBL aims to shift business priorities toward long-term sustainability rather than short-term profit maximization. While it is often used as an internal management framework, it aligns closely with external assessment mechanisms such as Environmental, Social, and Governance (ESG) criteria, which hold companies publicly accountable for their sustainability efforts. The TBL helped popularize the integration of environmental and social concerns into corporate strategy, laying the groundwork for modern Corporate Social Responsibility (CSR) practices. By linking sustainability principles to corporate decision-making, the TBL reflects a growing expectation for companies to actively contribute to global environmental goals, an expectation increasingly reinforced by regulatory frameworks and stakeholder pressures.

The frameworks presented above do not claim to be exhaustive, other influential models, such as Doughnut Economics (Raworth, 2018), also contribute to shaping contemporary sustainability thinking, but they nonetheless provide a robust foundation for understanding the environmental imperatives that frame this thesis.

1.1.3. Policy and regulatory responses to environmental challenges

Numerous environmental regulations have emerged over the years, playing a crucial role in translating the aforementioned global concerns into enforceable standards at international, regional, and national levels. As with the previous section on conceptual frameworks, the regulatory initiatives presented below do not represent an exhaustive list. Rather, they highlight key instruments, particularly those that have influenced the context and development of this thesis.

Environmental regulations can be broadly defined as government interventions aimed at shaping economic activities to protect the environment. Regulation in general refers to the promulgation, monitoring, and

enforcement of rules that influence market behavior. In this context, environmental regulation is understood as a formal response to societal risks posed by environmental degradation (Moosa, 2016). Contrary to the common perception that such regulations may hinder competitiveness, they can, under the right conditions, especially when combined with innovation incentives and flexible policy instruments, stimulate efficiency, technological progress, and long-term competitive advantage (Iraldo et al., 2011).

1.1.3.1. Sustainable Development Goals: A global policy framework

In this context, the Sustainable Development Goals (SDGs) were established by the United Nations in 2015 as part of the 2030 Agenda for Sustainable Development (UN, 2015b) . They comprise 17 interconnected goals that form a universal call to action to end poverty, protect the planet, and ensure peace and prosperity for all (Figure 2). The SDGs recognize that eradicating poverty and other deprivations must go hand in hand with strategies to improve health and education, reduce inequalities, foster economic growth, and address climate change while safeguarding natural ecosystems. As an example, we can find among them, the SDG 12 – Responsible consumption and production, particularly relevant for manufacturing sector, such as the pharmaceutical industry, calling for more sustainable production models, and environmental reduction throughout the value chain.



Figure 2. Overview of the Sustainable Development Goals (SDG), from the UN, 2015

Each year, progress toward the SDGs is monitored and reported. According to the latest update, only 35% of the targets are currently on track or moderately advancing, while nearly half show stagnation or limited progress, and 18% have regressed from their 2015 baselines. These setbacks are largely driven by growing inequalities, worsening climate impacts, increasing debt, and continued underinvestment in key systems like food, education, and data. Without stronger and more coordinated action, these issues could undermine the success of the 2030 Agenda (UN, 2025).

Although the SDGs are not legally binding, they constitute a widely endorsed global policy framework. Their influence extends across national and regional agendas, including pivotal strategies (e.g., European Green Deal) and they provide a shared reference for aligning policy, research, and industrial action toward sustainability.

1.1.3.2. International environmental agreements and norms

The growing awareness of humanity's environmental footprint has prompted decades of international coordination to establish shared principles and legal frameworks for sustainability. These efforts began with major multilateral declarations that laid the groundwork for future treaties and technical standards. In 1972, the United Nations Conference on the Human Environment (Stockholm) marked a turning point, placing environmental concerns at the top of the global political agenda. It resulted in the Stockholm Declaration and Action Plan for the Human Environment, which articulated foundational principles for environmental protection and cooperation (UN, 1972) .

A major conceptual milestone between these two conferences was the 1987 report of the Brundtland Commission, which defined sustainable development as "meeting the needs of the present without compromising the ability of future generations to meet their own needs" (WCED, 1987). It clarified that environmental, economic, and social dimensions are intrinsically linked, a view that guided the agenda of the 1992 Earth Summit and underpins the systemic approach embedded in the Sustainable Development Goals.
Twenty years later, in 1992, the Earth Summit in Rio de Janeiro deepened this global commitment. It produced several landmark documents and treaties, including Agenda 21, the Rio Declaration on Environment and Development (UN, 1992a) , the United Nations Framework Convention on Climate Change (UNFCCC) (UN, 1992b), and the Convention on Biological Diversity (UN, 1992c) . These frameworks established the need for sustainable development as a guiding paradigm and formally acknowledged the global nature of environmental risks.

Building on these foundations, numerous binding international agreements have emerged to operationalize these principles. Among the most significant is the Paris Agreement, adopted in 2015 by 195 countries at COP21 (UN, 2015c). It succeeds the Kyoto Protocol of 1997, which was the first treaty to impose binding emission reduction targets on developed nations (UN, 1998). Although Kyoto was a critical milestone, its limited scope and uneven obligations ultimately prompted the search for a more inclusive and ambitious framework.
The Paris Agreement engages both developed and developing countries under a shared legal structure. It aims to limit global warming to well below 2°C above pre-industrial levels, with further efforts to cap the rise at 1.5°C. This target reflects the growing scientific consensus that exceeding 1.5°C would significantly exacerbate climate-related risks, including extreme weather events, droughts, and biodiversity loss (IPCC, 2023). To stay within this threshold, global greenhouse gas emissions must peak before 2025 and decline by 43% by 2030. Each country outlines its Nationally Determined Contributions (NDCs), subject to periodic review and revision to align with global objectives.

In parallel, international standards such as those developed by the International Standard Organization (ISO) provide structured, widely accepted approaches for improving environmental performance across industries. Although they are generally voluntary, they play a key role in aligning private-sector practices with global sustainability objectives. ISO 14001 – Environmental Management Systems is the most prominent, offering a robust framework for organizations to manage and reduce their environmental impacts (ISO, 2015) . Other standards, such as ISO 14040 and 14044 on Life Cycle Assessment (ISO, 2006a, 2006b) , or ISO 14020–24 on environmental labels and declarations, enhance transparency and comparability of sustainability efforts (ISO, 2022) . Compliance with these norms helps organizations demonstrate environmental integrity, especially in contexts where trust, accountability, and regulatory alignment are critical.

In addition, sectoral conventions also shape global environmental governance. Notable examples include the Stockholm Convention on persistent organic pollutants, the Basel Convention on the control of transboundary movements of hazardous wastes, or the Montreal Protocol on substances that deplete the ozone Layer (UN, 1987; UNEP, 2023a, 2023b). These agreements target specific threats, such as hazardous chemicals, waste, or atmospheric degradation, and reinforce the principle of shared but differentiated responsibilities. Taken together, they demonstrate the evolution of international environmental law toward greater coherence, enforceability, and multilateral commitment.

1.1.3.3. European environmental policy

Given the European scope of this work, and the fact that the pharmaceutical industry operates within a tightly regulated framework, it is important to examine the foundations and evolution of environmental policy in the European Union (EU). Over the past decades, the EU has gradually established itself as a leading force in environmental regulation, with a growing body of legislation designed to address complex challenges such as climate change, pollution, biodiversity loss, and resource depletion. These efforts are based on four core principles that guide EU environmental law: precaution, prevention, pollution control at source, and the polluter pays principle.

Environmental protection became a formal policy area for the EU in the 1970s, with key milestones including the Single European Act (EC, 1986) , which gave the EU its first legal basis for environmental action, and the Treaty of Maastricht (EU, 1993), which reinforced the integration of environmental concerns into other policy areas.

More recent developments, such as the Treaty of Lisbon (EU, 2007) and the launch of the European Green Deal (EC, 2019a), have further strengthened the EU's role in driving sustainable transformation. The Green Deal positions environmental sustainability as a central pillar of European policy, aiming to make Europe climate-neutral by 2050. More recently, the Clean Industrial Deal (EC, 2025) was introduced as part of the Green Deal Industrial Plan, with the ambition of accelerating the deployment of clean technologies and reducing industrial emissions.

To better illustrate the diversity and structure of EU environmental policy, the Table 1 presents a selection of the main legislative initiatives and frameworks that are closely related to this research.

Table 1. Key European legislations and frameworks related to environmental sustainability

Item	Type	Description	Ref.
European Green Deal	Policy Strategy	EU's overarching roadmap for climate neutrality by 2050: drives regulatory reform, investment, and innovation.	(EC, 2019a)
Clean Industrial Deal	Industrial Strategy	Outlines concrete actions to make decarbonization a driver of growth and competitiveness for European industry.	(EC, 2025)
European Climate Law	Regulation	Legally binds the EU to reach climate neutrality by 2050, with an interim target of –55% GHG emissions by 2030, aligning all EU policies with this objective.	(EC, 2021)
Corporate Sustainability Reporting Directive (CSRD)	Directive	Requires large and listed companies to report on environmental and social risks, as well as the impacts of their activities on people and the planet.	(EC, 2022a)
Circular Economy Action Plan	Policy Framework	One of the pillars of the Green Deal, supports the transition to a circular economy, reducing pressure on resources and fostering sustainable growth.	(EC, 2020)
Waste framework directive	Directive	Establishes core concepts and definitions related to waste management, including recycling, recovery, and the waste hierarchy.	(EC, 2008)
Packaging and Packaging waste regulation	Regulation	Regulates packaging placed on the EU market, setting requirements for design, prevention, reuse, and recycling.	(EC, 2024a)
REACH	Regulation	Places responsibility on industry to manage risks from chemicals and to provide safety data via registration with the European Chemicals Agency (ECHA).	(EC, 2006)
Ecodesign for Sustainable Products Regulation	Regulation	Key regulation to improve product sustainability and circularity, supporting the Circular Economy Action Plan and EU competitiveness.	(EC, 2024a)
Single Use plastics directive	Directive	Aims to reduce the environmental and health impacts of certain plastic products, especially in the marine environment, and promote circular alternatives.	(EC, 2019b)
Green claims directive	Directive	Seeks to prevent misleading environmental claims by setting clear criteria (status: currently under discussion and potentially withdrawn).	(EC, 2023)

In addition to binding regulations, directives, and overarching strategies, the European Commission has developed methodological tools to support the implementation of sustainable practices. Notably, the Environmental Footprint (EF) methods, comprising the Product Environmental Footprint (PEF) and the Organization Environmental

Footprint (OEF), offer detailed guidance for modeling, calculating, and reporting life cycle environmental impacts (Damiani et al., 2022). These methods are grounded in internationally recognized standards (ISO 14040 and 14044), and aim to enhance consistency, reliability, and comparability of environmental claims.

1.1.3.4. National policies

Although this section does not aim to provide an exhaustive overview of national regulations, it underscores an important trend: environmental issues are receiving increasing policy attention at the national level, creating mounting regulatory pressure on organizations. Many countries have developed their own laws or transposed supranational directives (e.g., from the EU) into local legislations. In China, for instance, the Circular Economy (CE) was introduced in policy as early as 2002 and has since evolved into a national development strategy. In 2020, China also committed to peak carbon emissions before 2030 and achieve carbon neutrality by 2060 (Bleischwitz et al., 2022; Chen, 2023). In France, several frameworks have been adopted, such as the Anti-Waste for a Circular Economy law (Legifrance, 2020) , the ecolabelling, or the extended producer responsibility schemes embedded in the French Environmental Code (Legifrance, 2025) . These examples illustrate how national policies are reinforcing the imperative for companies to adapt, depending on where they operate, and to embed environmental performance into their strategies.

1.1.3.5. Overall regulatory trends

In conclusion, the growing body of environmental regulation, whether global, regional, or national, reflects increasing recognition of the urgent need to curb environmental degradation (Figure 3). Over the past decades, the number and diversity of environmental policy instruments have expanded significantly, with more than 4,100 mechanisms now deployed across 134 countries (OECD, 2023).

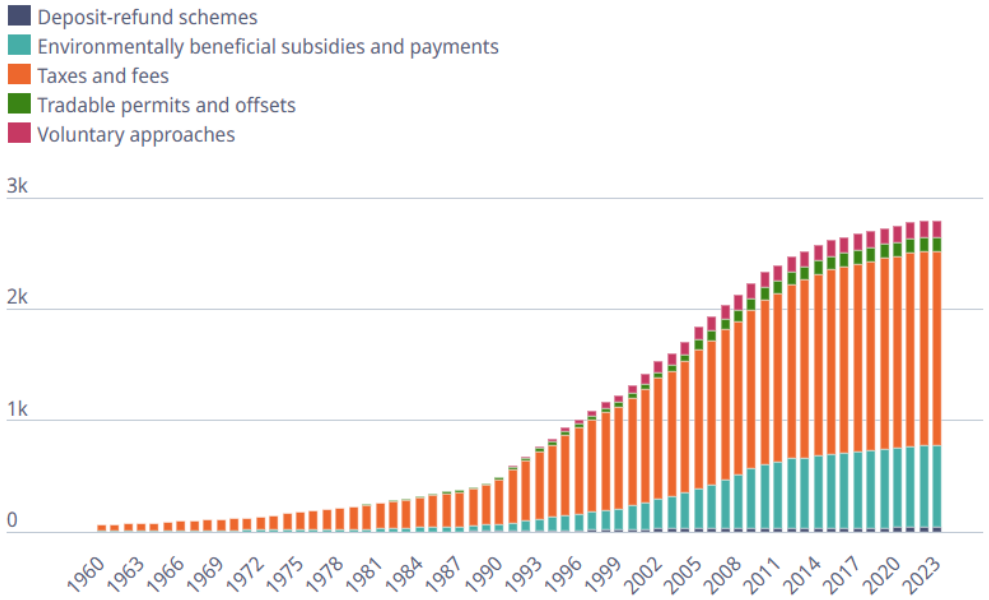

Figure 3. Number of environmental policy instruments over time (Source: OECD, 2023)

Despite initial concerns, evidence suggests that implementing more stringent environmental regulations has not substantially harmed overall industrial economic performance or employment. In fact, while such policies deliver measurable environmental benefits, their economic impact tends to be modest on average, though localized effects can be more pronounced, particularly for the most polluting and least efficient firms. For example, OECD modelling of Europe's Fit for 55 package projects only a small reduction in GDP, but anticipates sectoral shifts in employment, with certain blue-collar and agricultural jobs declining more than they would have without the policy (Borgonovi et al., 2023). These findings highlight the importance of designing environmental regulations that not only reinforce environmental integrity but also support equitable transitions, mitigating negative impacts on vulnerable industries and workers while fostering innovation and long-term economic resilience. However, regulatory progress is not guaranteed, and recent rollbacks in major economies (e.g., U.S. efforts to dismantle EPA authority) highlight how enviromental policy can shift rapidly depending on political leadership (Hejny, 2018).

1.1.4. Positioning of this research within the environmental context

This section has outlined the critical dimensions of today's environmental context. The severity of current ecological challenges underscores the urgent need to rethink the way we live, produce, and consume. Conceptual frameworks such as the planetary boundaries or the SDGs illustrate the global nature of these pressures, and the systemic transformations required to address them. However, these frameworks remain broad in scope and raise a central question: How can such high-level frameworks be translated into actionable strategies within specific industrial contexts, such as the pharmaceutical sector?

At the same time, the growing number of environmental policies and regulations, from international agreements to EU and national laws, reinforce the obligation for companies to act. Regulatory pressure is intensifying, requiring firms not only to comply, but to proactively embed sustainability into their operations, decision-making, and innovation processes. Yet recent shifts in political priorities have also shown that environmental policies are not guaranteed to follow a linear trajectory, and may evolve or weaken over time, creating an additional layer of uncertainty for long-term sustainability efforts (Csaky, 2025).

In response to these needs, this thesis positions itself at the intersection of environmental urgency, regulatory transformation, and industrial responsibility. It aims to develop practical tools, models or frameworks to support the pharmaceutical industry in addressing key environmental challenges, in particular by contributing to the achievement of SDG objectives in a concrete, sector-specific way.

1.2. INDUSTRIAL CONTEXT

This thesis was conducted within Sanofi, a major pharmaceutical company engaged in the development and delivery of medicines and vaccines to populations worldwide. To better understand the specificities of this type of industry, this section introduces the pharmaceutical sector, its historical evolution, current trends, and environmental implications. It also presents the industrial partner in which this research was carried out and concludes with a discussion of how the work positions itself within this industrial context.

1.2.1. The role of pharmaceutical companies

The pharmaceutical industry is a cornerstone of modern societies, playing a vital role in advancing public health, improving quality of life, and supporting national healthcare systems. It is one of the world's most research-intensive sectors, continuously producing new treatments and vaccines that prevent, manage, or cure diseases (Scherer, 2000). As such, it contributes directly to Sustainable Development Goal 3: "Ensure healthy lives and promote well-being for all at all ages" (UN, 2015b).

In addition to its scientific and economic contributions, the pharmaceutical industry must also take an active role in ensuring equitable access to medical innovation. Its mission is not only to develop new medicines but also to help ensure that appropriate patients benefit from them (Durrant, 2001). This dual responsibility places the sector at the heart of broader discussions on health equity, access, and sustainability.

More broadly, the pharmaceutical industry forms one of the critical components of the healthcare sector, understood as the entire system of organizations, infrastructures, and services involved in delivering care, promoting health, and maintaining well-being. This includes not only hospitals, clinics, and health professionals, but also pharmaceuticals, medical devices, insurance schemes, and upstream support industries (e.g., transportation, energy, waste management) (Eckelman et al., 2020; Klinton, 2020). A robust healthcare system being an important pillar of every country's socio-economic development process (IFPMA, 2022).

1.2.2. Historical background of the pharmaceutical industry

The origins of pharmaceutical activity can be traced back to ancient civilizations, with early medicinal practices rooted in plant-based remedies and empirical knowledge (Luu, 2023a). However, the foundations of the modern pharmaceutical industry were laid in the late 19th century, evolving from apothecary practice toward an industrial

chemical sector, particularly in Germany and Switzerland, where companies like Bayer, Hoechst, and Sandoz leveraged advances in organic chemistry to produce and commercialize medicinal compounds (Malerba and Orsenigo, 2015).

From this foundation, the industry evolved through several major phases (Luu, 2023a; Malerba and Orsenigo, 2015):

- **Emergence of industrial pharmaceuticals (1870-1930):** this period marked the transformation of traditional apothecaries into structured manufacturers of patented drugs. Firms focused on the commercialization of known compounds such as morphine, opium, and early synthetic painkillers like phenacetin and acetanilide.

- **The "Golden Age" of pharmaceutical innovation (1930–1960)**: advances in organic chemistry and biology enabled the discovery of key therapeutic classes such as antibiotics, hormones, and vitamins. Milestones include the development of sulfonamides and penicillin, which revolutionized medical treatment and were accompanied by growing public investment in health-related R&D. However, this period also has a darker side, marked by coercive and unethical human experimentation under the Nazi regime, which later prompted the development of modern research-ethics standards (e.g., Nuremberg Code) (Jr., 2010)

- **Rise of specialization and regulation (1960–1980)**: scientific progress in pharmacology, physiology, and biology facilitated the emergence of specialty drugs such as antidepressants, antihistamines, and oral contraceptives. The increasing cost and complexity of development also led to the expansion of regulatory frameworks requiring efficacy and safety.

- **Biotechnological shift and globalization (1980-present)**: the rise of biotechnology, exemplified by the founding of Genentech in 1976 and the earlier work of Cetus, originated in a new era of large molecule development, including monoclonal antibodies and recombinant proteins (Bains, 2020). Pharmaceutical R&D became increasingly globalized, data-driven, and collaborative. Recent decades have seen a strategic focus on personalized medicine and new R&D models such as public–private partnerships and open innovation (Schuhmacher et al., 2021).

This historical trajectory illustrates the industry's growing reliance on scientific innovation, regulatory oversight, and international collaboration. It also sets the stage for understanding the pharmaceutical sector's current transformations, responsibilities, and impacts.

1.2.3. Pharmaceutical legislation: a highly regulated industry

Pharmaceutical regulations are designed to ensure patient safety, and both efficacy and quality of medicines throughout their lifecycle. Defined as the set of legal, administrative, and technical measures implemented by national and international authorities, these regulations govern all stages of pharmaceutical development, manufacturing, and distribution (Klinton, 2020; Rägo and Santoso, 2008). Regulatory bodies such as the Food & Drug Administration (FDA) in the US, the European Medicine Agency (EMA) in Europe, the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, or the National Medical Products Administration (NMPA) in China, impose distinct requirements, although efforts toward harmonization, such as the International Council for Harmonization (ICH), have facilitated some convergence.

These requirements influence key aspects of the pharmaceutical development process (PDP), including stability testing, clinical trial readiness, and packaging choices, with stability data often required well in advance of clinical phases. The need to meet these standards has a direct impact on R&D timelines and technical decisions. They also extend to industrial-scale manufacturing, where regulatory expectations shape production processes, analytical methods, quality controls, and validation activities.

Regulatory frameworks vary considerably across jurisdictions. The World Health Organization (WHO) has highlighted that fewer than 30% of national regulatory authorities (NRAs) globally are currently considered

capable of ensuring that medicines, vaccines, and other health products are safe, effective, and quality assured. This capacity gap has prompted efforts to strengthen regulatory systems, particularly in low- and middle-income countries, through targeted capacity building and international collaboration (IFPMA, 2024).

1.2.4. Future trends

The pharmaceutical industry continues to evolve under the pressure of global health needs, scientific advances, demographic shifts, and economic constraints. Regulatory agility is increasingly recognized as a strategic lever to ensure that innovations reach patients in a timely and equitable manner (IFPMA, 2024). In particular, ageing populations across OECD countries are placing growing demands on healthcare systems. The share of citizens aged 65 and over has doubled in the past decades, challenging the sustainability of care models and reinforcing the need for efficient, high-quality therapies (OECD, 2021).

1.2.4.1. R&D intensity and innovation pressure

Innovation remains the cornerstone of pharmaceutical activity. The development of new medicines is a complex, costly, and high-risk process: only 0,01–0,02% of synthesized compounds reach the market, and just 10% of clinical candidates are successfully commercialized. Clinical trials alone account for nearly half of total R&D expenditures. In this context, intellectual property rights (IPRs) play a vital role in incentivizing investment by protecting the outcomes of long-term, capital-intensive research (IFPMA, 2024).

Pharmaceuticals rank among the most R&D-intensive sectors. Across OECD countries, the industry shows an average R&D intensity of 30%, far exceeding that of electronics (23,5%) and aerospace (14,7%). In 2022, the top 50 pharmaceutical companies invested over USD 167 billion in R&D, a figure expected to exceed USD 200 billion by 2025, with annual growth projected at 6,7% (IFPMA, 2024).

1.2.4.2. Synthetics, biologics, biosimilars and generics

Pharmaceutical pipelines increasingly balance two complementary approaches: chemically synthesized molecules (small molecules) and biologically derived medicines (large molecules). Small molecules remain dominant due to their manufacturing simplicity, cost-efficiency, and oral availability. Biologics, however, offer highly specific mechanisms of action, which are particularly effective for complex diseases such as autoimmune conditions or certain cancers. While biologics are more sensitive and expensive to produce, they are gaining market share, with improved delivery systems and comparable development timelines to synthetics (Ascendia, 2021).

Biologic medicines already benefit more than 350 million patients globally. Recent innovations include gene and cell therapies, grouped under the category of Advanced Therapy Medicinal Products (ATMPs), which offer new hope for patients with rare or refractory diseases (IFPMA, 2024). In Europe, biologics accounted for over 200 of the 640 EMA-approved drugs between 1995 and 2012, particularly in oncology, diabetes, and autoimmune disorders (Kyriakopoulos and Kontoravdi, 2013).

In parallel, generics and biosimilars play a key role in supporting healthcare access. They represent over 90% of drug volume in the US and contribute to cost savings by leveraging established innovation cycles. The predictability of IP frameworks ensures a sustainable pipeline for both innovative and follow-on therapies, reinforcing the overall resilience of healthcare systems (IFPMA, 2024).

1.2.4.3. Strategic focus and therapeutic pipelines

Recent years have seen a growing emphasis on therapeutic specialization. As emphasized in Figure 4, companies that concentrate over 70% of their revenue on a few therapeutic areas (TAs) have outperformed diversified peers, achieving 65% higher total shareholder return (Bleys et al., 2025). Strategic focus allows firms to consolidate expertise, build scale, and accelerate innovation in key disease areas.

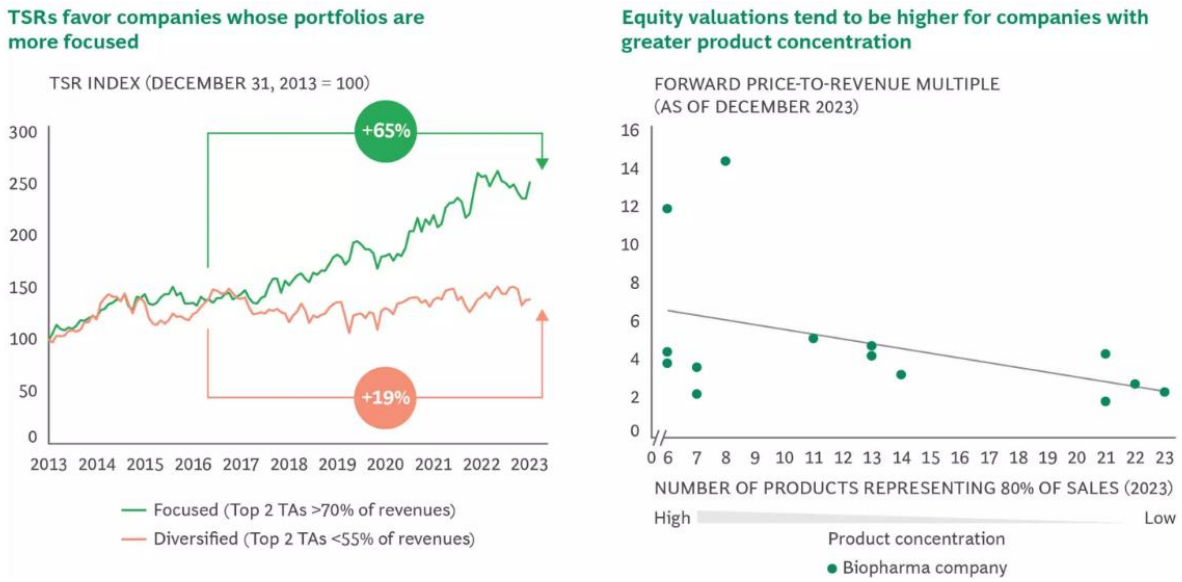

Figure 4. Total Shareholder Return (TSR) for focused or diversified pharmaceutical companies (Source: Bleys et al, 2025).

This shift is reflected in global drug development pipelines. Between 2004 and 2023, more than 940 novel active substances (NASs) were launched, addressing conditions ranging from cancer and cardiovascular disease to emerging infections such as Ebola. Currently, over 12,700 drug candidates are under clinical development, half of which are biologics. However, only 14% have reached Phase III, underscoring the significant barriers to regulatory approval and market entry.

Emerging markets, notably China, are also increasing their presence in the global innovation landscape. The number of investigational new drug (IND) applications has risen steadily, with a growing share of biologics alongside traditional chemical drugs (Figure 5) (Su et al., 2022).

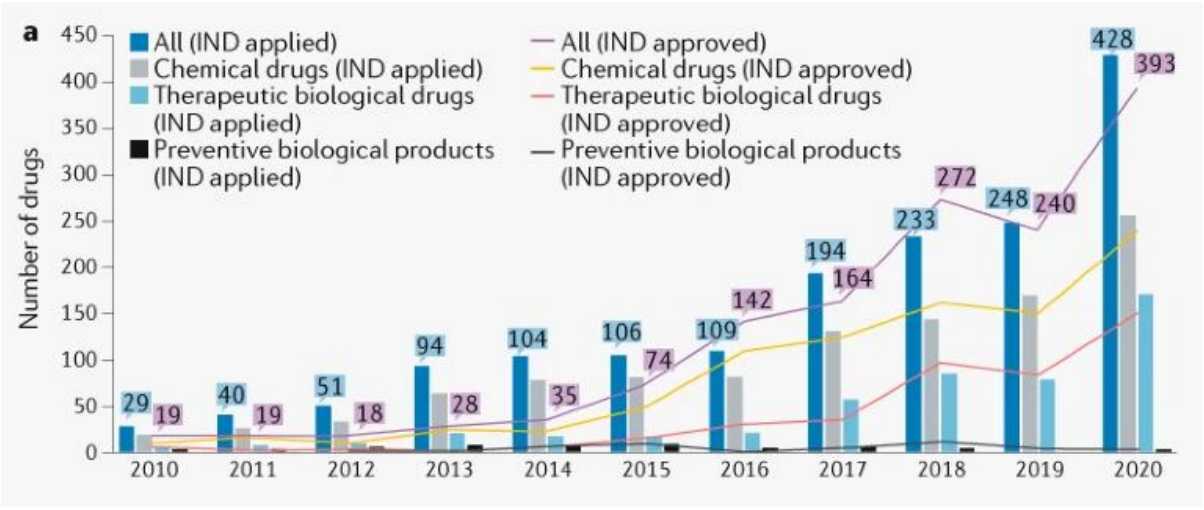

Figure 5. Annual number of INDs and NDAs for innovative drugs in China (Source: Su et al., 2022)

1.2.4.4. Perspectives

Despite major advances, unmet medical needs persist, especially for rare diseases and hard-to-treat cancers. More than 6,000 rare diseases remain without therapeutic solutions, and several cancers continue to show 5-year survival rates below 35% (IFPMA, 2024). In response, Artificial Intelligence (AI) is increasingly being explored to enhance early-stage drug discovery and molecular design, offering new pathways for accelerating innovation.

The future of pharmaceutical R&D will likely hinge on a dual ambition: delivering targeted, high-impact therapies while adapting to increasing complexity in science, regulation, global health priorities, and sustainability.

A growing trend shaping the industry is the increasing reliance on Contract Development and Manufacturing Organizations (CDMOs). Driven by rising scientific complexity and the need for specialized, flexible capacity,

outsourcing now represents a significant share of development and manufacturing activities (Neuland, 2025). This shift has direct implications for environmental sustainability: as production becomes more distributed, ensuring consistent environmental performance and aligned sustainability practices across external partners becomes more challenging.

1.2.5. The environmental impacts of pharmaceutical industries

Although the pharmaceutical industry's primary mission is to improve human health, it also contributes significantly to global environmental pressures. As part of the broader healthcare sector, it operates within what is considered the most carbon-intensive service industry in industrialized countries (Pichler et al., 2019). The healthcare sector is responsible for approximately 4,4 to 4,6% of global greenhouse gas emissions, stemming both from direct facility operations and the indirect impacts of complex supply chains (Eckelman et al., 2020).

However, environmental impacts extend well beyond carbon emissions. The planetary boundaries framework reminds us that climate change is only one of several critical Earth system processes affected by human activity, including biodiversity loss, freshwater use, land system change, and chemical pollution (Richardson et al., 2023; Rockström et al., 2009). Pharmaceutical activities, across the entire life cycle of products, contribute to all of these environmental dimensions. For example, Active Pharmaceutical Ingredients (APIs), the active substances in medicines and vaccines, and their metabolites have been detected in rivers and aquatic ecosystems worldwide, with demonstrated ecotoxicological effects, including harm to biodiversity and ecosystem functioning (Daughton and Ternes, 1999; Wilkinson et al., 2022). Improper disposal of household pharmaceutical waste and insufficient wastewater treatment at production sites further exacerbate these risks (OECD, 2022).

In addition, the volume of healthcare waste is growing rapidly. While the World Health Organization (WHO) estimates that 85% of healthcare waste is non-hazardous (WHO, 2019), common disposal practices such as incineration and landfilling can generate harmful emissions and toxic by-products. The COVID-19 pandemic clearly illustrated this trend, with biomedical waste volumes per hospital bed increasing five- to six-fold during the crisis (Capoor and Parida, 2021; Kenny and Priyadarshini, 2021).

These environmental burdens feed back into human health. As exemplified by climate change, one of the most widely used indicators of environmental disruption, we can already observe its impact on the global disease landscape, notably by facilitating the spread of vector-borne diseases such as malaria, dengue, and Lyme disease into new geographic areas (IFPMA, 2024; Ogden and Gachon, 2019). This evolving risk profile underscores the systemic interconnections between human health, industrial activity, and environmental sustainability.

1.2.6. Sanofi: an R&D-driven biopharmaceutical company in transformation

Sanofi is a global biopharmaceutical company in which this research was conducted. The group originated in 1973 and progressively expanded through several acquisitions and integrations, most notably the 2004 merger between Sanofi-Synthélabo and Aventis. These consolidations shaped a diversified pharmaceutical profile combining small-molecule heritage, biologics expansion, and a long-standing vaccines division. Today, Sanofi operates in more than 160 countries and is structured around three core business units: Specialty Care, General Medicines, and Vaccines, supported by integrated R&D and manufacturing capabilities (Sanofi, 2025a). As with other large pharmaceutical firms, Sanofi's strategic orientations and organizational structure have changed considerably over the past decade, reflecting evolving scientific opportunities, patent dynamics, competitive pressures, and internal restructurings.

1.2.6.1. Therapeutic portfolio and R&D ambition

Sanofi's portfolio covers major therapeutic areas such as immunology and inflammation (e.g., Dupixent®), rare diseases (e.g., Cerezyme®), oncology (e.g., Sarclisa®), neurology (e.g., Aubagio®), diabetes (e.g., Toujeo®), and vaccines (e.g., influenza and COVID-19). In recent years, the company has significantly increased its focus on biologics and high-value specialty medicines, illustrated by the growth of assets such as Dupilumab, while gradually reducing its exposure to older primary-care portfolios.

The company's R&D ambition is framed around the development of "first- or best-in-class" medicines and vaccines. The pipeline includes a growing proportion of biologics, RNA-based technologies, and early initiatives in cell and gene therapies. AI-enabled approaches are increasingly used across discovery and clinical development.

Sanofi's recent R&D trajectory has been marked by several reprioritizations and cost-containment measures. These adjustments reflect both the scientific challenges associated with developing complex biologics and the financial pressures linked to high-risk therapeutic areas. Overall, they signal a shift away from a historically broad portfolio toward a more focused, innovation-driven model.

1.2.6.2. Manufacturing capabilities and trends

Sanofi operates a large global manufacturing network that spans most stages of the pharmaceutical value chain, from the production of Active Pharmaceutical Ingredients (APIs), formulation into drug or vaccine products, the development and manufacturing of medical application devices, and final packaging, although some activities are also supported through external partners and CDMOs. This network includes more than 50 production sites, supplemented by collaborations with external partners and contract development and manufacturing organizations (CDMOs).

Over the past decade, Sanofi has reconfigured parts of its industrial footprint through site divestments, carve-outs, or partnership models (Bayer, 2024; Reuters, 2023). Examples include the progressive disengagement from segments of its Consumer Healthcare (CHC) operations and restructuring of several manufacturing facilities in Europe (Sanofi, 2025b, 2023). These changes correspond to broader shifts in the company's strategy: reduced emphasis on mature product lines, consolidation of biologics capacity, and strengthening of vaccine manufacturing platforms. Sanofi's Manufacturing & Supply organization has also undergone internal harmonization efforts (e.g., the Sanofi Manufacturing System) aimed at improving quality, reliability, and cross-site alignment.

Product development trends

The analysis of Sanofi's net sales by portfolio and global business units reflects the same sectoral trends discussed in the previous section on pharmaceutical innovation and product development [Figure 6].

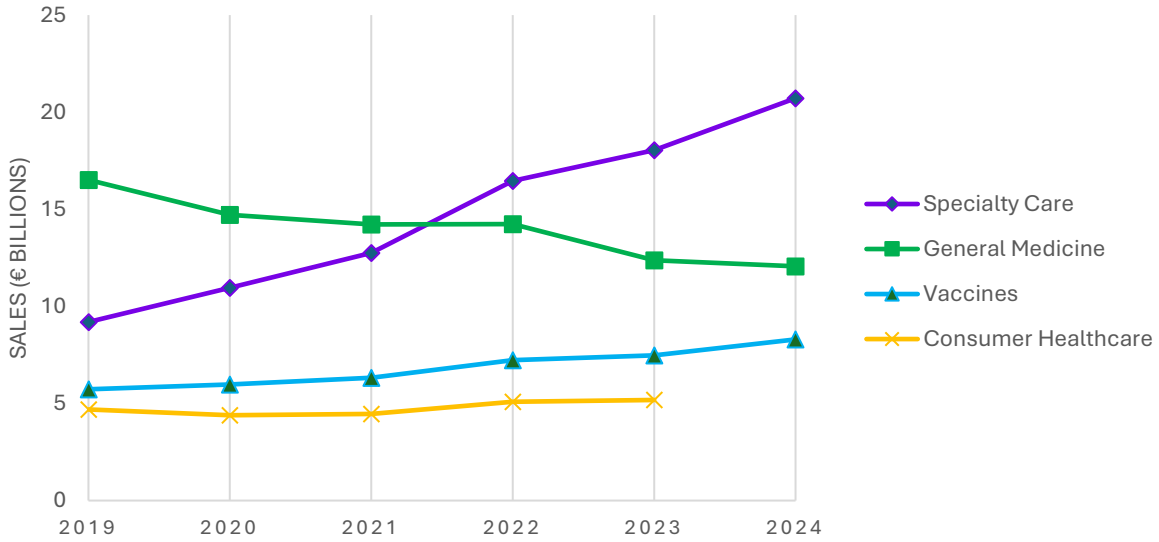

Figure 6. Evolution of Sanofi's net sales by Global Business Units (GBU) (Source: Sanofi public financial reports)

- **Specialty Care** has expanded rapidly and now contributes the largest share of revenue, driven mainly by biologics in immunology and rare diseases.
- **Vaccines** have shown steady growth, supported by influenza, pediatric vaccines, and more recently mRNA platform investments.
- **General Medicines** continue to generate significant revenue but follow a declining trajectory due to patent expirations, increased competition, and a shift in strategic priorities.
- **Consumer Healthcare** has been progressively separated from Sanofi's core prescription-medicine business and has now been fully carved out, operating independently under the name Opella.

These trends also reflect changes in the underlying product mix. Several monoclonal antibodies historically listed under General Medicines and small-molecule therapies present in Specialty Care illustrate the complexity of categorizing portfolios based solely on business-unit boundaries. This complexity is relevant to understanding Sanofi's innovation strategy, manufacturing needs, and the evolution of its development processes.

Additionally, Sanofi is undergoing a broad digital transformation aiming to integrate data science and AI across the value chain. Applications include accelerated molecule screening, predictive modeling for clinical trials, digital quality systems, and real-time supply-chain optimization. While positioned as a strategic differentiator, this transition also responds to internal efficiency needs and the limitations of traditional R&D productivity, an issue widely recognized across the pharmaceutical sector.

1.2.6.3. Environmental Sustainability and Planet Care strategy

Sanofi has set sustainability targets under its Planet Care program, which addresses the environmental impacts of its operations and products across their full lifecycle (Sanofi, 2025c). The company is committed to achieving net zero greenhouse gas emissions across all scopes by 2045, with interim targets including a 55% reduction in scopes 1 and 2, and a 30% reduction in scope 3 emissions by 2030 (vs. 2019 baseline). These goals are validated by the Science Based Targets initiative (SBTi). Environmental efforts span Eco-design, Circular Economy practices, waste reduction, water management, and biodiversity protection. By 2025, Sanofi aims to recycle or recover 90% of its operational waste and implement wastewater emission controls for all production sites. An eco-design approach is now being systematically applied to new medicines and vaccines and will extend to its top 20 products by 2030.

In recognition of these efforts, Sanofi was ranked among the Top 10 companies in TIME Magazine's Top 500 Most Sustainable Companies list in 2024 and secured the #1 position within the global pharmaceutical sector, underscoring its leading role in sustainable development (TIME, 2025). Although these commitments position Sanofi among the more advanced pharmaceutical actors in sustainability rankings, implementation remains uneven and depends on complex interactions between regulatory requirements, manufacturing constraints, and product-development timelines. The company's efforts reflect both internal ambitions and growing external pressures from regulators, investors, and healthcare systems.

1.2.6.4. Strategic engagement in health and climate resilience

Sanofi's sustainability strategy also focuses on strengthening healthcare systems' resilience to environmental change. The company actively contributes to global initiatives such as the Sustainable Markets Initiative (SMI), the Pharma LCA Consortium, or Pharmeco, promoting low-carbon supply chains, digitized clinical trials, decarbonized patient care pathways, and safe and sustainable design practices in pharmaceutical manufacturing (Pharmeco, 2025; SMI, 2025; SMI and PEG, 2025).

Recent internal research shows that 70% of Sanofi's marketed indications and 78% of its pipeline are affected by environmental hazards, particularly air pollution and climate variability (Sanofi, 2024). This evidence is driving a cross-functional response: adapting the company's portfolio, enhancing access to care for vulnerable populations, and supporting global health infrastructure through public-private partnerships.

1.2.7. Positioning of this research within the industrial context

Pharmaceutical companies are, above all, manufacturing industries. Their core mission is to provide high-quality medicines aimed at improving health and well-being globally. Yet, like all industrial sectors, pharmaceuticals generate environmental pressures throughout their products life cycle, from the sourcing of raw materials to manufacturing, distribution, use, and end-of-life. This creates an inherent paradox: while the sector is dedicated to safeguarding public health, its activities can simultaneously degrade the environmental conditions that underpin long-term health outcomes.
This tension is particularly striking given the industry's societal role. As emphasized earlier, the pharmaceutical sector directly contributes to Sustainable Development Goal (SDG) 3 - "Ensure healthy lives and promote well-

being for all at all ages" - but it must now also respond to global calls for environmental responsibility, reflected in regulatory developments, market expectations, and evolving stakeholder demands.

Pharmaceutical innovation is complex, costly, and risky. Developing a new drug can take more than a decade and require millions of euros in investment, with no guarantee of success given the high attrition rates in clinical development (Sertkaya et al., 2024). These constraints raise legitimate concerns about how and when environmental sustainability can be integrated into pharmaceutical R&D and manufacturing without compromising product safety, efficacy, or economic viability.

Against this backdrop, several key questions emerge: *How can the pharmaceutical industry reduce its environmental footprint while meeting growing global demand for treatments? How can sustainability be embedded in highly regulated, complex development processes? Where and when should environmental decisions be made to avoid trade-offs with patient safety or clinical performance?* This research positions itself at the intersection of these challenges. Its purpose is to support pharmaceutical companies in integrating environmental sustainability into product and process development, reducing environmental impacts while preserving product safety, efficacy, and long-term economic value. In doing so, it contributes to a broader shift underway in the industry: toward more responsible, systemic innovation capable of delivering both health and environmental benefits.

1.3. SCIENTIFIC CONTEXT

The challenges outlined in the previous sections are inherently interdisciplinary. They span environmental sciences (e.g., ecosystems, pollution pathways, planetary boundaries), pharmaceutical sciences (discovery, development, manufacturing of drugs, e.g., chemistry, biology, biotechnology), and design sciences (e.g., product and process development, innovation, systems thinking). The present research is framed within the field of Design for Sustainability (DfS), also referred to as Sustainable Design, which operates at the intersection of design sciences and engineering, environmental sciences, and in pharmaceutical sciences.

This interdisciplinary positioning is not merely a source of complexity; it also offers valuable opportunities. By bridging these domains, the research aims to propose integrative approaches capable of addressing both environmental and industrial constraints in pharmaceutical product and process development.

This section is structured into several sub-sections. It begins by introducing design sciences and engineering as foundational contextual elements. It then presents environmental and sustainability-oriented approaches, including Design for Sustainability, Eco-design, and Circular Economy. Then, the discussion turns to the need for integrating knowledge across domains, with attention to the concepts of multidisciplinarity, interdisciplinarity, and transdisciplinarity. The section concludes by positioning this research within the broader scientific context.

1.3.1. Design sciences and engineering

Within the Design Research Methodology (DRM), design is presented as a multifaceted activity that may originate from a wide range of impulses: a user need, a technological opportunity, regulatory pressure, or a strategic ambition. It can be carried out by individuals or teams, in industrial or academic settings, and the resulting solutions may be physical (e.g., a device), digital (e.g., software or a process), or hybrid (e.g., a product–service system). Design outcomes encompass not just artefacts, but also the underlying knowledge, processes, and systems that shape their life cycle, from conception and development to production, use, and end-of-life (Blessing and Chakrabarti, 2009a). Design, as a field and as a practice, resists a single universal definition. It is a multifaceted activity that spans cultures, disciplines, and industries. In the context of engineering and industrial innovation, design refers to the set of activities that transform a need, idea, or technology into a fully specified product or system, meeting stakeholder requirements and societal expectations (Blessing and Chakrabarti, 2009a; Pahl et al., 2007a).

As emphasized by Simon (1996), design is a purposeful, social, and cognitive activity aimed at "changing existing situations into preferred ones." It is inherently interdisciplinary and knowledge-intensive, drawing on expertise

from engineering, natural sciences, economics, ergonomics, psychology, sociology, or else (Simon, 1996). Designers often operate in uncertain contexts and must deal with incomplete knowledge, relying on assumptions, heuristics, and iterative problem-solving.

Importantly, design is situated within a dynamic environment. Needs evolve, regulations tighten, teams change, and new technologies emerge. The uniqueness and unpredictability of each design project create both challenges and opportunities, not only for practitioners, but also for researchers studying how design happens, how it can be improved, and how it contributes to innovation (Blessing and Chakrabarti, 2009a).

Design sciences in engineering

Within the engineering sciences, design science refers to the structured body of knowledge that informs and supports the practice of design. It seeks to formalize how design is performed, analyzed, and improved, through theories, methods, and tools that guide designers throughout their work. According to Hubka and Eder (1987), design science comprises four main domains (Hubka and Eder, 1987):

1. **Theory of technical systems**: This domain focuses on understanding the object of design (the artefact) by modeling its structure, mechanical or functional properties, cost, and context of use. It includes all knowledge about the technical system being developed and its interactions with its environment, both technical and social. This theory underpins the "what" of design: what is being designed, how it functions, and what constraints it must meet.

2. **Theory of the design process**: Centered on the activity of designing itself, this domain encompasses the processes, strategies, and tools used by designers to move from need to solution. It formalizes design knowledge and know-how, enabling reflection on how designers operate and how their practices can be supported or improved. It also provides a foundation for design education and skill development.

3. **Theories from the human sciences**: This domain explores the human dynamics of design: how design teams function, how knowledge is generated, transferred, and shared, and how individual and collective cognition affect the outcome. It draws from psychology, sociology, and communication studies to better understand collaborative and interdisciplinary design contexts.

4. **Design methodologies**: This area seeks to move beyond intuitive or ad hoc design by developing structured approaches and models to guide design activities. Methodologies aim to integrate key factors such as performance, quality, risk, or sustainability as early as possible in the design process. It provides frameworks that support decision-making under uncertainty and foster a systemic view of product and process development.

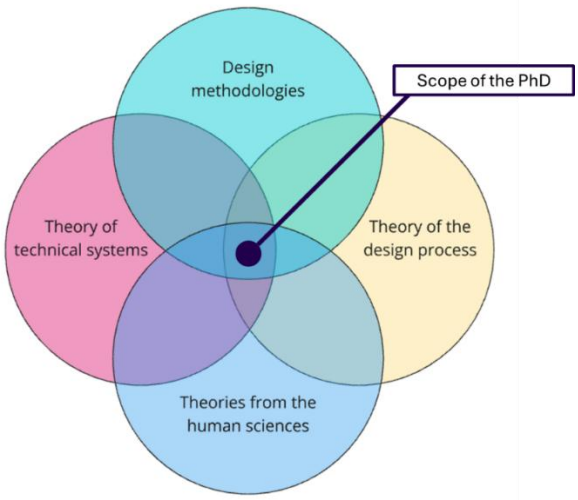

Figure 7. Scope of the PhD according to the design science framework (adapted from Hubka and Eder, 1987)

Within this context, our research is positioned at the intersection of these four domains (Figure 7). It contributes to the field of design methodologies through the development and adaptation of structured approaches and tools that support the integration of environmental sustainability into pharmaceutical product and process development. The work also draws from the theory of the design process, by embedding eco-design and circular economy strategies into concrete development and manufacturing activities, and by analyzing how these practices are operationalized within regulated industrial environments. In addition, the research is informed by theories from the human and social sciences, particularly in relation to communication, knowledge sharing, and change management, all of which are critical for the appropriation and dissemination of sustainability practices across organizational boundaries. Finally, through the application of Life Cycle Assessment (LCA) of pharmaceutical products, the work also contributes to the theory of technical systems, by providing insights into the environmental characteristics, functioning, and impacts of the technical artefacts being designed.

1.3.2. Design for Sustainability

Design for Sustainability (DfS) is a holistic approach that integrates environmental, social, and economic dimensions into the design process. It aims to guide innovation toward sustainability at various levels, from product optimization to the transformation of broader socio-technical systems. As Rocha et al. (2019) define it, DfS is "a holistic design approach that enables the integration and assessment of sustainability dimensions in different stages of the product or product-service development process toward the required scale of incremental and/or radical innovations" (Rocha et al., 2019).

Initially focused on reducing the environmental impact of materials and components, DfS has progressively expanded its scope. Ceschin and Gaziulusoy (2016, 2019) describe four key levels of intervention: the product level, focused on eco-design and life cycle optimization; the product–service system level, which integrates services with products; the spatio-social level, engaging users and communities; the socio-technical system level, which addresses infrastructure, policy, and cultural shifts (Ceschin and Gaziulusoy, 2020, 2016).

This systemic perspective recognizes that challenges like climate change or resource depletion are not solely technical but embedded in social and institutional contexts. DfS therefore combines engineering methods with broader strategic, participatory, and interdisciplinary approaches.

Eco-design remains a central practice within DfS, often relying on tools such as Life Cycle Assessment (LCA). However, DfS extends beyond eco-efficiency to question what is produced, how, and for whom. It encourages organizations to pursue not only reduced harm but also enhanced positive contributions to people and planet. As Spangenberg (2010) aptly summarizes: "Without the contribution of design, the full potential of sustainable production and consumption cannot be realized. Similarly, only in a sustainability perspective can the full potential of design be released" (Spangenberg et al., 2010).

1.3.3. Eco-design

Eco-design (ED) is a key component of Design for Sustainability (DfS), focused on minimizing environmental impacts throughout the life cycle of products. According to ISO 14006:2020, it is defined as "a systematic approach that considers environmental aspects in design and development with the aim of reducing adverse environmental impacts throughout the life cycle of a product" (ISO, 2020). This life cycle perspective, from raw material extraction to end-of-life, differentiates eco-design from earlier "green design" approaches limited to isolated stages.

The Eco-design approach emerged in the 1990s and has since become a robust framework for improving environmental performance in industrial contexts. It prioritizes environmental considerations alongside traditional design drivers such as cost, function, or aesthetics (Brezet et al., 1997; Schäfer and Löwer, 2020). Common tools include environmental Life Cycle Assessment (LCA), used to identify environmental hotspots and guide decision-making during early design stages (Jolliet et al., 2019). These tools can be qualitative, semi-quantitative, or quantitative, depending on design maturity and data availability (Zhang et al., 2013).

Despite its maturity, eco-design faces well-documented challenges. Its product-centric scope limits its capacity to address systemic sustainability issues such as rebound effects, resource distribution, or consumption patterns (Ceschin and Gaziulusoy, 2020; Pigosso et al., 2013). Additionally, the integration of environmental data into early design decisions remains difficult due to uncertainty and limited information (Devanathan et al., 2010; Gargalo et al., 2016; Luu et al., 2022b). Social and economic aspects are often overlooked, prompting calls to broaden ED frameworks and integrate sustainability dimensions more comprehensively (Ahmad et al., 2018). In this research, Eco-design serves as a foundational approach to improve the environmental performances of products and processes.

1.3.4. Circular Economy

Emerging in the 1990s and gaining momentum in the last two decades, the Circular Economy (CE) draws from various schools of thought to propose an alternative to the linear "take–make–dispose" model of production and consumption (Ghisellini et al., 2016). In a landmark analysis of 114 definitions, Kirchherr et al. (2017) identified common themes across interpretations, including resource efficiency, value retention, and the creation of loops, short, medium, and long, across product life cycles (Kirchherr et al., 2017). One of the most widely cited definitions, proposed by the Ellen MacArthur Foundation (EMF) (2013), frames CE as "A systems solution framework that tackles global challenges like climate change, biodiversity loss, waste, and pollution. It is based on three principles, driven by design: eliminate waste and pollution, circulate products and materials (at their highest value), and re-generate nature [...]" (EMF, 2013b).

The growing interest in CE is partly explained by its perceived capacity to operationalize sustainable development in industry (Kirchherr et al., 2023, 2017). The transition to CE is considered not only desirable but necessary to address rising global pressures. According to the European Commission (2020), global resource consumption is expected to double within 40 years, while waste generation may increase by 70% by 2050 (EC, 2020). Circular models offer a path to mitigate these trends by reducing raw material extraction, extending product life, and shifting toward regenerative resource flows. Yet despite increasing institutional adoption, the world economy remains only 7.2% circular as of 2023, down from 9.1% in 2018 (Circle Economy, 2023). The persistence of ecological overshoot, as illustrated by the Global Footprint Network's national "overshoot days," reflects systemic shortcomings in current production-consumption patterns (Global Footprint Network, 2025).

As emphasized in the definition from the EMF (EMF, 2013b), design plays a pivotal role in enabling the circular transition. The European Commission estimates that up to 80% of a product's environmental impacts are determined at the design stage, making it a critical intervention point (EC, 2020). CE implementation thus relies heavily on design strategies that preserve value, extend product lifetimes, and close material loops. A broad range of Design for X (DfX) approaches has been developed to support this shift, ranging from design for durability, reuse, and disassembly to more systemic logics such as design for system change or resource conservation (Sassanelli et al., 2020). These methodologies equip designers to respond to the CE's core principles while addressing context-specific constraints and opportunities. From a design science perspective, CE is more than a set of environmental strategies, it is a design-driven paradigm shift that challenges conventional models and embeds sustainability into the core of value creation processes. However, as Lonca et al. (2020) emphasized, CE alone cannot guarantee sustainability and thus requires to be combined with other methods (Lonca et al., 2020).

1.3.5. Multidisciplinarity, interdisciplinarity, transdisciplinarity in design

The complexity of contemporary societal and industrial challenges increasingly calls for approaches that go beyond the boundaries of individual disciplines. As highlighted by Choi and Pak (2006), multidisciplinarity draws on knowledge from different fields while maintaining the distinct methods and perspectives of each. Interdisciplinarity, in contrast, involves synthesizing and coordinating the contributions of several disciplines to create a coherent understanding of a shared problem. Transdisciplinarity goes a step further by transcending disciplinary boundaries altogether, enabling the formation of novel conceptual and methodological frameworks that are often co-produced with non-academic actors (Figure 8) (Alvargonzález, 2011; Choi and Pak, 2006; McPhee et al., 2018). In design science, these modalities of knowledge interaction play a central role, particularly when tackling complex issues such as environmental sustainability (Lang et al., 2012).

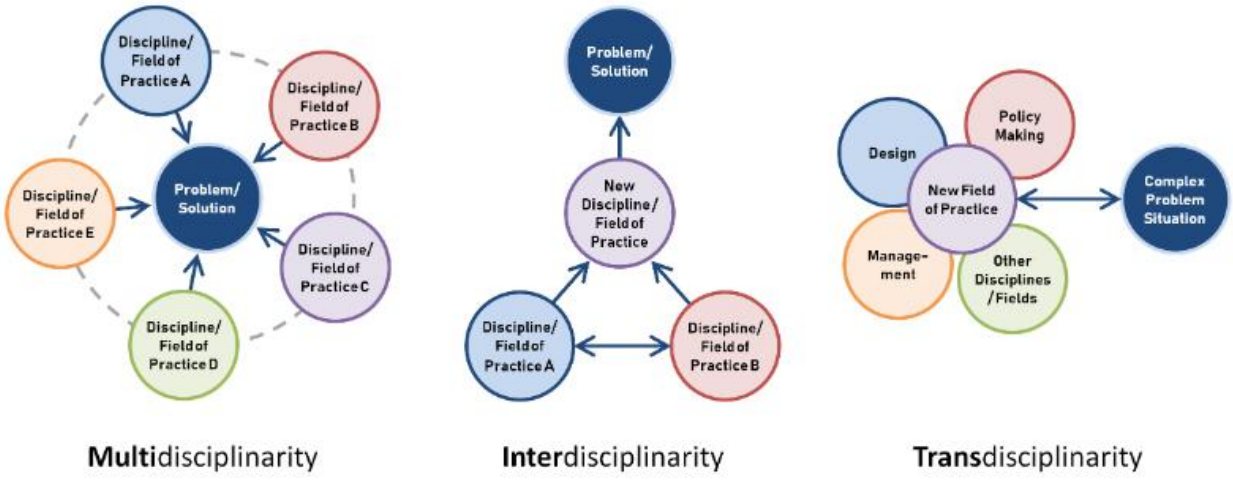

Figure 8. Comparison of multi-, inter-, and trans-disciplinarity in innovation (Source: McPhee et al. 2018)

This thesis is embedded in a highly interdisciplinary context, combining design methodologies, environmental sciences, engineering, and pharmaceutical sciences. It further leans toward a transdisciplinary posture, as it aims to co-develop actionable knowledge at the interface of science, industry, and society, responding to both environmental imperatives and sector-specific constraints. This alignment reflects a shift in design research from discipline-specific problem-solving toward integrated, collaborative approaches capable of addressing complex transitions such as those required for sustainable pharmaceutical innovation.

1.3.6. Positioning of this research within the scientific context

The present research is situated at the intersection of design science, environmental sciences, and pharmaceutical sciences. It draws on structured design methodologies, environmental assessment tools, and pharmaceutical development knowledge to address the pressing need for more sustainable industrial practices. Grounded in the DRM, the work aligns with the principles of Design for Sustainability (DfS), with eco-design and circular economy acting as core strategic levers.

The research contributes to design science by developing and adapting methods and tools that support the integration of environmental concerns into pharmaceutical product and process development. Simultaneously, it contributes to sustainability science by applying and contextualizing life cycle-based approaches within a highly regulated industrial setting. This dual contribution reinforces the importance of methodological rigor and real-world applicability in addressing complex sustainability challenges.

Methodologically, the thesis adopts an interdisciplinary posture, combining several disciplines. It further leans toward transdisciplinarity through its collaborative approach, engaging various stakeholders to co-develop actionable knowledge. In this way, the research responds not only to scientific questions but also to societal and industrial needs. By embedding environmental sustainability at key decision points in development and manufacturing, this work supports the systemic transformation of pharmaceutical practices in alignment with current and future environmental challenges.

1.4. RESEARCH LABORATORY CONTEXT

The Product Design and Innovation Laboratory (Laboratoire Conception de Produits et Innovation, LCPI, EA 3927) is a research laboratory of the Arts et Métiers Institute of Technology, affiliated with the field of Industrial Engineering. Founded in 1978 by Professor Robert Duchamp, the laboratory develops a coherent and interdisciplinary research program centered around the optimization of the design and innovation process. Its three core missions: teaching, research, and industrial valorization, are closely interlinked and collectively contribute to addressing industrial challenges through design and innovation.

The LCPI benefits from strong academic foundations and close ties with industry, fostering a research environment grounded in both theoretical rigor and real-world application. Its team is multidisciplinary, reflecting the diversity of stakeholders involved in design activities. The laboratory draws primarily on engineering sciences but also integrates human and social sciences to address the full complexity of design situations.

1.4.1.1. Laboratory positioning

The LCPI is structured into two major scientific themes: **Engineering design**, focused on product and process development, and **Management and support systems**, which addresses decision support, awareness-building, development of methods and tools, etc. These themes are further structured into research axes, reflecting key methodological and knowledge domains, and competency platforms, which support applied research, tool development, and experimental validation (Figure 9).

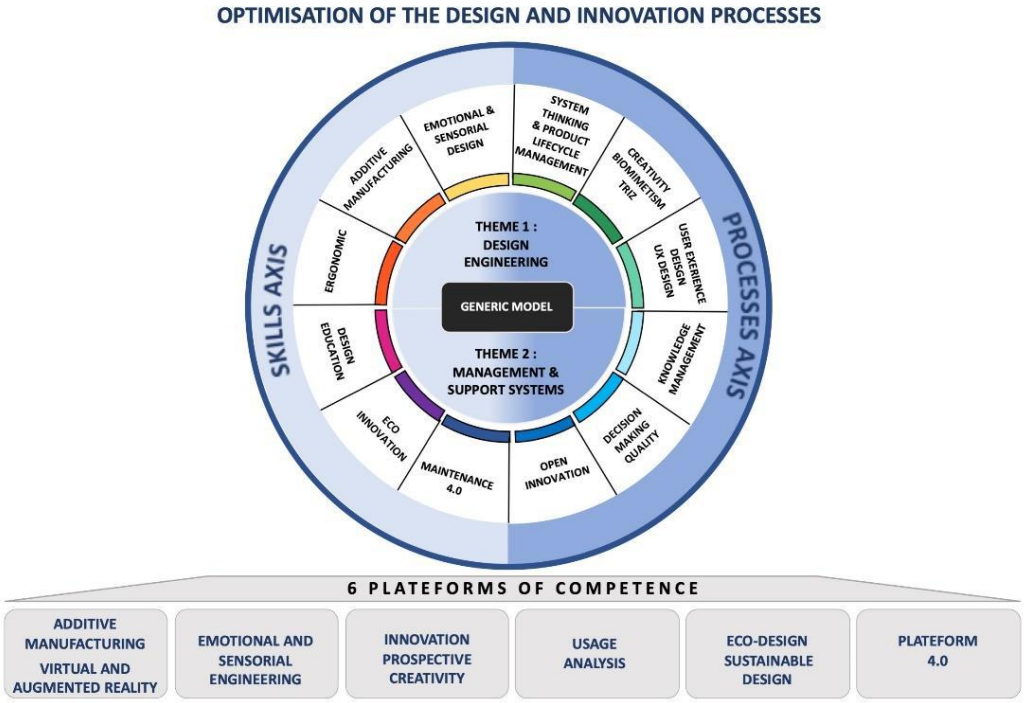

Figure 9. Overview of the LCPI with its scientific themes, divided into key axes and competency platforms (Source: LCPI)

This thesis contributes to three key research axes of the laboratory: Eco-innovation, Knowledge management, and Product lifecycle management. It also relates directly to the Eco-design and sustainable design platform of competence, which gathers tools, methods, and frameworks supporting the integration of environmental considerations throughout the design process.

1.4.1.2. LCPI legacy and continuity of research

The historical positioning of this work builds on an analysis previously conducted by Luu (2023), who identified key thematic continuities in the LCPI's doctoral research archives (Luu, 2023a) . According to this analysis, the Eco-innovation research axis has been present at LCPI since at least 2000, starting with the work of Marc Janin (Janin, 2000). Since then, 22 PhD projects have contributed to this domain. The Knowledge Management axis has similarly supported around 22 theses, while the broader axis of System thinking and Product Lifecycle Management accounts for 46 doctoral works since 2000 (Luu, 2023a). The present research aligns with and contributes to these three axes, extending them into the field of pharmaceutical sustainability and bridging them through a systemic and design-driven lens.

In addition to this thematic continuity, the LCPI has also established collaborations with the healthcare sector over the years. At least three doctoral projects have addressed medical devices, one focused specifically on drug acceptability, and finally one focusing on the implementation of eco-design within the pharmaceutical industry, providing an institutional foundation for this work.

1.5. STAKES OF THE WORK

Building on the contextual elements previously discussed, this research is situated at the intersection of several major challenges and opportunities. The stakes of this work can be articulated across three dimensions: societal, scientific, and industrial.

Societal stake: Addressing the environmental crisis
Contemporary modes of production and consumption are pushing planetary systems beyond their safe operating limits. Although pharmaceuticals play a vital role in improving global health, their development and manufacturing are not environmentally neutral. A paradox emerges: how can we meet the healthcare needs of current populations without compromising the well-being of future generations or the planet? This work aims to contribute to this broader societal challenge by proposing ways to integrate environmental sustainability into pharmaceutical production and innovation. More broadly, it seeks to reduce the environmental burden of human activity while preserving the life-saving benefits of healthcare products.

Scientific stake: Understanding integration pathways in the pharmaceutical industry
Environmental sustainability in design is a well-established field. However, its application in highly regulated sectors such as pharmaceuticals remains underexplored. Many uncertainties remain about how environmental considerations can be operationalized within product and process development, and what levers are most effective. This thesis contributes to the scientific understanding of these questions by exploring how environmental sustainability can be meaningfully embedded into pharmaceutical industries. It aims to clarify the challenges, enablers, and methodological adaptations required to advance sustainable design practices in this complex context.

Industrial stake: Structuring environmental sustainability in the pharmaceutical sector
Numerous studies have demonstrated the potential of eco-design and life cycle thinking to reduce environmental impacts. Yet, their implementation within pharmaceutical companies remains limited. The industrial stake of this research lies in translating environmental approaches into actionable, structured methods that align with pharmaceutical development constraints and priorities. This includes creating tailored tools, fostering internal capability-building, and identifying strategic entry points for environmental sustainability integration. Ultimately, the objective is to support the pharmaceutical sector in reconciling its environmental responsibilities with its core mission of delivering safe and effective healthcare solutions.

1.6. SYNTHESIS OF THE RESEARCH CONTEXT

This first chapter established the general framework of the doctoral research, grounded in societal, industrial, scientific, and academic contexts. It highlighted the urgent environmental challenges facing our societies, and the specific tensions that emerge when seeking to reduce the environmental footprint of highly regulated sectors such as pharmaceuticals.

The work is positioned at the intersection of several domains: design sciences, environmental sciences, and pharmaceutical development. It builds on existing scientific approaches such as Design for Sustainability (DfS), eco-design, and circular economy, while adopting an interdisciplinary and transdisciplinary posture to address the complexity of sustainability transitions in industry. The work is also embedded in the legacy of the LCPI laboratory, particularly its contributions to eco-innovation, knowledge management, and product lifecycle management. In doing so, it both extends and renews previous research lines by bringing these frameworks into dialogue with the environmental challenges specific to the pharmaceutical sector.

This thesis therefore aims to contribute to both scientific understanding and industrial practice, by proposing structured, actionable methods to support the integration of environmental sustainability into pharmaceutical product and process development. Achieving this objective requires building on and critically examining existing research. The next chapter therefore turns to the state of the art, consolidating current knowledge while highlighting its limitations and unresolved challenges. This review provides the scientific foundation of the thesis and prepares the ground for the problem statement and the formulation of the research hypotheses.

Résumé en français - Chapitre 1 : Contexte et motivations

Ce chapitre positionne la recherche à l'intersection de quatre contextes complémentaires : environnemental, industriel, scientifique et institutionnel.

Contexte environnemental : Les activités humaines sont aujourd'hui reconnues comme la cause principale de la dégradation environnementale planétaire (changement climatique, perte de biodiversité, pollution), un constat renforcé par le dernier rapport du GIEC (2023) et amplifié par la croissance démographique mondiale. Plusieurs cadres conceptuels structurent la réflexion actuelle sur ces enjeux : les limites planétaires (Planetary Boundaries), dont sept des neuf frontières sont désormais dépassées ; le Jour du dépassement (Overshoot Day) ; l'indicateur de circularité mondiale (Circularity Gap, en baisse à 6,9% en 2025) ; ou encore le Triple Bottom Line, qui articule performance économique, sociale et environnementale. Ces constats s'accompagnent d'un cadre réglementaire de plus en plus dense, des accords internationaux (Objectifs de Développement Durable, Accord de Paris, normes ISO) aux politiques européennes (Green Deal, CSRD, REACH) et nationales, renforçant la pression sur les entreprises pour intégrer la durabilité, malgré une progression jugée insuffisante et parfois réversible selon les contextes politiques.

Contexte industriel : L'industrie pharmaceutique, pilier de la santé publique (ODD 3), est un secteur fortement réglementé et intensif en R&D, dont l'évolution historique (des officines artisanales aux biotechnologies actuelles) reflète une sophistication scientifique croissante. Si sa mission est de préserver la santé humaine, elle génère paradoxalement des impacts environnementaux significatifs tout au long du cycle de vie de ses produits (émissions de GES du secteur de la santé, résidus pharmaceutiques dans les écosystèmes aquatiques, déchets de soins). Sanofi, partenaire industriel de cette thèse, illustre cette tension : entreprise biopharmaceutique mondiale structurée autour de trois activités (Specialty Care, Vaccins, Médecine Générale), elle a engagé une stratégie de durabilité ambitieuse (Planet Care,) tout en faisant face à des contraintes fortes liées à l'innovation, la réglementation et la viabilité économique.

Contexte scientifique : La recherche s'inscrit dans le champ du Design for Sustainability (DfS), à l'interface des sciences de la conception, des sciences environnementales et des sciences pharmaceutiques. Elle mobilise notamment l'éco-conception (fondée sur l'Analyse de Cycle de Vie) et l'économie circulaire comme leviers stratégiques, tout en s'appuyant sur les domaines de la science de la conception définis par Hubka et Eder (théorie des systèmes techniques, théorie du processus de conception, sciences humaines, méthodologies de conception). La thèse adopte une posture résolument interdisciplinaire, voire transdisciplinaire, en cherchant à co-construire des connaissances actionnables avec les acteurs industriels.

Contexte institutionnel : Les travaux sont menés au sein du LCPI (Arts et Métiers), laboratoire ancré dans l'innovation et la conception, mais aussi engagé sur l'éco-innovation, la gestion des connaissances et le cycle de vie des produits, dans la continuité de plusieurs thèses antérieures portant sur la santé et l'éco-conception.

Enjeux de la thèse : Trois enjeux structurent la recherche : (1) un enjeu sociétal, contribuer à résoudre le paradoxe entre besoins de santé et préservation de l'eveninronnement ; (2) un enjeu scientifique, comprendre comment la durabilité peut être opérationnalisée dans un secteur fortement contraint et réglementé ; (3) un enjeu industriel, traduire les approches soutenables en outils et méthodes concrètes, adaptées aux spécificités du développement pharmaceutique.

Ce chapitre pose ainsi les bases justifiant la nécessité d'un état de l'art approfondi, objet du chapitre suivant, afin d'identifier les limites des approches existantes et de formuler la problématique de recherche.

Chapter 2. State of the Art

The goal of this chapter is to explore the foundations, developments, and gaps that inform the systemic integration of environmental sustainability in organizations, and more specifically in the pharmaceutical industry. The purpose is to position the research within existing knowledge and conceptual frameworks, thereby clarifying how design sciences, sustainability-oriented approaches, and organizational theories converge to support systemic integration.

Different types of reviews were conducted across this chapter, ranging from systematic literature reviews to semi-systematic reviews (Snyder, 2019), depending on the scope and objectives of each section. This flexible approach ensured both comprehensive coverage of established fields and targeted exploration of emerging or sector-specific topics.

The chapter is structured into five sections, as illustrated in Figure 10, which also emphasizes the logical progression between them. The first introduces design sciences and engineering, which provide the methodological and epistemological foundations of the research. The second examines Design for Sustainability (DfS), tracing its evolution and highlighting eco-design as one of its most operationalized approaches. The third reviews the Circular Economy (CE), presenting its principles, frameworks, and tools, with a specific focus on its application in the pharmaceutical industry through bibliometric and content analyses. The fourth turns to systemic transition and organizational transformation, addressing how strategies, organizational learning, change management, and capabilities enable the institutionalization of sustainability practices. Finally, the fifth section focuses on the pharmaceutical industry, outlining its specificities and analyzing its environmental impacts.

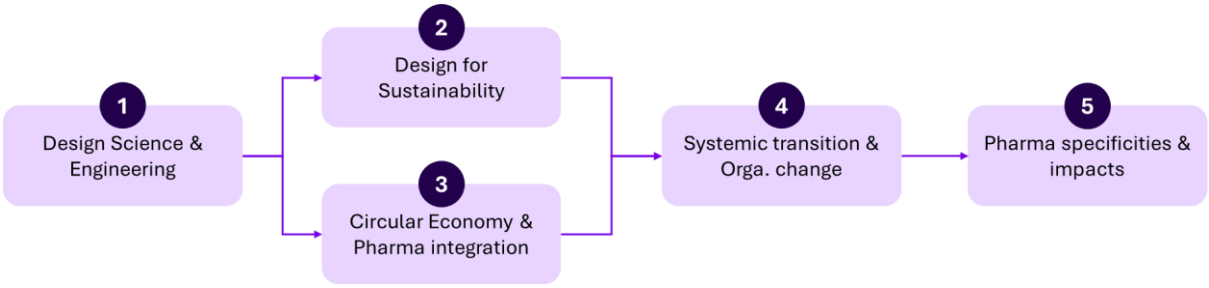

Figure 10. Structure of the State of the Art

This progression provides a comprehensive view of the conceptual and practical landscape in which the research is situated, while progressively narrowing the focus toward the pharmaceutical sector and the organizational integration of sustainability.

2.1. DESIGN SCIENCES AND ENGINEERING DESIGN

In light of the challenges outlined in Chapter 1, this research aims to contribute to the formalization of methods and frameworks for designing environmentally sustainable pharmaceutical products and processes. To support this ambition, the field of design sciences and engineering provides the conceptual and methodological foundations of the work. This section retraces the historical development of design sciences, clarifies its key concepts and theoretical structure, and highlights how these foundations underpin sustainability-oriented approaches such as eco-design, Design for Sustainability, and Circular Economy.

2.1.1. Historical development

The formalization of design sciences emerged in the second half of the twentieth century, shaped by technological advances and the growing need to rationalize design processes (Fayemi, 2016; Graeff, 2020). Although early structured approaches can be traced back to Zwicky (1948), the field gained international momentum in the 1960s, following initiatives such as the 1962 Conference on Design Methodology in London and the creation of the Design Research Society in 1966 (Cross, 2001a; Vries et al., 1993). Early pioneers, Asimow (1962), Alexander (1964), Archer (1964), and Jones (1963), sought to structure design through models inspired by systems theory and operations research, producing the first formalized, often linear, representations of design such as the analysis–synthesis–evaluation model (Wynn and Clarkson, 2005a).

By the 1970s, these mechanistic approaches faced growing criticism for their rigidity and limited capacity to address real-world complexity. Scholars such as Jones (1977) and Alexander (1971) called for more adaptive and reflective practices, while Simon's (1996) notion of bounded rationality reframed design as an iterative and situated activity (Simon, 1996). The concept of "wicked problems" (Rittel and Webber, 1973) further emphasized the need for approaches that could navigate uncertainty, iteration, and value conflicts.

In the 1980s and 1990s, the field consolidated institutionally with the creation of dedicated journals (Design Studies, Research in Engineering Design) and conferences (e.g., ICED). European authors such as Hubka and Pahl established systematic and rational methodologies for engineering design (Pahl et al., 2007a), while concurrent and integrated design approaches emerged to manage increasing complexity. From the 2000s onward, design sciences became progressively interdisciplinary, integrating insights from cognitive science, management, and sustainability studies. Scholars such as Blessing, Chakrabarti, or Hatchuel emphasized the need to bridge theory and practice and to support collaborative, knowledge-intensive innovation (Blessing and Chakrabarti, 2009a; Hatchuel and Weil, 2003).

Today, sustainability has become a central concern within design sciences. The integration of ecological constraints, social needs, and systemic interdependencies has transformed sustainability from an external constraint into a structuring principle. Frameworks such as Ceschin and Gaziulusoy's (2020) multi-level model of Design for Sustainability illustrate this shift and directly inform the approach developed in this research (Ceschin and Gaziulusoy, 2020).

2.1.2. Concepts and definitions

The field of design sciences is both complex and evolving, spanning theory, practice, and epistemology. Clarifying its conceptual landscape is necessary to position this research within an appropriate scientific and methodological frame.

Design and its relation to science

The question of whether design qualifies as a science has long been debated. Although it does not conform to the traditional criteria of repeatability and falsifiability, design has progressively structured itself around systematic approaches, rational models, and formalized methodologies. Three interconnected notions frame this scientific anchoring (Cross, 2007, 2001b; Hubka and Eder, 1987):

- **Scientific Design** refers to the practice of design guided by scientific knowledge. It emerged to address the limits of intuitive approaches in modern industrial contexts, relying on formalized procedures and data-informed decision-making.
- **Design Science** denotes a field that organizes and systematizes knowledge related to design activity. It includes methodologies, models, and principles that enable reproducible and rational design processes. Cross (2001) describes it as an explicitly organized and systematic approach to design.
- **Science of Design** considers design as a subject of scientific investigation. It reflects on the principles, practices, and processes of designing, aiming to understand and improve them through empirical and theoretical studies.

Together these notions reveal a continuum: scientific design applies scientific methods to practice, design science systematizes knowledge of design, and science of design investigates design as a phenomenon. This continuum provides the basis for considering design as a scientific discipline, or at least recognizing its scientific dimension (Fayemi, 2016).

Organization of design knowledge

Building on this scientific positioning, design sciences are frequently structured around hierarchical frameworks of abstraction. Several authors (Lahonde, 2010a; Tomiyama et al., 2009) distinguish between different levels, summarized in Table 1.

Table 2. Classification of design theories and methodologies (adapted from Tomiyama et al., 1997)

Abstraction level	General	Specific
Abstract	Theories of design (e.g. GDT, C-K)	Math-based methods
Concrete	Design methodologies (e.g. systematic design, DfX)	Processes, methods, tools

Design theories provide high-level conceptual frameworks; methodologies prescribe structured approaches for defined problems (Lahonde, 2010a). Methods define step-by-step reasoning procedures aimed at achieving design goals, and tools, such as matrices, checklists, or LCA software, operationalize these methods in practice. This hierarchical view, consistent with the frameworks proposed by Tomiyama (2006) and Lahonde (2010), clarifies how different levels of abstraction complement each other (Lahonde, 2010b; Tomiyama, 2006). Among these levels, methodologies and methods play a central role in linking theoretical knowledge to practical application, a particularly relevant aspect to this research and to the adoption of the Design Research Methodology (DRM) (Blessing and Chakrabarti, 2009b).

Defining design

The term "design" remains polysemic, referring both to process and outcome (Choulier, 2009; Dorst and Dijkhuis, 1995). In this thesis, engineering design refers to the practice of conceiving technical systems, while design sciences designate the academic field that studies and structures this practice (Fayemi, 2016). Within this framing, the DRM provides the overarching structure of this research, integrating both analytical (understanding existing practices) and constructive (developing and validating new supports) dimensions of inquiry (Blessing and Chakrabarti, 2009b). The application of DRM within this thesis is detailed in Chapter 3.

2.1.3. Design theories and models

Design theories have evolved to capture the growing complexity of design activity and to bridge theory with practice. They can be grouped into three complementary families that together constitute the backbone of design sciences.

Formal scientific theories

Theories such as General Design Theory (GDT) (Tomiyama, 1994), Universal Design Theory (UDT) (Grabowski et al., 1999; Lossack, 2000), and Axiomatic Design (Park, 2007; Suh, 2001) sought to formalize design as a scientific discipline. They established design as a mapping process between needs, functions, and attributes, providing rigorous principles for reducing complexity and ensuring coherence among design parameters. Although often abstract, these theories laid the foundation for later methodological developments.

Methodological and procedural models

Approaches such as Systematic Design (Pahl et al., 2007b), New Product Design (NPD) (Aoussat et al., 2000), and Stage-Gate (Cooper, 1994; Cooper et al., 2016; Cooper and Sommer, 2016; Ulrich and Eppinger, 2012) translated theoretical insights into structured processes applicable in industry. They introduced task clarification, functional analysis, and decision checkpoints, bringing traceability and quality control to design projects. Systematic Design remains a foundational reference and forms the basis of many Design for X (DfX) approaches, including eco-design. Its emphasis on clarifying the problem, analyzing functions, and systematically exploring alternatives has strongly influenced both academic research and industrial design practice. Modern adaptations, such as Agile–Stage-Gate hybrids (Cooper and Sommer, 2018), have increased flexibility and responsiveness under uncertainty.

Creative and cognitive models

Theories including C–K Theory (Hatchuel and Weil, 2003), Design Thinking (Design Council, 2005; Rowe, 1991), Synectics (Gordon, 1961), and TRIZ (Altshuller and Altov, 1996) focus on the generative and exploratory dimensions of design reasoning. They formalize creativity, analogical reasoning, and problem reframing, enabling the exploration of novel concepts and the resolution of design contradictions. The evolution of the Double Diamond (2005) toward the Systemic Design Framework (2021) exemplifies this trajectory, expanding from simple divergence–convergence cycles to approaches that address complex socio-technical and environmental

challenges (Design Council, 2021). This shift introduces principles such as long-term stewardship, vision setting, and relationship building, marking a move from product-focused creativity to systemic and regenerative forms of design. These developments reinforce the relevance of creative and cognitive models for sustainability, where innovation requires reframing problems, engaging stakeholders, and navigating interdependent systems.

Synthesis of design theories and models.

Design theories and models have evolved along complementary trajectories, each illuminating different facets of design activity. Formal scientific theories (e.g., GDT, UDT, Axiomatic Design) establish the conceptual foundations of design; methodological models (e.g., Systematic Design, NPD, Stage-Gate) translate these insights into structured processes; and creative or cognitive models (e.g., C–K Theory, Design Thinking, Synectics, TRIZ) expand the generative and exploratory capacity of design. Their complementarities are summarized in Table 3, highlighting their respective strengths, limitations, and relevance for sustainability.

Table 3. Comparative synthesis of major design theories and models

Theory / Model	Pros	Cons	Relevance for sustainability
General Design Theory (GDT)	Establishes design as a scientific discipline; emphasizes knowledge representation	Highly abstract, limited practical application	Provides conceptual basis for knowledge-intensive eco-design methods
Universal Design Theory (UDT)	Highlights role of abstraction levels; interdisciplinary orientation	Limited adoption and practical use	Supports integration of multiple domains (technical, environmental, social)
Axiomatic Design	Rigorous framework; ensures independence of requirements; reduces complexity	Mathematically abstract; difficult in ill-defined problems	Robust, low-complexity designs align with eco-efficiency goals
Systematic Design	Clear stepwise process; widely taught; foundation for DfX approaches	Can be too linear and prescriptive	Basis for eco-design as a *Design for X* methodology
New Product Design (NPD)	Strong link between user needs and product validation; iterative	Can be too linear	Anchors sustainability by aligning functional specifications with user/stakeholder needs
Stage-Gate (and Agile–Stage-Gate)	Provides control, milestones, and portfolio management; aligns with quality standards	Bureaucratic, potentially rigid	Agile variants improve adaptability, useful for uncertain sustainability challenges
C–K Theory	Models generative reasoning; supports radical innovation	Abstract; requires adaptation to practice	Enables reframing and exploration of new circular/sustainable concepts
Design Thinking	Human-centered; collaborative; accessible across fields	Methodological vagueness; risk of oversimplification	Supports creativity, systemic design, stakeholder engagement, and user acceptance of sustainable solutions
Synectics	Encourages analogical thinking and problem reframing; structured creativity method	Subjective, less formalized	Helps break entrenched assumptions, opening new sustainability solution spaces

TRIZ	Systematic heuristics for inventive problem solving; strong idea generation	Complex, steep learning curve; cultural barriers	Useful for resolving trade-offs (e.g. performance vs. environmental impact)

Together, these theories show that design cannot be reduced to a single model: it is simultaneously scientific, procedural, and creative. Their complementarity enables designers to combine rational structuring, methodological rigor, and creative exploration, qualities essential for addressing sustainability transitions.

2.1.4. Design sciences and processes

Because design is inherently a complex, iterative, and ill-structured activity (Rittel and Webber, 1973), many attempts have been made to model the design process. Wynn and Clarkson (2005) categorize process models along three main dimensions (Wynn and Clarkson, 2005a):

- **Stage-based vs. activity-based**: sequential models offer clarity and control, while activity-based ones capture iteration and feedback loops (Blessing, 1994; Evans, 1959; Hubka, 2015).
- **Problem- vs. solution-oriented**: some approaches emphasize analytical problem definition, others early solution exploration (Lawson, 2005; Wynn and Clarkson, 2005b).
- **Abstract vs. procedural vs. analytical**: abstract models support general understanding; procedural ones prescribe concrete steps; analytical ones describe specific project instances (Browning, 2001; Steward, 1981).

Taken together, these perspectives show that no single model captures the full reality of design. Stage-based, problem-oriented, or abstract representations offer structure and clarity, while activity-based, solution-oriented, and procedural models better reflect the iterative and exploratory nature of real design practice. In practice, effective design work relies on combining these approaches to balance structure with flexibility, analysis with exploration, and generality with practical guidance. This integrative perspective is particularly important for sustainability-oriented design, which must navigate multiple and sometimes conflicting objectives, high uncertainty, and diverse stakeholder perspectives.

2.1.5. Synthesis on Design sciences and Engineering design

This section has established engineering design as a scientific and methodological discipline structured around interlocking theories, methodologies, methods, and tools. Its historical development shows a progression from early linear models to increasingly iterative, interdisciplinary, and systemic approaches. Formal theories strengthen the scientific grounding of design, methodological models provide structure and traceability, and creative or cognitive approaches expand its generative and exploratory capacity.

Together, these perspectives illustrate the inherently multifaceted nature of design: it operates through the interplay of rational analysis, methodological rigor, and creative exploration. This plurality is precisely what makes design sciences a fertile foundation for sustainability integration. Designing environmentally sustainable pharmaceutical products and processes requires approaches that combine systematic analysis with creativity, procedural control with flexibility, and technical rigor with stakeholder engagement.

Building on these foundations, the next section turns to Design for Sustainability (DfS), which operationalizes sustainability principles within design practice. It traces the evolution from early eco-design toward systemic frameworks that address environmental, social, and economic dimensions, and sets the stage for examining how sustainability can be embedded into both design processes and organizational contexts.

2.2. DESIGN FOR SUSTAINABILITY

Design for Sustainability (DfS) represents a paradigm that seeks to translate the principles of sustainable development into actionable approaches within design sciences. Over the past decades, it has evolved from early

notions of green design to more systemic frameworks that integrate environmental, social, and economic dimensions into design practice. This section first introduces the foundations, evolution, and key frameworks of DfS. It then examines eco-design as one of its most established and operationalized approaches, emphasizing its principles, applications, and limitations. Finally, it considers the organizational integration of DfS and eco-design in organizations.

2.2.1. DfS: foundations and evolutions

DfS has emerged as a paradigm that seeks to align design practice with the principles of sustainable development. At its core, DfS aims to integrate environmental, social, and economic dimensions into design activities, not only at the level of products, but also across services, organizations, and socio-technical systems (Ceschin and Gaziulusoy, 2016; Clark et al., 2009). Rocha et al. (2019) define it as a holistic design approach that enables the integration and assessment of sustainability considerations throughout product and product–service development, supporting both incremental and radical innovation (Rocha et al., 2019).

Design and sustainability

The role of designers in contributing to sustainability has long been acknowledged. However, explicit sustainability-oriented design approaches only gained prominence in the late twentieth century, initially through "green design" and "eco-design" strategies that sought to reduce environmental impacts of individual products (Brezet et al., 1997; Ceschin and Gaziulusoy, 2016; Klostermann and Tukker, 1997). These approaches emphasized redesign for material efficiency and life-cycle assessment, thereby improving eco-efficiency but remaining largely confined to the environmental dimension (Spangenberg et al., 2010). In the early 2000s, the field expanded significantly with the development of concepts, models, methods, and tools aimed at embedding sustainability more comprehensively into industrial innovation processes (Joore and Brezet, 2015).

Over time, the scope of DfS has broadened from a technical and product-centric focus towards a systemic perspective, in which sustainability is understood as a socio-technical challenge (Ceschin and Gaziulusoy, 2020, 2016). This expansion reflects the recognition that addressing climate change and resource scarcity cannot be limited to technical efficiency but also requires transformation of the systems and structures that shape consumption and production patterns (Manzini, 1999; Spangenberg et al., 2010). The focus on product–service systems (PSS) illustrate this shift: instead of optimizing standalone artefacts, design increasingly targets integrated solutions that simultaneously involve products, services, organizational models, and networks of actors (Tukker and Tischner, 2006; Vezzoli and Manzini, 2008).

Evolution and trends

The evolution of sustainability-oriented design approaches is often described through different levels of innovation. Brezet et al (1997) proposed four levels: (1) product improvement, focused on incremental impact reduction in existing products; (2) product redesign, in which products are redeveloped from a life cycle perspective; (3) functional innovation, where alternative ways of fulfilling a given function are explored, often through product–service systems (PSS); and (4) system innovation, which entails radical changes to socio-technical systems, including infrastructure, business models, and cultural norms (Brezet et al., 1997). This progression illustrates the shift from narrow product-centric improvements to systemic reconfigurations of how societal needs are met. Building on this logic, Ceschin and Gaziulusoy (2016) proposed the DfS Evolutionary Framework, which synthesizes how sustainability-oriented design has developed over time (Ceschin and Gaziulusoy, 2016). They describe two key dimensions of this evolution: a shift from technology-driven to people-centered approaches, and a shift from insular, firm-level innovations to systemic, multi-actor transformations. Mapping design approaches along these dimensions results in four nested innovation levels:

- **Product innovation level**: design approaches focusing on improving existing or developing completely new products.
- **Product-Service System innovation level**: here the focus is beyond individual products towards integrated combinations of products and services (e.g. development of new business models).
- **Spatio-Social innovation level**: here the context of innovation is on human settlements and the spatio-social conditions of their communities. This can be addressed on different scales, from neighborhoods to cities.

- **Socio-Technical System innovation level**: here design approaches focus on promoting radical changes on how societal needs, such as nutrition and transport/mobility, are fulfilled, and thus on supporting transitions to new socio-technical systems.

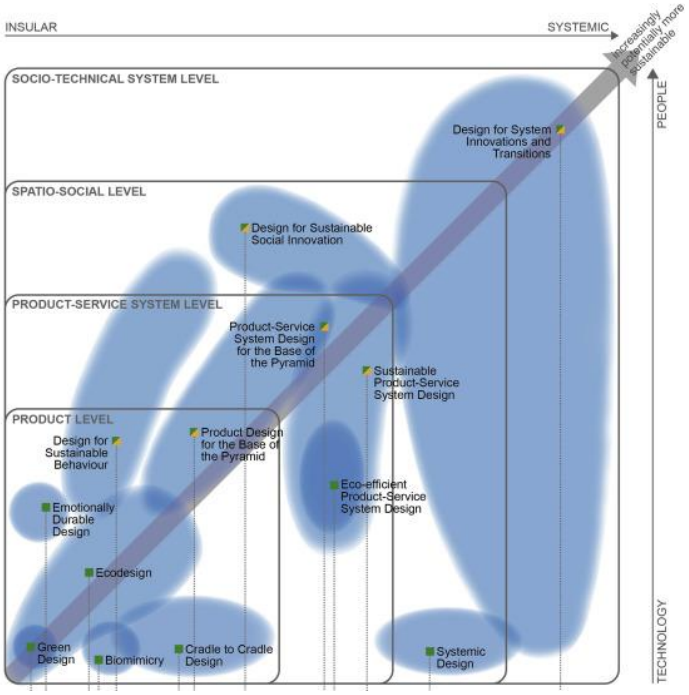

Figure 11. DfS evolutionary framework (Source: Ceschin and Gaziulusoy, 2016)

This framework highlights both the historical narrative and the overlaps between different design approaches. For instance, eco-design can span multiple levels, bridging product-level efficiency with implications for services and broader systems. In addition, by coding approaches according to the sustainability dimensions they address (environmental, social, or both), the framework also provides a comparative lens that situates DfS as a multidimensional and evolving paradigm (Figure 11). These frameworks illustrate how DfS has broadened its scope from product improvement to systemic change, aligning design practice with sustainability transitions research.

Eco-design and DfS

Spangenberg et al (2010) further differentiates between eco-design and DfS, noting that while eco-design primarily addresses environmental and economic performance through life cycle analysis and eco-efficiency, DfS extends the scope to all dimensions of sustainability (Spangenberg et al., 2010). It asks fundamental questions about production and consumption, seeks to deliver real "satisfiers" of human needs, and aspires to transform the systems of provision that underpin society. In this view, DfS becomes a practice of problem-solving that requires interdisciplinarity, integrative methodologies, and transdisciplinary collaboration, engaging not only designers and engineers but also stakeholders, consumers, and institutions.

Clark et al. (2009) capture this expanded ambition building on eco-design while incorporating economic and social concerns and explicitly addressing both incremental and radical innovation (Clark et al., 2009). Companies adopting DfS within long-term product innovation strategies aim to reduce negative impacts across the supply chain while also generating social value and competitiveness. In this sense, DfS is not limited to environmental performance but serves as a strategic orientation capable of reshaping production–consumption systems and supporting societal transitions towards sustainability.

2.2.2. Eco-design

Eco-design is both one of the origins of Design for Sustainability (DfS) and a subset of its current approaches. Emerging in the 1990s from the field of environmental engineering and product development, it emphasizes the systematic integration of environmental considerations into design, alongside traditional criteria such as

functionality, cost, and aesthetics (Brezet et al., 1997; ISO, 2020; Schäfer and Löwer, 2020). Its overall objective is to minimize environmental impacts across the life cycle of products while preserving or enhancing their benefits for users. In this sense, the environment is placed on an equal footing with established industrial values such as quality, ergonomics, and profit (Ceschin and Gaziulusoy, 2020).

Definition and principles

Eco-design has been defined in various ways, but a common emphasis is its life-cycle orientation. Schäfer and Löwer (2021) describe it as "*lowering environmental impact focusing on the whole life cycle of products from extraction of raw materials to final disposal*" (Schäfer and Löwer, 2020) Similarly, ISO 14006 (2020) defines it as the "*integration of environmental aspects into product design and development, with the aim of reducing adverse environmental impacts throughout a product's life cycle*" (ISO, 2020). These definitions underline the centrality of life-cycle thinking in eco-design, and its ambition to systematically embed environmental objectives in product development.

Eco-design is grounded in three core principles (Schäfer and Löwer, 2020):

(1) **Product-oriented design**: it is applied directly to the design and development of products.
(2) **Environmental improvement**: its primary aim is to reduce the environmental impacts associated with those products.
(3) **Life-cycle perspective**: it considers the full set of stages, from raw material extraction through production, use, and end-of-life.

Methods and tools

To operationalize these principles, a wide variety of methods and tools have been developed over 600 identified in the literature (Schäfer and Löwer, 2020). These range from qualitative tools (e.g. design checklists, guidelines), to semi-quantitative tools (e.g. scoring matrices, eco-indicator schemes), to quantitative approaches (e.g. material flow analysis, cost–benefit models) (Figure 12). Eco-design has thus been supported by instruments that vary in scope, precision, and data requirements (Pigosso et al., 2015). Bovea and Pérez-Belis (2012) further classify them into two main groups (Bovea and Pérez-Belis, 2012):

- **Environmental evaluation tools**: Qualitative (e.g. checklists, MET-matrix, "Ten Golden Rules"), quick and simple, but superficial. Semi-quantitative (e.g. ERP matrix, streamlined LCA), identify hotspots with moderate accuracy. Quantitative (e.g. indicators, full LCA), robust and detailed, but data-intensive and often applied late in design.
- **Integrated eco-design tools**: combine environmental aspects with other requirements (e.g. cost, safety, customer needs). Examples include QFD-based approaches (Green-QFD, LC-QFD), Value Analysis (Eco-VA, LCECA), Eco-FMEA, and hybrid methods combining TRIZ, QFD, and LCA.

Among these, Life Cycle Assessments (LCA) play a central role as they provide a systematic method to identify environmental "hotspots" across the life cycle of products and direct engineering activities toward the most impactful stages (Jolliet et al., 2019). Its integration into eco-design allows designers to compare alternatives, quantify trade-offs, and support evidence-based decision-making.

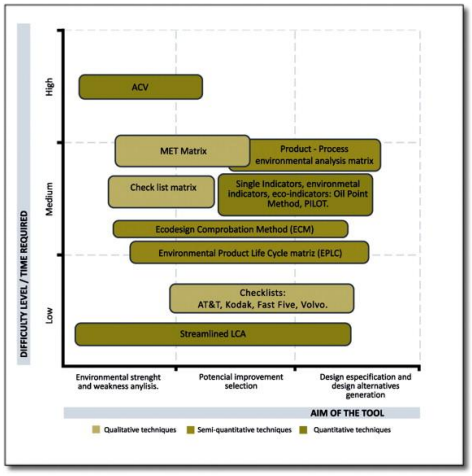

Figure 12. Classification of methods for evaluating the environmental requirement of a product (Source: Bovea and Perez-Beliz, 2012)

2.2.3. Integration of DfS and Eco-design in organizations

Despite the plurality of methods and tools, the actual implementation of DfS and eco-design in industrial practice remains limited. The multiplicity of DfS approaches makes it difficult to establish a common framework for practice, particularly in corporate contexts where sustainability is often compartmentalized (Rossi et al., 2016). Faludi et al. (2020) further explored this gap in their Research Roadmap for Sustainable Design Methods and Tools (SDMTs) (Faludi et al., 2020). They observed that, despite the proliferation of hundreds of design methods and tools, covering eco-design, circular design, and Design for X, industrial uptake remains low due to their complexity, lack of alignment with business incentives, and disconnection from industry realities. The result is a fragmented and redundant landscape with limited impact on actual practice. To address this, they proposed a ten-year roadmap structured around four research questions: understanding industry needs, improving SDMTs, strengthening research and development processes, and fostering industry integration. The roadmap emphasizes co-development with industry, simplification and digitalization of tools, consolidation of redundant approaches, and integration with business value. It also highlights the importance of embedding sustainability into education and professional training. Their vision for 2030 is one where such methods are mainstreamed in product development, directly linked to business strategy and the UN Sustainable Development Goals.

Complementing this forward-looking roadmap, other scholars have focused on practical frameworks for embedding eco-design in organizations. For instance, Brones and Monteiro de Carvalho (2015) reviewed 52 models which highlights the long-standing efforts in this field, with the first frameworks dating back to 1993 (Brones and Carvalho, 2015). From these insights they developed an harmonized integration model (Figure 13) which distinguishes between two dimensions of integration:

- **Vertical integration**: spanning three interlinked levels, the macro level relates to strategy and global objectives, such as quantified corporate sustainability targets (e.g. “all new products following an eco-design approach by 2030”). The meso level refers to embedding environmental requirements into product or service development processes, by identifying decision points where environmental performance is shaped. The micro level concerns the specific tools and methods used by teams to support decision-making.
- **Transversal integration**: addressing the “soft side” of change, including cultural factors, communication, and human behavior. Change management literature highlights that these dimensions are critical, yet often underexplored in eco-design research (Boks, 2006; Brones et al., 2014).

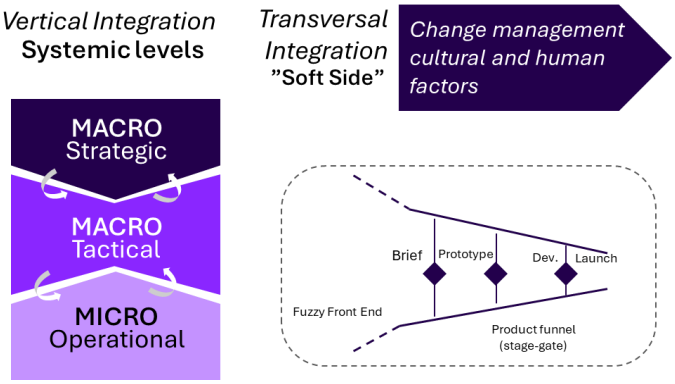

Figure 13, Eco-design integration framework (adapted from Brones and Monteiro de Carvalho, 2015)

Other authors similarly stress that eco-design implementation should be viewed as a process of continuous improvement requiring organizational learning (Buckingham et al., 2014). Embedding sustainability at the macro, meso, and micro levels ensures alignment between strategy, processes, and daily design practices.

Enablers and barriers

Research consistently identifies both drivers and obstacles to eco-design integration. Key enablers include management commitment, clear goal-setting, alignment with regulatory frameworks, and the availability of practical guidelines such as ISO/TR 14062 (Brones et al., 2014; Xavier et al., 2020). Education and training play a decisive role, as employees require not only technical knowledge but also awareness and motivation to embed

sustainability in their practice. Policy and regulation remain powerful drivers of adoption, particularly in industries where compliance is central.
Conversely, barriers are often linked to "soft factors": resistance to change, lack of communication, and divergent personal views and objectives within organizations (Boks, 2006; Rossi et al., 2016; Schäfer and Löwer, 2020). Moreover, eco-design tools frequently fail to meet industrial needs, being either too complex, poorly adapted to early development phases, or disconnected from strategic priorities.

This persistent implementation gap has also been evidenced recently. Vilochani et al. (2025) investigated the extent to which sustainable product development (SPD) practices are applied in manufacturing companies, using a consolidated set of 61 management practices (Vilochani et al., 2025, 2024). Their survey revealed that although companies increasingly recognize the importance of sustainability, actual adoption remains partial and uneven across organizations and product development stages. Environmental practices are more frequently addressed, while social and systemic practices are far less integrated. These findings reinforce earlier observations that, despite the availability of numerous methods and frameworks, DfS and eco-design often remain confined to isolated initiatives rather than becoming systematically embedded in industrial practice.

2.2.4. Key gaps and needs related to DfS and Eco-design

The literature on DfS and eco-design highlights persistent gaps that limit their effective adoption and underline the need for deeper integration into industrial practice.

Fragmented landscape of methods and tools
Hundreds of design methods and tools have been developed (Faludi et al., 2020; Schäfer and Löwer, 2020), yet many are redundant, overly complex, or disconnected from industrial realities.
➔ *There is a need to consolidate and simplify tools, making them more accessible, interoperable, and aligned with business value.*

Limited industrial uptake
Despite decades of research, adoption in practice remains partial and uneven, often confined to isolated initiatives (Rossi et al., 2016; Sherwin, 2004; Vilochani et al., 2025).
➔ *There is a need to develop approaches that support systematic integration across organizations and throughout product development processes.*

Narrow environmental focus
Eco-design remains predominantly oriented towards environmental efficiency, often neglecting social and systemic dimensions of sustainability (Ceschin and Gaziulusoy, 2020; Spangenberg et al., 2010).
➔ *There is a need to extend eco-design approaches to integrate social and economic considerations, and to connect product-level improvements with systemic sustainability transitions.*

Barriers to organizational integration
Implementation is hindered by soft factors such as lack of training, resistance to change, and insufficient management commitment (Boks, 2006; Brones et al., 2014; Brones and Carvalho, 2015; Verhulst et al., 2007).
➔ There is a need for capability development, education, and change management strategies that enable organizations to embed DfS principles into culture and practice.

Overall, these gaps confirm that the main challenge is not the absence of DfS and eco-design methods, but their effective and systemic integration into organizations. Addressing these gaps requires simplified and interoperable tools, stronger organizational capabilities, and approaches that extend eco-design beyond environmental efficiency to support genuine sustainability transitions.

2.2.5. Synthesis of Design for Sustainability

The review shows that DfS has evolved from early notions of green design toward broader, systemic frameworks that integrate environmental, social, and economic dimensions into design practice (Ceschin and Gaziulusoy, 2016;

Rocha et al., 2019). Eco-design, as one of its most established approaches, remains largely focused on environmental efficiency through life-cycle thinking and related tools (Brezet et al., 1997; ISO, 2020; Schäfer and Löwer, 2020). Despite the proliferation of methods, industrial uptake has been partial and fragmented, constrained by redundancy, complexity, and disconnection from business priorities (Faludi et al., 2020; Rossi et al., 2016; Vilochani et al., 2025). Organizational enablers such as management commitment, training, and cultural alignment are recognized as critical but remain inconsistently addressed (Boks, 2006; Brones et al., 2014; Brones and Carvalho, 2015; Verhulst et al., 2007).

In summary, the literature confirms that the challenge is not the lack of methods, but their limited integration into industrial practice. Bridging this gap requires simplifying and consolidating tools, embedding them into organizational routines and capabilities, and extending eco-design beyond environmental efficiency to support systemic sustainability transitions (Ceschin and Gaziulusoy, 2020; Spangenberg et al., 2010).

2.3. THE CIRCULAR ECONOMY AND ITS APPLICATION IN THE PHARMA INDUSTRY

Circular Economy (CE) has emerged as a central paradigm for advancing sustainability by shifting from linear "take–make–dispose" models toward closed-loop systems that prioritize resource efficiency, waste reduction, and value retention. This section reviews the state of the art on CE with a dual objective. First, it introduces the main building blocks of CE, its principles and definitions, established frameworks, and the role of tools and indicators, including the connections with Eco-design and Design for Sustainability (DfS). Second, it examines how CE is operationalized within organizations, highlighting integration challenges and enablers. Building on this foundation, the section then turns to its core focus: the application of CE in the pharmaceutical industry. This includes an analysis of existing literature, bibliometric trends, thematic clusters, and consolidated reviews, before identifying key gaps and needs that motivate the present research.

2.3.1. CE: Core principles and definitions

The concept of the Circular Economy (CE) has gained remarkable momentum over the past two decades, both in academic research and in policy agendas. Although the term was popularized in the early 2010s by the Ellen MacArthur Foundation (EMF, 2013b), its intellectual roots can be traced to earlier research fields. This evolution is highlighted by Pigosso and McAloone (2017), who emphasize how CE builds upon traditions such as industrial ecology, eco-design, sustainable design, life cycle thinking, product–service systems, business model innovation, and Cradle-to-Cradle approaches (Pigosso and McAloone, 2017a). For this reason, CE is often described as an umbrella concept that integrates diverse approaches under the common objective of improving resource efficiency and reducing environmental burdens (Homrich et al., 2018; Lonca et al., 2020).

What is the Circular Economy?

As the concept has diffused, numerous definitions have been advanced by academics, practitioners, and policymakers. Kirchherr et al. (2017), in their review of 114 definitions published between 2005 and 2017, highlighted the heterogeneity of interpretations but also several consistent features: CE is positioned as an alternative to the linear "take–make–use–dispose" model, it emphasizes resource management across life cycles, and it seeks to retain the value of products, components, and materials through loops of varying lengths (Kirchherr et al., 2017). These loops, short (e.g. reuse, repair), medium (remanufacturing), and long (recycling), are generally understood as hierarchically differentiated, with shorter loops retaining more value and thus being environmentally preferable.

An updated review by Kirchherr et al. (2023), based on 221 academic definitions published between 2017 and 2022, confirms both consolidation and diversification in how CE is conceptualized (Kirchherr et al., 2023). Core principles such as reuse and recycling remain dominant, but there is a growing emphasis on regenerative framing, supply chain perspectives, and macro-level systemic change. The aims associated with CE have also broadened: sustainable development, environmental quality, and social equity are increasingly referenced, alongside emerging debates on decoupling, sufficiency, and intergenerational justice. Furthermore, enablers are no longer limited to

consumers and business models but increasingly encompass producers, policymakers, academia, and technology, pointing to the need for broad multi-stakeholder alliances to drive systemic transitions. From this analysis, Kirchherr et al. (2023) propose a meta-definition of CE as a regenerative economic system that replaces the "end-of-life" paradigm with strategies of reducing, reusing, recycling, and recovering, aiming to maintain value and foster sustainable development for present and future generations (Kirchherr et al., 2023).

Among the various definitions, the one advanced by the Ellen MacArthur Foundation (2013) remains one of the most influential in academia and industry. CE is defined as "*a systems solution framework that tackles global challenges like climate change, biodiversity loss, waste, and pollution. It is based on three principles, driven by design: eliminate waste and pollution, circulate products and materials (at their highest value), and regenerate nature*" (EMF, 2013b). Transitioning to a CE is therefore framed as a systemic, deep, and transformative shift, seen as essential to improving the environmental performance of industries. This vision has also been institutionalized at the policy level, notably through the European Union's New Circular Economy Action Plan (EC, 2020) and the more recent proposal for a Regulation establishing a framework for sustainable products (EC, 2024b).

Why a Circular Economy?

Beyond definitional debates, multiple arguments highlight why CE is increasingly adopted as a foundation for industrial and societal transformation. Zils et al. (2022) emphasize CE as a basis for new forms of value creation and capture, enabling exponential gains in resource productivity and environmental benefits, including reduced externalities and the rebuilding of natural capital (EMF, 2013b; Geissdoerfer et al., 2020; Geng et al., 2019; Zils et al., 2023). In this sense, CE is not only an environmental strategy but also an opportunity to enhance competitiveness.

Similarly, Barreiro-Gen and Lozano (2020) position CE as one of the most recent approaches to address sustainability challenges, noting that its benefits extend to both environmental performance and economic outcomes (Barreiro-Gen and Lozano, 2020; Murray et al., 2017; Vijkman and Skanberg, 2017). The European Commission (2020) underscores this dual role, stressing that CE can significantly reduce the impacts of resource extraction and waste generation, while also contributing to biodiversity restoration, GDP growth, and job creation. At the product level, design is a key enabler: with up to 80% of environmental impacts determined during the design phase (EC, 2020), CE provides a framework to embed circularity into product and system development from the outset.

The applicability of CE spans multiple levels. At the macro level, regions, cities, and nations deploy CE strategies to address systemic sustainability challenges. At the meso level, eco-industrial networks and symbioses enable resource exchanges across firms, where one company's by-product becomes another's input. At the micro level, organizations implement CE to improve their own performance through resource efficiency, waste minimization, and circular product design (Barreiro-Gen and Lozano, 2020). This scalability illustrates the versatility of CE in addressing both global challenges and firm-level practices.

Despite these opportunities, the current global situation illustrates the urgency of CE adoption. CE is often described as an umbrella concept precisely because it seeks to unify separate approaches under the common goal of resource efficiency and impact reduction (Homrich et al., 2018; Lonca, 2020; Lonca et al., 2020). Yet the world today remains less than 10% circular: global circularity declined from 9.1% in 2018 to only 7.2% in 2023 (Circle Economy, 2023). Rising material extraction, projected to double within the next forty years, coupled with a 70% increase in waste by 2050, further exacerbates pressures on natural systems (EC, 2020). Earth Overshoot Day, which marks the point at which humanity's annual demand for resources exceeds what Earth can regenerate, continues to advance earlier each year, reflecting this unsustainable trajectory (Global Footprint Network, 2025). Together, these indicators highlight that CE is not only desirable but essential to realign industrial systems with planetary boundaries and long-term competitiveness.

2.3.2. Conceptual frameworks for CE

Given the plurality of definitions and interpretations of the CE, a wide range of frameworks have been developed to explain the concept and support its application. These frameworks differ in scope and focus depending on

disciplinary origins, intended audiences, and domains of application. Some aim to provide a high-level conceptualization of CE, others translate its principles into actionable business strategies, while more specialized frameworks target specific sectors, policy agendas, or supply chain structures.



Figure 14, 9R Framework (Source: Kirrcherr et al., 2017, adapted from Potting et al., 2017)

Among the most prominent are the R-frameworks, often described as the practical "how-to" of CE (Kirchherr et al., 2017). The 3R framework (reduce, reuse, recycle) has long been the most recognized, and was codified in legislation such as the 2008 Circular Economy Promotion Law in China (Chen, 2023). In Europe, the Waste Framework Directive expanded this logic to 4R by introducing "recover" (EC, 2008). Further extensions such as the 6R and 9R frameworks have since been proposed (Figure 14), the latter incorporating strategies such as refuse, rethink, repair, refurbish, remanufacture, and repurpose. Despite differences in scope, all R-frameworks share a hierarchical logic that prioritizes value-preserving actions (e.g. refuse, reduce, reuse) over end-of-life treatments (e.g. recycle, recover).

Beyond the R-frameworks, other influential models include the butterfly diagram (EMF, 2013b), which illustrates continuous flows of materials across biological and technical cycles, and the ReSOLVE framework (McKinsey and EMF, 2015), which translates CE principles into six business actions (Regenerate, Share, Optimize, Loop, Virtualize, Exchange). More recent frameworks have further diversified, focusing for example on clarifying process–impact relationships (Ortiz-de-Montellano and Meer, 2022), establishing universal policy goals (EMF, 2021), guiding circular supply chains (Amir et al., 2023), or designing circular business models (Lewandowski, 2016).

Table 4. Overview of key Circular Economy frameworks

Framework	Focus	Key elements	Reference
3R	Foundational hierarchy of CE actions	Most common conceptualization of the "how-to" of CE; basis for many adaptations (4R, 6R, etc.). • Reduce: consumption of natural resources/materials • Reuse: discarded product used by another consumer • Recycle: processing materials/products to obtain the same or lower quality	(Kirchherr et al., 2017)
9R	Expended R-hierarchy	More nuanced; adds refuse, rethink, repair, refurbish, remanufacture, repurpose.	(Kirchherr et al., 2017)
Butterfly diagram	Systemic flows for a CE	Represents continuous flows of materials divided into biological and technical cycles; distinguishes short loops (inner) and long loops (outer).	(EMF, 2013b)
ReSOLVE	Business action framework	Translates CE principles into six actions: Regenerate, Share, Optimize, Loop, Virtualize,	(McKinsey and EMF, 2015)

		Exchange. Actions can be applied individually or combined for compounding effects/	
Circular processes vs impacts	Clarifies indicator usage	Distinguishes between metrics/indicators of circular processes (value-retention strategies) and circular impacts (social, environmental, economic outcomes).	(Ortiz-de-Montellano and Meer, 2022)
Universal CE policy goals	Policy alignment	Defines five universal goals for governments and businesses to coordinate CE transition.	(EMF, 2021)
CE Monitoring Framework	CE improvement with indicators	Update of the previous monitoring framework, provides key elements to be considered when monitoring CE.	(EC, 2018; E. C. EC, 2020)
Circular Supply Chains	Supply chain improvements	Structures circular supply chain drivers, decision levels, and mechanisms for loop closure.	(Amir et al., 2023)
Circular Business Model canvas	Circular business model creation	Extends the Business Model Canvas with 11 building blocks, including material loops and adaptation factors.	(Lewandowski, 2016)
CVORR	System-wide value recovery	Whole-system perspective; identifies where value is created, lost, or dissipated; evaluates loops and governance context.	(Iacovidou et al., 2017)
Sustainability oriented innovation (SOI-CE)	Sustainability & CE innovation	Multi-level approach linking CE with sustainability-oriented innovation; emphasizes stakeholder integration and SDG alignment/	(Koval et al., 2022)
Circular Design framework	Design-business model interface	Maps circular design strategies to business model archetypes; aligns value creation with circular design.	(Moreno et al., 2016)
CE-SCM processes	CE & Supply chain integration	Maps and structures supply chain management processes to CE loops.	(Hazen et al., 2021)

These frameworks help both to conceptualize the CE and to support its application in specific domains. The examples presented in Table 4 do not form an exhaustive list, as many more frameworks exist, often following similar logics of smaller or larger loops. For instance, domain-specific frameworks have been developed for sectors such as water and wastewater (Smol et al., 2020) or for pharmaceutical circularity (Ang et al., 2020). Their diversity highlights that CE cannot be reduced to a single prescriptive model; rather, frameworks provide complementary perspectives that can be selected and adapted depending on context and purpose.

2.3.3. Tools & Indicators for a CE

Turning the principles of the CE into practice requires tools and indicators capable of capturing how circular a product, company, or system actually is. Over the past decade, research has produced a proliferation of indicators, with reviews identifying more than 100 sets and over 350 individual metrics (Saidani et al., 2022b, 2022a, 2019; Valls-Val et al., 2022). These contributions illustrate both the diversity of available tools and the persistent challenges of consistency, comparability, and integration with sustainability goals.

One strand of research has examined how indicators should be structured and selected. Elia et al. (2017) proposed a four-level monitoring architecture: strategic, tactical, operational, and performance, and reviewed established methods such as Life Cycle Assessment (LCA), material flow analysis (MFA), and ecological, carbon, or water footprints (Elia et al., 2017). Their central argument is that indicator choice should follow problem definition, boundary setting, and data availability, rather than convenience, to avoid method–strategy mismatches.
To bring order to a fragmented field, Saidani et al. (2019) developed a comprehensive taxonomy of CE indicators to date, classifying 55 sets by implementation level (micro, meso, macro), the loops they address (maintain, reuse, remanufacture, recycle), and whether they measure intrinsic circularity or wider impacts (Saidani et al., 2019). This taxonomy makes visible strong imbalances: recycling dominates, while earlier loops such as maintenance and reuse remain underrepresented. An update by Saidani (2022) expanded the mapping to 105 sets of indicators,

showing that most were developed in academia, with construction emerging as the most advanced sector (Saidani et al., 2022b). Less than a third of indicators assess "circularity potential" (i.e. readiness before end-of-life), limiting their usefulness for design decisions.

Parchomenko et al. (2019) applied Multiple Correspondence Analysis to 63 metrics, finding that most focus on materials and products, while company- and sector-level metrics remain underdeveloped (Parchomenko et al., 2019). They also identified three main clusters of metrics: resource efficiency, material stocks and flows, and product-centric measures. Both studies highlight redundancies and gaps: many indicators overlap, while value retention, longevity, and cascading use, core CE objectives, remain underexplored. The implication is that portfolios should be curated for complementarity, not breadth.

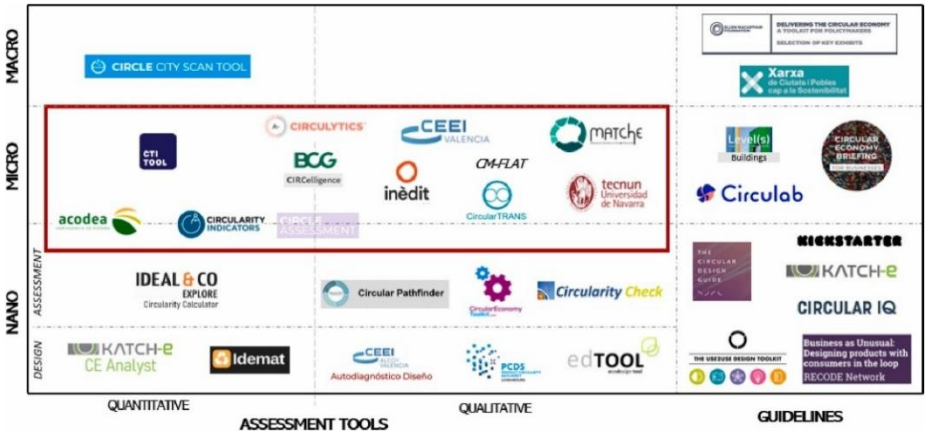

Figure 15. Existing tools for evaluating CE in different areas (Source: Valls-Val et al., 2022)

At the firm / organizational level, Valls-Val et al. (2022) reviewed ten dedicated tools, including CTI, Circulytics, and MATCHe (Figure 15) (Valls-Val et al., 2022). These instruments vary widely in scope and data requirements, ranging from simple calculators to sophisticated design-support platforms. They typically cover material flows, energy, waste, life-cycle aspects, and economic performance. Yet results can differ dramatically depending on the chosen tool, reflecting what other authors have described as a lack of standardization and shared methodology (Corona et al., 2019; Pascale et al., 2021).

A further line of research has clarified what these tools are actually measuring (Figure 16). Ortiz-de-Montellano and van der Meer (2022) stress that many debates around CE metrics are confused by the conflation of process indicators (value retention strategies such as reuse, repair, recycling) with impact indicators (the social, environmental, or economic consequences of those processes) (Ortiz-de-Montellano and Meer, 2022). They propose a framework structured around 27 "Value Retention Stages" that helps distinguish means from ends and avoid overlap.

This concern is echoed by critical assessments. Corona et al. (2019) concluded that no single metric can capture CE in its entirety and warned of burden shifting, where apparently "more circular" options lead to greater energy or water use (Corona et al., 2019). Zils et al. (2023) similarly show that pairing LCA with CE indicators is crucial, as return loops can generate unexpected environmental burdens (Zils et al., 2023). Rigamonti (2021) similarly emphasizes the need to match indicators to scale: product-level metrics like the Material Circularity Indicator (MCI) are useful for design and procurement, company-level metrics allow comparison across product ranges, while macro-level indicators based on MFA support national monitoring (Rigamonti and Mancini, 2021). Importantly, they argue that circularity indicators on their own are not sufficient and must be complemented by sustainability assessments to capture trade-offs. Kravchenko et al. (2020) add that current indicators overwhelmingly focus on material and energy flows while neglecting social and systemic dimensions, reinforcing the need to combine CE metrics with sustainability indicators (Kravchenko et al., 2020a). Several authors have highlighted the risk of circularity indicators being used in isolation. Corona Measurement is also becoming institutionalized at policy level. The European Commission updated its CE Monitoring Framework in 2023, adding a new dimension on global sustainability and resilience, and introducing indicators such as the material footprint, resource productivity, consumer footprint, GHG emissions from manufacturing, and material dependency. MFA,

LCA, and the Product Environmental Footprint (PEF) were reaffirmed as the recommended methods for evaluating CE strategies (EC, 2018; E. C. EC, 2020).

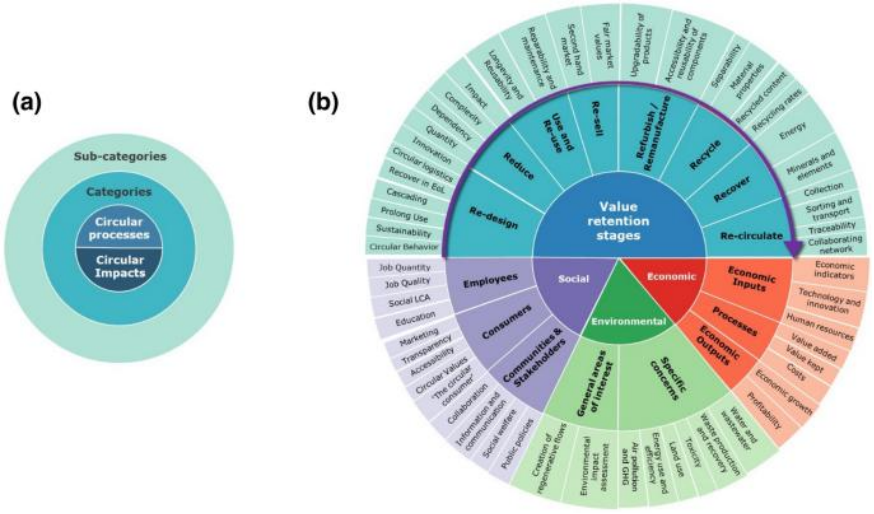

Figure 16. Summary of CE framework, a representation of the three layers of the CE framework; b categories and subcategories found in the literature review (Source: Ortiz-de-Montellano & van der Meer, 2022)

Finally, some scholars question the very capacity of CE indicators to reflect sustainability. They situate CE measurement in the broader debate on decoupling economic growth from environmental degradation, highlighting thermodynamic limits and contradictions between CE levers (Lonca et al., 2020; Walzberg et al., 2021). They argue that indicators should be interpreted within absolute sustainability frameworks such as planetary boundaries or the IPAT equation, otherwise CE risks being reduced to a relative efficiency strategy.

In summary, the literature shows a field that has matured considerably, with taxonomies, statistical analyses, and practical tools helping to structure measurement. Distinctions between processes and impacts have improved clarity, while integration with LCA and policy frameworks has extended applicability. However, persistent challenges remain, indicators are unevenly distributed across loops and levels, social and systemic aspects are underrepresented, and comparability is weak. The consensus is clear that no single indicator can capture CE in its entirety; robust assessment requires portfolios of indicators tailored to context, embedded in life-cycle thinking, and aligned with sustainability objectives.

Synthesis of the literature on CE indicators

The literature on Circular Economy (CE) indicators and tools reveals a rapidly growing but fragmented field. Despite hundreds of metrics proposed in recent years, their scope, scale, and objectives vary considerably. This diversity reflects the richness of approaches but also complicates comparability and practical adoption. Table 5 synthesizes the main findings across major contributions.

Table 5. Overview of main findings from the CE indicator literature.

Issue	Main findings	Implications	Ref
Fragmentation & lack of standardization	• Hundreds of metrics and tools exist • No consensus • Results vary strongly depending on tool and scope.	Difficult comparability; need for clearer selection criteria and standardization.	(Corona et al., 2019; Elia et al., 2017; Valls-Val et al., 2022)
Recycling bias & longer-loop focus	• Majority of indicators focus on recycling and waste disposal • Short loops (prevention, reuse, repair) underrepresented.	Measurement overlooks higher-value strategies; rebalancing toward short loops is needed	(Parchomenko et al., 2019; Saidani et al., 2022b, 2019)

Process vs. impact confusion	• Many indicators mix value-retention processes with outcome measures • Product, company, and macro scales unevenly covered.	Must distinguish means (processes) from ends (impacts); indicators should be scale-sensitive.	(Ortiz-de-Montellano and Meer, 2022)
Integration with sustainability & LCA	• No single metric captures CE in full • "More circular" options not always more sustainable • Material/energy flows dominate.	CE indicators should be paired with LCA and broader sustainability metrics to avoid burden shifting.	(Corona et al., 2019; Kravchenko et al., 2020b, 2020a; Rigamonti and Mancini, 2021; Zils et al., 2023)
Sector-specificity & applicability	• Most indicators are generic • Only some tailored to sectors (e.g. construction most advanced) • Organizational tools proliferate but diverge.	Need for sector-sensitive, operational indicators to support decision-making in practice.	(Saidani et al., 2022b, 2022a; Valls-Val et al., 2022) Saidani (2022); Valls-Val et al. (2022)
Critical perspectives & absolute sustainability	• Questions whether CE can deliver absolute sustainability • Systemic limits can challenge decoupling narratives.	Indicators should be contextualized within frameworks like planetary boundaries or IPAT.	(Lonca, 2020; Lonca et al., 2020; Walzberg et al., 2021)

Effective measurement requires portfolios of complementary indicators that are tailored to context, rebalanced toward value-preserving loops, embedded in life-cycle thinking, and connected to broader sustainability objectives. At the same time, the abundance and heterogeneity of approaches highlight a persistent fuzziness in how circularity is assessed. This underscores a simple but fundamental principle: circular practices cannot be improved if they cannot be measured. Developing and applying robust indicators is therefore a prerequisite for translating CE ambitions into tangible progress.

2.3.4. The link between CE and DfS

As we highlighted in the previous sections, the CE is often described as a holistic and integrative concept, bringing together approaches from eco-design, life cycle thinking, and design for sustainability (DfS). It is considered an "umbrella concept" because it connects different knowledge areas and practices under the shared objectives of resource efficiency and reduced environmental impacts (Homrich et al., 2018; Lonca et al., 2020; Walzberg et al., 2021).

CE is frequently framed as a pathway towards sustainability, with a strong emphasis on environmental and economic aspects (Barreiro-Gen and Lozano, 2020; Geissdoerfer et al., 2020; Pieroni et al., 2019). Authors highlight its potential to move beyond incremental improvements and serve as an operative strategy for systemic change (Kirchherr et al., 2017; Klein et al., 2022). Zils et al. (2023) also point to the relevance of CE for advancing the UN SDG, particularly through slowing and closing material loops with practical guidance for design(Zils et al., 2023).

Design emerges as a central enabler of CE. According to Pigosso and McAloone (2017), engineering design and product development are repeatedly identified as key factors for supporting the transition (Pigosso and McAloone, 2017b). Products and services must be conceived to enable value retention through durability, reparability, modularity, and remanufacturing. Circular strategies can be grouped into three archetypes: slowing loops, closing loops, and narrowing flows (Bocken et al., 2016). In addition, design guidelines emphasize systemic change, multi-life cycles, adaptive systems, and collaboration across the value chain (Moreno et al., 2016). These contributions show how CE builds directly on eco-design traditions while expanding them toward broader systemic objectives.

From Moreno et al. (2016), the evolution from Design for X (DfX) to "designing for circular cycles" illustrates this shift (Moreno et al., 2016). Although concepts such as cradle-to-cradle or dematerialization already introduced restorative design principles, circular design reframes them within a systemic perspective that integrates multiple life cycles, modularity, repair, and recovery. The authors argue that systems thinking, and circular design together redefine the role of design, positioning it as a driver of new business models and socio-technical transitions.
At the same time, some authors warn against conflating CE with sustainability too easily. Lindgreen et al. (2020) caution that CE is valuable only if it provides a pathway to sustainability, otherwise, it risks focusing on resource efficiency gains while neglecting systemic ecological and social challenges (Lindgreen et al., 2020). This perspective highlights the importance of ensuring that CE strategies remain embedded within the broader sustainability agenda.

In summary, the literature shows that eco-design and DfS offer established foundations for integrating environmental considerations into product and service development. CE, rooted in principles of natural and material cycles, complements these approaches by emphasizing the preservation of materials, value, and functionality within circular systems. Rather than forming a hierarchy, the two perspectives are best viewed as mutually reinforcing, with CE complementing or extending the scope of eco-design from product and service development toward system-level transformation.

2.3.5. Implementing CE into organizations

Translating CE principles into organizational practice is widely recognized as both necessary and difficult. There is no single approach for implementation, since integration depends heavily on firm-specific products, services, and contexts (Barreiro-Gen and Lozano, 2020). Despite this diversity, the literature provides valuable insights into how CE can move from principle to practice.

A first stream of work highlights the conceptual role of CE in sustainability transitions. Evans (2023) argues that CE contributes strongly to the environmental dimension of sustainable development, but that its societal aspects are often marginalized (Evans, 2023). Integrating CE more explicitly with sustainability can help rebalance this limitation, for example by linking circular practices to human wellbeing, equity, and new business models that disrupt existing socio-economic structures. The authors have developed a CE integration model (Figure 17) that positions sustainable production at the center of a CE, being a key characteristic of sustainable development and a driver of systemic transformation. The model highlights three contributions: (1) CE directly strengthens sustainable production, (2) integration with sustainability helps overcome CE's traditional limitations by embedding societal dimensions such as human wellbeing and capability development, and (3) CE can disrupt existing socio-economic systems, creating opportunities for alternative business models that foster equity and equality. This framing underscores that CE integration is not limited to environmental gains but extends to social and institutional transformation.

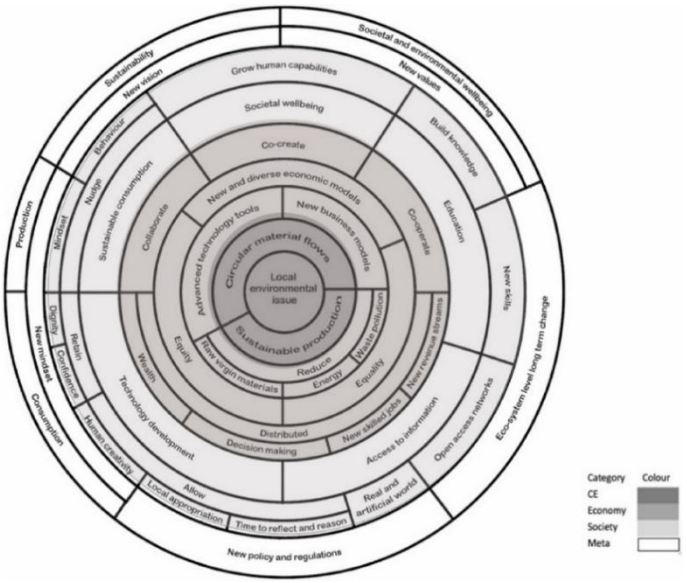

Figure 17. CE Integration Model (Source: Evans, 2023)

Similarly, Guzzo et al. (2022) emphasize that CE should be understood as part of a wider system rather than a standalone agenda, reinforcing the idea that its integration requires systemic, not isolated, change (Guzzo et al., 2022). They distinguish between two complementary streams for transition: top-down approaches, driven by policies and regulations, and bottom-up initiatives, emerging from businesses and communities (Figure 18). Both are necessary to enable a full transition, though they differ in scope, speed, and the types of impacts they generate.

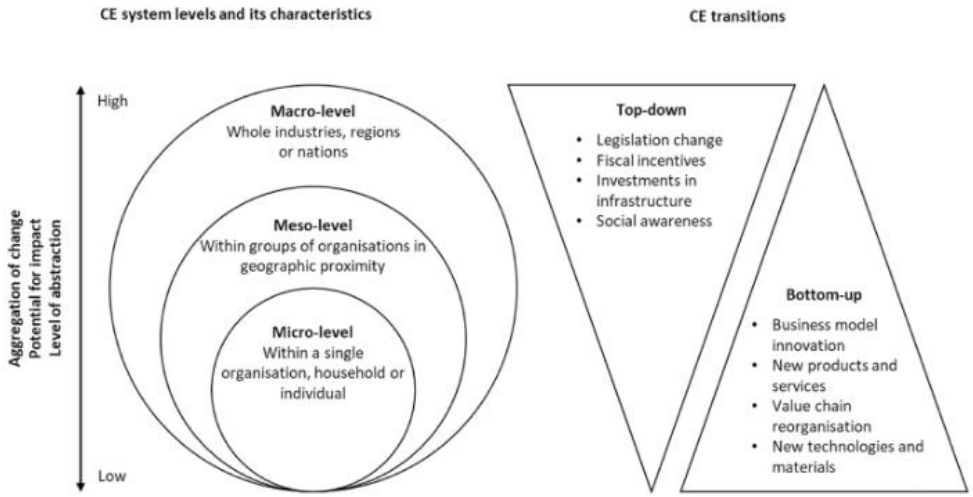

Figure 18. CE system levels and their characteristics concerning CE transition (Source: Guzzo et al., 2022)

At the same time, research points to the barriers that hinder organizational adoption. Klein et al. (2022) show that most initiatives remain incremental, rooted in linear "business as usual" logics that deliver efficiency gains but fall short of systemic transformation (Klein et al., 2022). Ritzen (2017) further identifies barriers at multiple levels: financial, structural, operational, attitudinal, and technological (Ritzen and Lindahl, 2001). Overcoming these requires aligning sustainability with business development, bridging functions and hierarchies, and fostering collaboration across the value chain.

Another important strand of the literature concerns the role of business models as levers for CE integration. Geissdoerfer (2020) defines circular business models as those that cycle, extend, intensify, or dematerialize material and energy loops (Geissdoerfer et al., 2020). These models combine strategies such as reuse, repair, remanufacturing, longer product lifetimes, and service-based solutions. Their implementation requires collaboration across value chains, particularly to enable reverse flows and take-back systems, and positions CE not just as an environmental agenda but as a source of competitive advantage.

Building on this, Chen et al. (2020) advance a structured transition flow for circular business model adoption (Chen et al., 2020). Their framework outlines four iterative stages: diagnosis, design, implementation, and review, that collectively provide a process logic for moving from linear to circular practices (Figure 19). In doing so, they highlight the importance of feedback loops, stakeholder engagement, and The proposed staged approach provides a useful baseline for understanding how organizations can structure their transition pathways and can be adapted to sector-specific requirements when coupled with additional layers of governance and risk management.

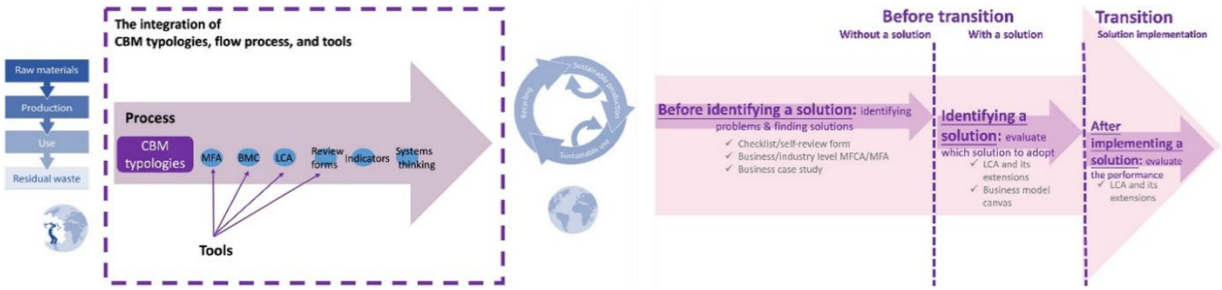

Figure 19. CE transition process (Source: Chen et al., 2020)

Scheepens et al. (2016) complement this perspective by proposing a Circular Transition Framework (CTF) that maps the multi-level environment in which circular business models must operate (Scheepens et al., 2016). The framework identifies four interlinked system levels: (i) product–technology, (ii) services and infrastructure, (iii) regulation and subsidies, and (iv) the broader societal system (Figure 20). By showing how products interact with infrastructures, policy instruments, and societal acceptance, the CTF underscores that business model innovation cannot be developed in isolation. Instead, it must align with supporting infrastructures, enabling regulations, and social legitimacy to become scalable and durable. In this sense, the CTF adds a systemic lens to the discussion of business models, clarifying how organizational efforts connect with broader institutional and societal enablers. In healthcare, Daú et al. (2019) further show how Industry 4.0 technologies and corporate social responsibility (CSR) can facilitate this alignment, supporting resource optimization and stakeholder legitimacy (Daú et al., 2019). Although their focus lies on hospital infrastructures their findings underline the importance of digital tools and CSR framing as operational enablers of CE transitions.

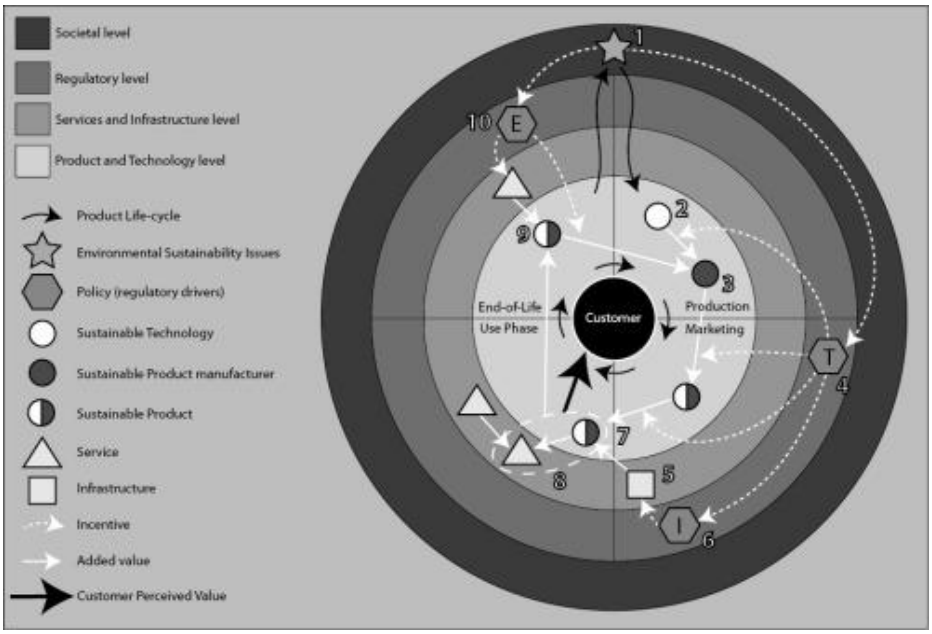

Figure 20. Circular Transition Framework (Source: Scheepens et al., 2016)

Finally, several authors stress the importance of system-level enablers. Geng (2019) highlights global resource challenges and argues that organizational integration must be supported by broader infrastructures such as data platforms, knowledge-sharing mechanisms, international alliances, and regulatory standards (Geng et al., 2019). Similar arguments are found in sectoral studies, such as those by EFPIA (2020), which underline the role of cross-industry collaboration and policy support in embedding CE principles into design, supply chains, and resource management (EFPIA, 2020). Di Vaio et al. (2022) reinforce this by emphasizing that accountability and measurement systems are essential to make CE transitions operational (Vaio et al., 2023). Their review highlights the role of accounting, digitalization, and governance mechanisms in enabling transparency and alignment with the SDGs, thereby providing the data backbone needed to support organizational and systemic integration.

In summary, these contributions show that CE integration in organizations cannot be reduced to isolated practices such as recycling or efficiency improvements. It requires tackling internal barriers, innovating business models, and embedding circularity within broader systems of collaboration and governance. The literature thus positions CE integration as a systemic challenge, one that goes beyond firm-level adjustments and demands alignment across organizational, sectoral, and policy domains.

2.3.6. CE in the Pharmaceutical Industry: State-of-the-Art

As established in the previous section, integrating CE into organizations is integral to sustainable development. This is no different for healthcare and pharmaceutical industries, where the sector's scale and footprint make circularity particularly interesting. Soares et al. (2023) synthesize the case succinctly: healthcare is economically

and socially significant, its ethical mandate to "do no harm" extends to its own environmental impacts, and its carbon footprint is material (Soares et al., 2023). In their review, the main drivers of impact are upstream supply chains, the widespread reliance on single-use devices, and the sizable contribution of pharmaceuticals to health-system emissions. On that basis, they argue that applying CE strategies, resource efficiency, reuse, recycling, and waste minimization, can align the sector with planetary-health objectives while reducing dependence on disposables (Soares et al., 2023).

2.3.6.1. Literature review

To better understand how CE has been studied in pharmaceutical contexts, we conducted a Systematic Literature Review (SLR) combined with bibliometric and content analysis. The aim was to identify sectoral trends, gaps, and key contributions linking CE and pharmaceutical industries.

The search was performed in Scopus and ScienceDirect, covering publications between 2005 and 2025. The following query was used: ("circular economy") AND ("pharmaceutical*" OR "pharmaceutical industry" OR "pharmaceutical sector" OR "healthcare" OR "drug manufacturing" OR "drug development" OR "medicine" OR "vaccine" OR "medical device").

Eligibility criteria restricted results to publications in English, including peer-reviewed research articles, review papers, and conference papers. Following the PRISMA protocol (Page et al., 2021), the initial search yielded 112 documents, which were screened for relevance and duplicates before proceeding to full review (Figure 21).

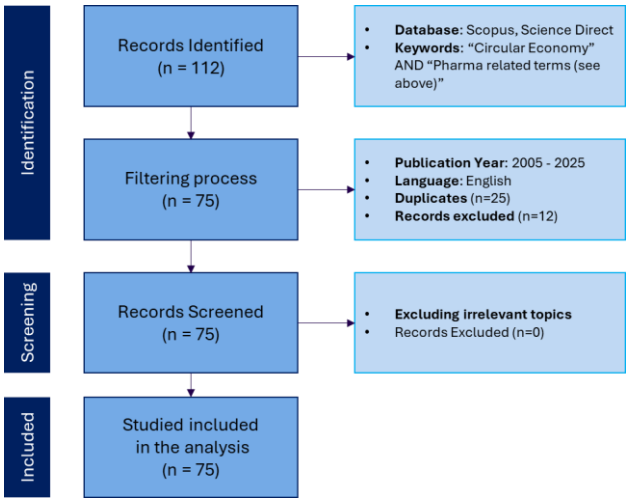

Figure 21. Selection process based on PRISMA method

2.3.6.2. Bibliometric trends in pharma-related CE literature

The bibliometric analysis provided a structured overview of how CE has been studied in healthcare and pharmaceuticals. Four dimensions were examined: the evolution of publications over time, the main journals and outlets, the keywords and thematic clusters, and the distinction between healthcare and pharmaceutical-focused studies. Together, these perspectives help reveal sectoral trends, research gaps, and emerging priorities.

Overall evolution of the literature

The analysis of publication trends highlights a clear growth trajectory for circular economy (CE) research. As shown in Figure 22, the field began to expand rapidly after 2015, coinciding with the diffusion of widely cited definitions and frameworks such as those proposed by the Ellen MacArthur Foundation (EMF) (EMF, 2013b, 2015a). A similar pattern is observable in healthcare and pharmaceuticals, though the take-off occurred later: the first noticeable rise appears around 2018, with a marked acceleration from 2021 onward.

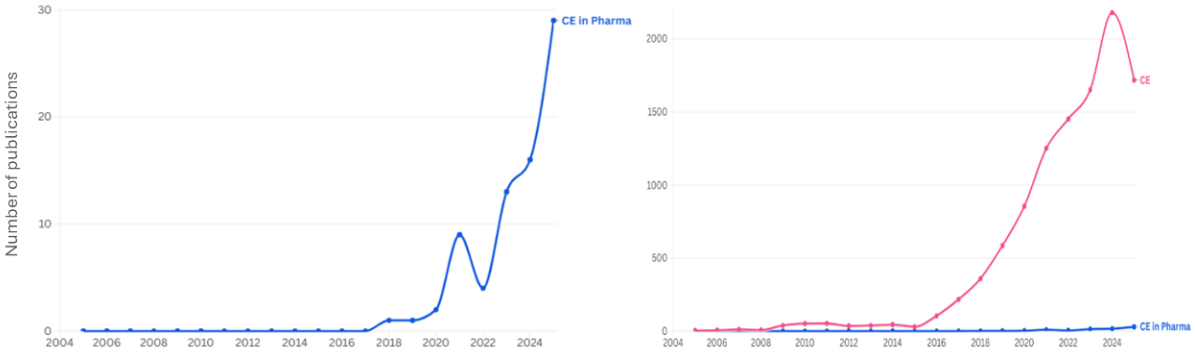

Figure 22. Publication gap between CE research and CE in healthcare/pharma.

Despite these parallel trends, the difference in scale is striking. Despite CE research overall surpassed 2,000 publications with "circular economy" in the title by 2024, only 16 papers over the same period explicitly focused on healthcare or pharmaceuticals.

This contrast highlights both the promise and the underdevelopment of CE research in the pharma sector. The sector follows the same upward trajectory as the broader CE field, but at a much smaller scale. The sharp discrepancy suggests that while CE is gaining visibility in healthcare debates, dedicated research and applied studies remain scarce. This reinforces the need for sector-specific investigations that can move beyond general principles and address the distinctive challenges of pharmaceutical systems.

Journal distribution

The distribution of publications shows that research on CE in pharmaceuticals is highly concentrated in a small set of journals. As shown in Figure 23, the Journal of Cleaner Production clearly dominates the field with eight publications, followed by Sustainability, Resources, Conservation and Recycling, and Circular Economy and Sustainability. Together, these four journals account for more than half of the total papers identified.

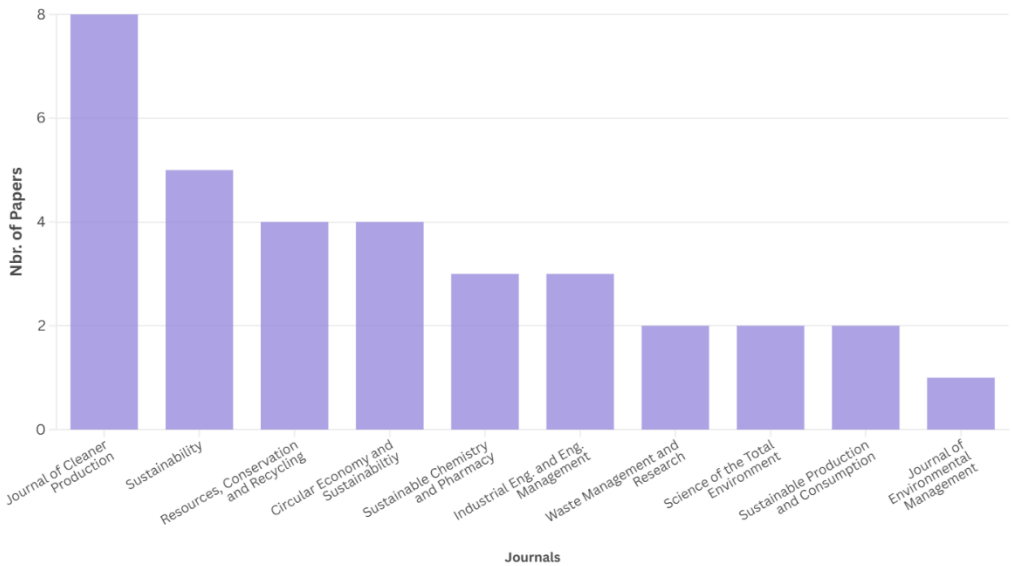

Figure 23. Journal distribution of publications on CE in pharmaceuticals

The thematic orientation of these outlets is revealing. The dominance of Journal of Cleaner Production, Sustainability, and Resources, Conservation and Recycling points to a focus on process substitution, waste reduction, and green chemistry approaches. Similarly, the presence of Sustainable Chemistry and Pharmacy reflects the emphasis on material innovation and eco-efficient production routes. The inclusion of engineering venues such as IEEE Industrial Engineering and Engineering Management highlights that part of the discussion is framed in terms of systems optimization and industrial processes rather than strictly pharmaceutical or clinical concerns.

By contrast, the presence of healthcare- or biomedical-oriented journals remains very limited, with only a handful of publications in medical outlets. This confirms that the CE–pharma debate is still anchored in sustainability and engineering circles, with only early and fragmented crossover into clinical or healthcare audiences. In practice, this means that although the literature advances technical solutions, it has not yet been widely mainstreamed within pharmaceutical science, medicine, or health policy communities.

Overall, this distribution shows that CE–pharma research remains anchored in sustainability and process-oriented outlets, with only marginal penetration into mainstream healthcare or biomedical journals. This underlines both the emerging interest in the topic and the current fragmentation of its publication landscape.

Keyword clusters and thematic positioning

Building on the journal analysis, which highlighted where CE research in healthcare and pharmaceuticals is being published, it is also important to examine how this research positions itself conceptually. A keyword co-occurrence analysis provides this perspective by mapping the main thematic clusters that structure the field (Figure 24).

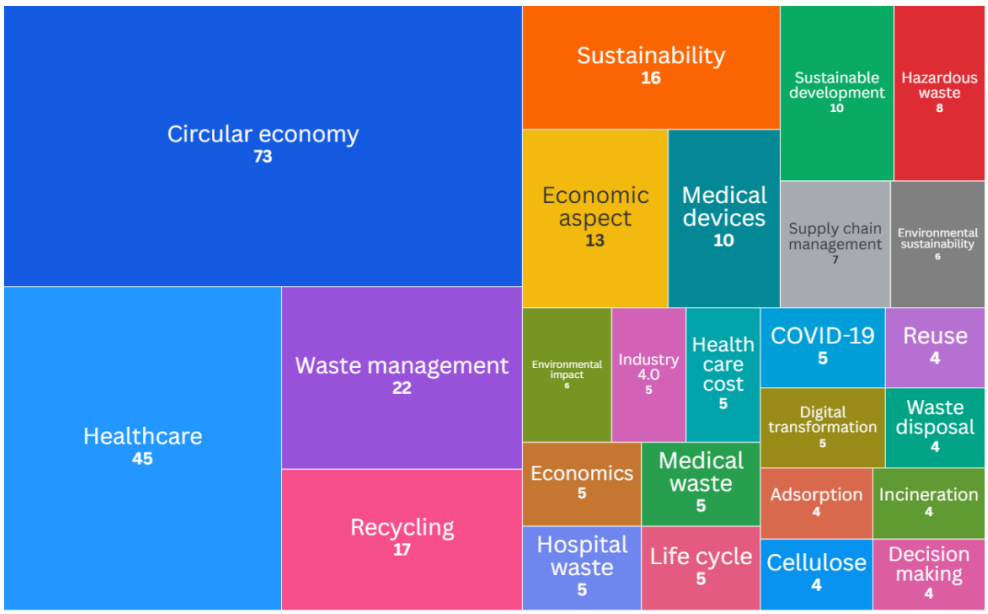

Figure 24. Keywords relative importance across the selected papers

From this analysis, several dynamics stand out:

- **Dominance of circular framing**: as expected, “circular economy” (n=73) and “healthcare” (n=45) dominate the dataset. This confirms that most publications explicitly frame their contribution in CE terms while situating the debate primarily within the broader healthcare sector rather than the pharmaceutical industry specifically.
- **Focus on waste management and recycling**: the first operational clusters relate to “waste management” (n=22) and “recycling” (n=17). Together, these account for almost one-third of the corpus, reflecting the continued predominance of end-of-pipe strategies such as improved disposal, recycling of single-use devices, or treatment of pharmaceutical residues.
- **Pharmaceutical-specific studies remain marginal**: keywords tied directly to pharmaceuticals: “medical devices” (n=10), “hazardous waste” (n=8), “pharmaceutical supply chain” (n=7), and “medical waste” (n=5), are far less represented. Despite pharmaceuticals being part of the query, applications to drug development, manufacturing, and packaging remain fragmented and comparatively underexplored.
- **Systemic sustainability framings are secondary**. terms such as “sustainability” (n=16), “sustainable development” (n=10), and “environmental impact” (n=6) occur less frequently than waste-related terms. This indicates that most contributions are problem- and technology-driven, with less emphasis on systemic perspectives such as sustainable manufacturing, SDG integration, or circular business models.
- **Emerging but scattered levers**: a smaller cluster relates to enabling approaches: “Industry 4.0” (n=5), “digital transformation” (n=4), and “decision-making” (n=4). These suggest a nascent interest in linking

CE to digital tools and managerial frameworks, though such discussions remain peripheral in the current literature.

In summary, the keyword landscape shows a field still anchored in healthcare-wide waste management, with limited traction in pharmaceutical-specific applications or systemic sustainability framings. This highlights both the current orientation of the literature and clear gaps for future research, notably, the integration of CE in pharmaceutical manufacturing, supply chains, and product/process design.

Comparing healthcare vs pharma focused literature

When disaggregating the literature, a clear imbalance appears between papers focusing on the broader healthcare sector and those specifically addressing the pharmaceutical industry. Around two-thirds of publications concern healthcare, while only one-third relate directly to the pharmaceutical industry (Figure 25). This reflects the broader dominance of global healthcare operations and hospital waste management in CE research, compared with the relatively later and narrower entry of applications in pharmaceutical development and manufacturing.
The temporal evolution (Figure Y) shows broadly similar trajectories but with consistently fewer publications for the pharmaceutical industry. In the early period (2018–2020), research was dominated by healthcare waste management and hospital supply chains. From 2021 onwards, however, the pharmaceutical stream began with systematic frameworks for manufacturing, supply chains, and regulatory enablers complementing the healthcare focus on digitalization and pandemic-driven waste challenges.

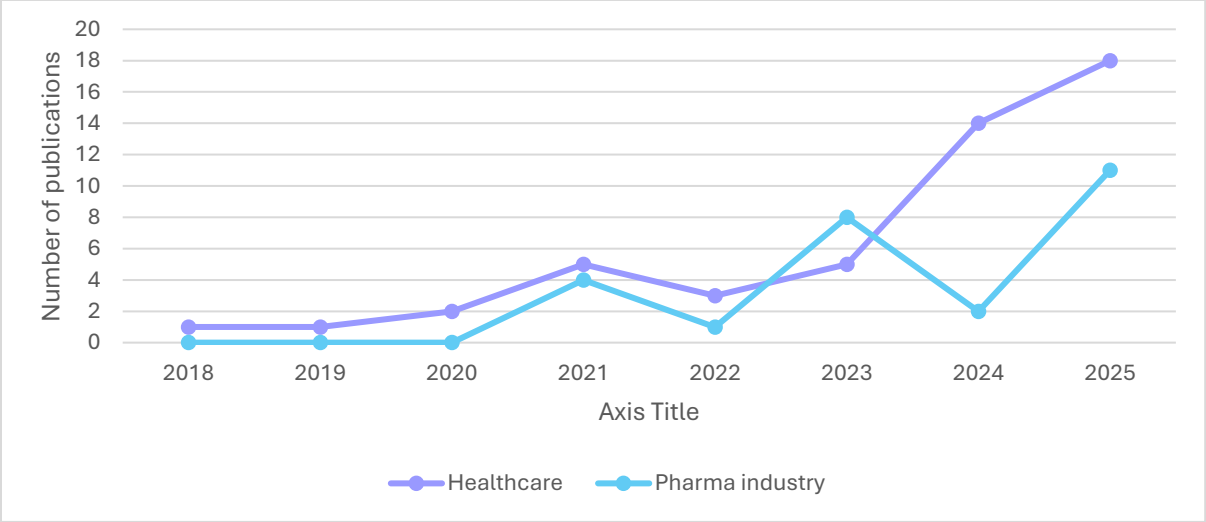

Figure 25. Publication trends in CE research: healthcare vs. pharma industry

By 2023, diversification became more visible. Healthcare studies increasingly emphasized risk management, hospital waste systems, and low-resource medical device design, whereas pharmaceutical research broadened to include packaging, supply chain resilience, and closed-loop models for drug recycling, alongside continued experimentation in wastewater treatment and API recovery. This diversification continued into 2024–2025: healthcare literature consolidated around system-level frameworks, while pharmaceutical studies embedded CE into reverse logistics, lean manufacturing, and digital enablers such as AI and blockchain.

Overall, healthcare research has historically dominated the field, often encompassing pharmaceuticals but extending well beyond. The pharmaceutical dimension has nonetheless grown rapidly in recent years. The two streams are now showing signs of convergence: healthcare increasingly frames CE as a systemic enabler of sustainability, while pharmaceuticals emphasize operational integration of CE across the product life cycle, with a strong focus on materials and manufacturing. Together, these developments suggest a shift from isolated, waste-driven interventions toward the systemic adoption of CE across the health sector.

Synthesis of the bibliometric study: patterns and insights

The bibliometric analysis shows that although the CE has become a mainstream topic within sustainability research, its application to healthcare and pharmaceuticals remains at an early stage. Publication trends indicate that the pharmaceutical sector follows the broader CE trajectory but at a much smaller scale, signaling both

growing interest and persistent underdevelopment. The keyword analysis reinforces this picture: contributions are still largely waste-oriented and end-of-pipe in nature, with only limited attention to pharmaceutical-specific challenges. Likewise, the comparison between healthcare and pharmaceutical domains reveals a structural imbalance. Healthcare dominates the discourse, particularly through studies on hospital operations and medical waste, whereas pharmaceutical research has only recently diversified beyond technical waste treatment to address supply chain resilience, packaging design, and manufacturing integration.

In summary, the bibliometric evidence suggests that CE in healthcare and pharmaceuticals continues to be framed primarily through waste management, with pharmaceutical industry opportunities being particularly underexplored and fragmented. Yet, the recent acceleration and diversification of publications point to a window of opportunity: the field is moving toward the integration of CE principles across pharmaceutical product lifecycles, supply chains, and organizational models.

2.3.6.3. Content analysis of pharma-related CE literature

To complement the SLR, we also performed a semi-systematic literature review (Snyder, 2019) using Scopus and Google Scholar. This approach allowed us to capture a broader range of publications, including grey literature and documents not easily retrieved through more restrictive systematic protocols. Because CE is an umbrella concept that encompasses diverse and sometimes loosely connected topics, it is difficult to obtain a complete and detailed overview through a single method. The additional semi-systematic review therefore aimed to identify complementary insights, acknowledging that some relevant documents may still have been missed.

This section is organized in three parts. First, we present the outcomes of the literature and the main thematic clusters that emerge. We then examine the three major reviews that provide consolidated perspectives on CE in pharmaceutical industry and healthcare sector. Finally, we synthesize the main insights and highlight persisting gaps in the literature.

Thematic mapping across the product life cycle

Current knowledge on CE in pharmaceuticals is unevenly distributed across the product life cycle. The mapping that we conducted in 2023 (Figure 26), which built on the work of Ang et al. (2020) and incorporated more than one hundred additional recent publications focusing on the pharmaceutical industry and manufacturing, showed that most studies concentrated on manufacturing and assembly, as well as on engineered materials and bulk processing (Ang et al., 2020; Massot et al., 2024). By contrast, very few contributions addressed end-of-life management, and research on raw material acquisition or the use and service phases was almost absent. This points to a persistent manufacturing bias in the literature, leaving critical upstream and downstream stages largely unexplored, even though they are essential for linking pharmaceutical industries to the broader logic of the concept of CE, and circular systems.

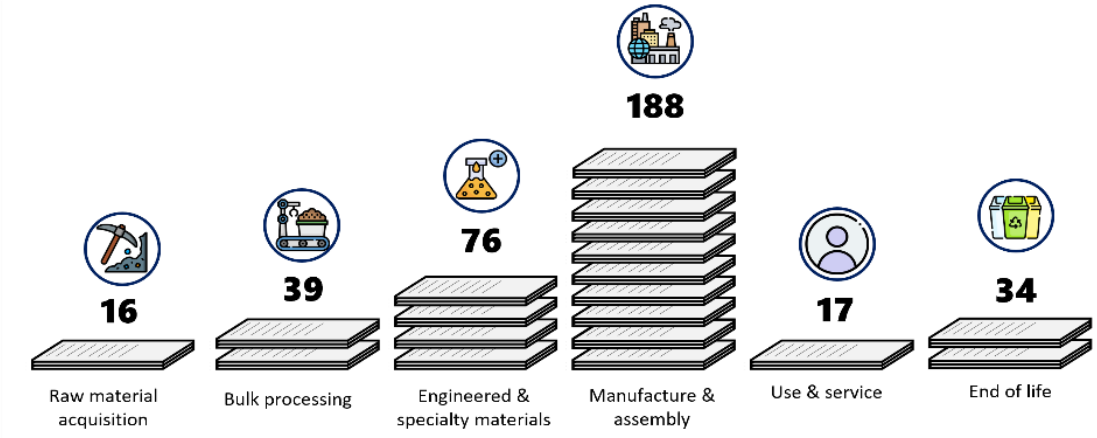

Figure 26. Breakdown of CE-related topics in the pharmaceutical industry mentioned in the literature, regarding product life cycle steps (Source: Massot et al., 2023)

Within this uneven landscape, the literature can be grouped in thematic clusters:

- ***Procurement and supply chain***. A first group of studies focused on procurement and supply chain levers, highlighting how purchasing practices could serve as a driver for circularity. Segura (2019) proposed that procurement criteria include supplier selection based on circularity, redistribution schemes for medicines approaching expiry, and new pay-for-performance purchasing models (Josep Maria Guiu Segura et al., 2019). EFPIA (2020) emphasized similar aspects, including supplier engagement, dosage optimization, and disease prevention as indirect circular strategies (EFPIA, 2020), while Mahdiraji et al. (2022) examined coordination contracts to strengthen supply chain resilience (Mahdiraji et al., 2022).

- ***Resource recovery and alternative feedstocks***. A second cluster concerned the recovery of resources and the development of alternative feedstocks. Guo (2019) argued that bio-waste could be integrated into chemical supply chains to create hub and fine chemicals (Guo et al., 2019), while the European Commission (2020) stressed the need for safe-by-design chemicals and improved methodologies to remove contaminants from recycled materials (EC, 2022b). EFPIA (2020) reported solvent and water recovery practices already in use in pharmaceutical manufacturing, but also underlined the limitations imposed by purity and quality requirements (EFPIA, 2020). Beyond technical recovery routes, chemical sciences have also advanced more systemic models that integrate eco-design and waste valorization. Zuin (2016), for instance, illustrates how integrated biorefineries can transform food residues (e.g. orange waste) into high-value chemicals such as d-limonene, pectin, and bio-based solvents, thereby embedding circularity into product and process design from the outset (Zuin, 2016). Such approaches highlight the potential of circular chemistry to create renewable feedstocks and zero-waste pathways, yet remain largely absent from the pharmaceutical literature, where resource recovery has been addressed in a more limited and process-specific manner.

- ***Waste management and reverse logistics***. Another line of research addressed waste management and reverse logistics, though this focus has been more pronounced in healthcare than in pharmaceuticals specifically. Wuyts e al (2020) and Govindan et al (2022) analyzed the dynamics of hazardous and non-hazardous waste streams (Govindan et al., 2022; Wuyts et al., 2020), and OECD (2022) documented the growing issue of household pharmaceutical waste, noting that take-back schemes remain limited in coverage and effectiveness (OECD, 2022). Ranjbari (2022) called for a comprehensive transition model for healthcare waste, emphasizing the neglected role of consumer behavior in reducing pharmaceutical waste generation (Ranjbari et al., 2022). Voudrias (2018) further framed healthcare waste management explicitly through a circular economy perspective, identifying actionable strategies such as establishing green teams, measuring material flows, environmentally preferable purchasing, and improving segregation to minimize hazardous fractions (Evangelos A. Voudrias, 2018). The study highlighted selective opportunities for circularity, including reuse of sharps containers, recycling of blue wrap and PVC devices, and reprocessing of certain single-use medical devices, while noting that infectious waste streams remain locked into linear disposal pathways.

- ***Single-use mindset and healthcare devices.*** The literature also highlighted the predominance of single-use practices within healthcare systems. MacNeill et al. (2020) argued that reliance on disposable devices is emblematic of linear logics, reinforced by regulatory asymmetries and perceptions of infection control (Macneill et al., 2020). They outlined a roadmap for change, combining procurement reform, investment in reprocessing, and circular product design. The COVID-19 pandemic amplified these dynamics: waste generation increased by 65% at its peak (Wuyts et al., 2020), while studies such as Kumar (2021) and Teymourian (2021) explored adaptive responses, from AI-based waste sorting to new decontamination technologies and bioplastics (Kumar et al., 2021; Teymourian et al., 2021). Complementing this, Voudrias (2018) provided evidence that reprocessing single-use devices can yield both financial and environmental gains (e.g., cost savings exceeding $600,000 annually and diversion of thousands of tons of waste in US hospitals), though ethical, legal, and safety concerns persist (E.A. Voudrias, 2018). This operational perspective illustrates that even within highly regulated contexts, partial shifts away from disposability are feasible.

- ***Technological innovations for remediation***. Finally, several studies focused on technological innovations for waste remediation and resource efficiency. Singh (2021) reviewed the application of nanomaterials for

pharmaceutical wastewater treatment, noting that current approaches remain dominated by short-loop strategies such as refuse, rethink, and reduce, while longer-loop recovery and recycling are less explored (Singh et al., 2021). Ghoushchi (2022) proposed decision-support tools to prioritize barriers in medical waste management (Ghoushchi et al., 2022), while digital solutions such as AI (Kumar et al., 2021) were tested to enable smarter waste sorting and data-driven CE practices.

In summary, this body of work illustrates both the breadth and the fragmentation of CE research in pharmaceuticals and healthcare. Technical studies dominate, particularly in relation to green chemistry, process optimization, and materials recovery, while systemic levers such as procurement, governance, and user behavior remain marginal and are often confined to policy or industry reports.

Consolidated reviews of CE in pharma and healthcare

The SLR conducted allowed the identification of three comprehensive reviews in the field of CE in the pharmaceutical and healthcare sectors. This section summarizes the reviews and presents a synthesis table that highlights key differences between them. The outcomes of these systematic reviews are then discussed.

Pharmaceutical manufacturing

The first attempt to consolidate CE literature to the pharmaceutical industry was provided by Ang et al., 2021 (Kun Liang Ang et al., 2021). With their research they aim to adapt the generic 9R framework to the pharmaceutical sector. This paper was the first structured attempt to review sustainable pharmaceutical manufacturing through a circular economy lens. Its originality lies in adapting the generic 9R framework into a pharma-specific PM9R, aligning each "R" with sectoral realities such as drug repurposing, solvent reclamation, or API redesign. By classifying 182 papers, the authors revealed a striking imbalance: 83% addressed short-loop strategies (Refuse, Rethink, Reduce), primarily in the form of green chemistry research, new catalysts, greener solvents, mechanochemistry, or solvent-free synthesis. These innovations, while scientifically significant, remain largely confined to laboratory scale and early design stages. Medium loops (Reuse, Repair, Refurbish, Repurpose) were rare, usually tied to solvent recovery or drug repurposing, and long loops (Recycle, Recover) almost absent, with only isolated studies on wastewater treatment or biofuel recovery.

The analysis highlighted three thematic areas: (1) alternative chemistry (dominant, but design-centric), (2) alternative processes (notably separation and recovery technologies like pervaporation, nanofiltration, and continuous flow), and (3) alternative functions (drug repurposing, agro-waste valorization). This mapping underlined a mismatch between academic focus and industrial needs: while academia prioritizes green synthesis routes, industry is constrained by the need for downstream solutions (solvent recovery, equipment reuse, robust process optimization). Moreover, the paper documented structural barriers: scaling gaps (lab results rarely translated into industrial-scale simulations or cost analyses), intellectual property restrictions that hinder repurposing or sharing, and stringent regulatory frameworks (FDA, EMA) that slow any modification in API design, process, or device.

In short, Ang et al. provided a conceptual foundation (PM9R) and diagnosed the main obstacles but offered little in terms of pathways for operationalization (Figure 27). The review effectively shows that CE in pharma research has been dominated by chemistry innovations, with systemic, organizational, and regulatory dimensions largely untouched.

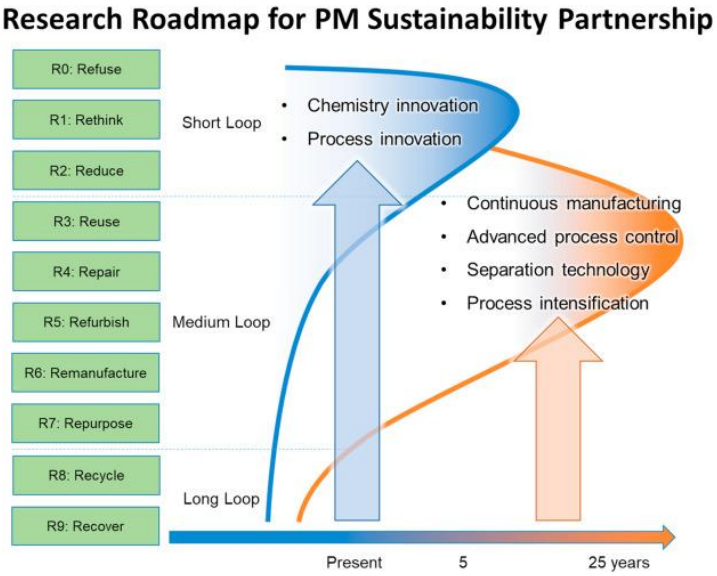

Figure 27. Research roadmap for sustainable pharma manufacturing (Source: Ang et al., 2021)

CE in the healthcare sector

The second review made available was the one from D'Alessandro et al., 2024 (D'Alessandro et al., 2024). This review broadened the scope from pharma to healthcare, using a systematic review (36 papers, 2016–2023) combined with bibliometric analysis. Its main contribution is a classification of CE practices into four categories: R-strategies (47%, e.g. recycling, reuse, reprocessing), design opportunities (25%, such as 3D-printed implants or gown material substitution), technological involvement (20%, including smart waste management, blockchain, Industry 4.0/5.0), and stakeholder involvement (8%, training and awareness). The areas of application mirrored this distribution: healthcare waste management and medical devices dominated (39% each), while supply chains, stakeholder engagement, construction, and treatment accounted for marginal shares.

The bibliometric analysis showed exponential growth from 2021, driven by Europe (58%) and Asia (22%), with key outlets such as the Journal of Cleaner Production and Resources, Conservation and Recycling. Keyword clustering revealed strong associations between "plastic waste," "LCA," "single-use," and "operating rooms," indicating where environmental hotspots have been conceptualized.

D'Alessandro et al. also surfaced key barriers: behavioral resistance (preference for disposables), high costs of technology adoption, and regulatory uncertainty. Importantly, they stressed that while R-strategies dominate, systemic enablers such as policy frameworks, supply chain coordination, or governance are underrepresented. Moreover, the integration of Industrial Ecology tools (LCA, MFA) was shown to be limited: only a handful of studies attempted to quantify impacts or flows, leaving most of the evidence base qualitative.

Thus, the paper succeeds in offering a first structured taxonomy of CE practices in healthcare but also illustrates the field's fragmentation and its tendency to treat circularity as isolated interventions (e.g. device reuse, recycling of plastics) rather than integrated transformations across healthcare systems.

CE in healthcare systems

The most recent review was published by Saha et al., 2025, and takes a more critical stance, arguing that healthcare CE research is locked in a "post-waste" paradigm, essentially reactive management of waste after it has been produced (K. Saha et al., 2025). Through a mixed-methods approach (bibliometric and content analysis of 75 papers), the authors identified four dominant themes: sustainable product design (44%), waste management (39%), economic and policy frameworks (16%), and education/stakeholder engagement (1%). Compared to earlier reviews, this categorization makes visible what is missing: systemic enablers such as procurement reform, financial mechanisms, regulatory harmonization, and professional training.

The bibliometric analysis mapped the intellectual structure of the field, showing clusters around waste treatment, product circularity, medical product design, and resource recovery, but little connection between them. The content analysis reinforced this: most studies were qualitative or case-based, with few quantitative or comparative studies, and almost no cost–benefit or feasibility analyses. Geographically, Europe led (28%), Asia followed (21%), North America lagged (19%), and South America and Africa were barely present.

What distinguishes this review from the others is its effort to reposition the debate: CE in healthcare should not be equated with end-of-pipe waste handling, but with preventive, systemic design of products, processes, and institutions. It explicitly called for integrating procurement policies (e.g. NHS Scotland trials), financial incentives, reverse logistics, and sustainability education into the CE agenda. However, the evidence base remains fragmented, with policy, economics, and training mentioned more as future directions than as established practices. Saha et al. thus mark a conceptual advance: they move the field beyond technical fixes and begin to articulate the systemic levers required for transition. Yet, their analysis confirms how underdeveloped these dimensions still are in practice, leaving healthcare CE dominated by product-level and downstream solutions.

Cross-review synthesis

To facilitate comparison, the key features, contributions, and gaps of the three reviews are summarized in Table 6 below.

Table 6. Comparison of key CE reviews in healthcare and pharmaceutical industry

Dimensions	Ang et al. (2020)	D'Alessandro et al. (2024)	Saha et al. (2025)
Scope	Pharma manufacturing (PM), processes, APIs, solvents	HC sector broadly (hospitals, supply chains, devices)	HC systems
Method	Review of 182 papers (1990–2019, WoS);	SLR + bibliometric; 36 papers (2010–2023, Scopus/WoS)	SLR + bibliometric + thematic coding; 75 papers (2014–2024)
Main focus	Short-loop Rs (83%): green chemistry, catalysts, solvents, API design	chemistry, catalysts, solvents, API design Waste & resource efficiency in hospitals, supply chains, medical devices	Waste management (39%) and product design (44%) dominate; systemic enablers remain marginal.
Underexplored areas	Medium/long loops (reuse, refurbish, recycle, recover); systemic integration	Systemic frameworks (policy, governance, business models)	Policy/economic enablers; education & stakeholder engagement; quantitative evidence
Barriers identified	• Scaling gaps • IP/patents • Regulatory hurdles	• Infection-control bias • Single-use reliance • Costs • Lack of systemic models	• Fragmented literature • Regulatory resistance • Patient safety & cost concerns • Lack of quantitative/ empirical data
Key contributions	• 1st pharma-specific CE framework • Maps short/ medium /long loops • Highlights academia–industry gap"	• 1st structured taxonomy of CE practices in HC • Emphasizes governance & systemic enablers	• Consolidates 10 years of CE research in HC • Shows "post-waste" industry focus • Sets future agenda: modular design, education, circular supply chains
Gaps & research agenda	• Industrial-scale validation & cost analysis • Regulatory adaptation • Academia–industry–regulator collaboration	• Develop systemic CE models for HC • Strengthen governance, procurement, and cross-sector partnerships	• Strengthen policy & education • Test circular supply chains & reverse logistics • Embed CE in healthcare curricula

The analysis of existing reviews makes clear that research on CE in this field has developed along two distinct paths. On the one hand, reviews such as D'Alessandro (2024) and Saha (2025) consider the healthcare sector broadly, covering hospitals, medical devices, supply chains, waste streams, and service delivery (D'Alessandro et al., 2024; K. Saha et al., 2025). These contributions capture systemic issues such as waste management, policy frameworks, supply chain resilience, and stakeholder engagement, but they address pharmaceutical production only as one element among many. On the other hand, Ang et al. (2021) focused specifically on pharmaceutical manufacturing, providing granular insights into chemistry, solvents, and process optimization through the PM9R framework (K.L. Ang et al., 2021). Despite this work delivers valuable technical depth, it remains largely confined to short-loop strategies and does not extend to governance or organizational integration. Taken together, these reviews show that existing knowledge is both fragmented and uneven: the healthcare-focused studies offer breadth

but little sectoral specificity, while the pharmaceutical review offers technical depth but little systemic scope. This contrast underscores the need for approaches that can bridge technical and organizational dimensions of circularity.

2.3.6.4. Synthesis of the literature review and common findings

The combined evidence from the bibliometric analysis, the content study, and the three consolidated reviews offers a coherent picture of how CE has been addressed in healthcare and pharmaceuticals to date. Several patterns can be identified:

(1) **Healthcare dominance:** the literature is largely driven by healthcare perspectives, particularly hospital waste management, medical devices, and disposal practices. Pharmaceutical-specific studies exist but remain a minority, and when present they are often restricted to manufacturing waste management or process-level substitution (e.g. solvents, catalysts, yields).
(2) **Short- vs long-loops:** across the two domains, CE research shows a structural imbalance. In pharmaceuticals, the focus lies upstream, on short-loop innovations such as green chemistry, new solvents, and process substitution. In healthcare, by contrast, most contributions address downstream challenges, particularly waste management, recycling, and the reprocessing of medical devices. By comparison, intermediate loops (e.g., reuse, remanufacture), as well as systemic enablers like global and procurement frameworks or governance models, are much less developed in the existing literature.
(3) **Weak systemic enablers:** issues such as governance, regulatory alignment, procurement reform, supply chain resilience, and stakeholder engagement appear only sporadically, mostly in policy or industry reports rather than peer-reviewed research. Even when acknowledged, as in Saha et al. (2025), these dimensions are framed as future directions rather than established fields of inquiry (K. Saha et al., 2025).
(4) **Barriers to implementation**: across both domains, persistent obstacles hinder translation into practice: scaling gaps between lab-scale innovations and industrial application, regulatory and intellectual property hurdles, entrenched reliance on single-use practices, and a lack of quantitative or empirical validation.

In summary, the literature reveals a field that is expanding but remains uneven and fragmented: healthcare-focused studies provide breadth but little sectoral specificity, while pharmaceutical work provides depth but limited systemic scope. This synthesis therefore points to the need for approaches that can connect technical innovation with organizational and systemic integration.

2.3.7. Key gaps and needs for CE integration in pharma

The analysis of the CE literature in general, and in the pharmaceutical industry more specifically, allowed a deeper understanding of what CE entails and what should be considered when applying it in practice. From this review, several key gaps were identified. These are not simply a matter of missing topics but reflect deeper imbalances in how the field has evolved.

Polarized focus across life cycle stages.
Current research is unevenly distributed, with pharmaceutical studies concentrating on upstream design and short-loop principles (e.g., green chemistry), while healthcare research emphasizes downstream waste management. The "middle loops" are scarcely addressed (K.L. Ang et al., 2021; D'Alessandro et al., 2024; K. Saha et al., 2025; Evangelos A. Voudrias, 2018). This polarization prevents a full life cycle perspective and hinders system-wide adoption.

➔ *There is a need to ensure that CE practices cover the entire life cycle and integrate short, medium, and long loops.*

Absence of integrative frameworks
Most contributions are either narrow and technical (pharmaceutical manufacturing) or broad and system-wide (healthcare systems), but few connect the two (K.L. Ang et al., 2021; D'Alessandro et al., 2024; K. Saha et al., 2025). Missing are approaches that bridge product- and process-level innovations with organizational, regulatory, and policy mechanisms that enable circularity at scale (EFPIA, 2020; Guzzo et al., 2022).

➔ *There is a need for integrative frameworks that connect product and process dimensions with organizational, regulatory, and policy mechanisms, aligning sector-wide strategies with pharmaceutical-specific practices.*

Weak organizational and governance dimensions
The literature gives little attention to enablers such as procurement, business models, governance models, supply chain alignment, or capability-building (Chen et al., 2020; EFPIA, 2020; Mahdiraji et al., 2023; Scheepens et al., 2016; J.M. Guiu Segura et al., 2019). As a result, many initiatives remain pilot projects or isolated technical fixes, rarely embedded into organizational routines or sectoral strategies (Macneill et al., 2020; Ritzén and Sandström, 2017).

➔ *Stronger attention should be placed on the organizational enablers of CE in pharmaceuticals, going beyond technical solutions to address systemic change, with governance structures, procurement criteria, and cross-sectoral collaboration mechanisms that embed circularity into the daily routines and decision-making processes of the industry.*

Limited translation into practice
A persistent gap separates research from implementation: technical studies often remain at laboratory scale, with scarce cost–benefit analyses or feasibility studies (K.L. Ang et al., 2021; Zuin, 2016). Regulatory complexity and intellectual property barriers exacerbate the problem, creating inertia between innovation and industrial uptake (K. Saha et al., 2025).

➔ There is a need for more applied and translational research, including techno-economic assessments, regulatory adaptation strategies, and industrial-scale validation and standardization.to close the gap between innovation and practice.

Neglected role of internal and external stakeholders
Pharmaceutical stakeholders, healthcare professionals, and patients are not always included in the CE debate, despite their central role in circular strategies such as process optimization, take-back schemes, optimized prescribing, and product–service models (EFPIA, 2020; K. Saha et al., 2025; Soares et al., 2023; Tan et al., 2020). Their exclusion narrows the scope of current research.

➔ *There is a need to engage internal and external stakeholders, integrating behavioral, cultural, and educational dimensions into CE strategies for the pharmaceuticals industry.*

The above-mentioned gaps reveal that, while CE research in pharma and healthcare has generated promising technical innovations, it has not yet developed pathways for systemic integration. Future progress depends on connecting technological advances with organizational capabilities, governance mechanisms, and stakeholder engagement to enable circularity across the sector.

2.3.8. Synthesis of CE and its integration in the pharmaceutical industry

The CE has matured into a central sustainability concept, structured by widely cited principles and frameworks (EMF, 2013b; Kirchherr et al., 2023, 2017). Tools and indicators have proliferated (Elia et al., 2017; Saidani et al., 2019; Valls-Val et al., 2022), but they remain fragmented and inconsistent, often emphasizing recycling over higher-value loops and lacking integration with life-cycle and absolute sustainability perspectives (Corona et al., 2019; Lonca et al., 2020; Zils et al., 2023).

In healthcare and pharmaceuticals, research remains both limited and uneven. Healthcare studies focus largely on downstream waste and medical device management (D'Alessandro et al., 2024; Macneill et al., 2020; Evangelos A. Voudrias, 2018), while pharmaceutical research emphasizes upstream innovations in chemistry and process substitution (K.L. Ang et al., 2021; Zuin, 2016). Mid-stream strategies such as procurement reform, reuse, or supply-chain circularity receive comparatively little attention (EFPIA, 2020; Mahdiraji et al., 2023; J.M. Guiu Segura et al., 2019). Bibliometric evidence reinforces this picture: fewer than 20 publications address pharmaceuticals explicitly, versus thousands on CE more broadly.
Existing comprehensive reviews of the literature further illustrate this imbalance. Ang et al. (2021) mapped pharma-related CE literature showing a dominance of short-loop strategies and proposed a PM9R framework (K.L. Ang et al., 2021). D'Alessandro et al. (2024) highlighted healthcare waste and device reuse but weak governance integration (D'Alessandro et al., 2024). Saha et al. (2025) argued the field remains locked in "post-waste" logics and called for systemic approaches spanning procurement, finance, and education (K. Saha et al., 2025).

In summary, CE in the pharmaceutical sector is promising but remains underdeveloped: even though technical innovations are emerging, they are fragmented and not yet systemically integrated. Organizational enablers and systemic frameworks are largely absent, making it essential to bridge these dimensions in order to embed CE across pharmaceutical life cycles and align the sector with broader sustainability transitions (Cerf, 2019; EFPIA, 2020; Soares et al., 2023).

2.4. SYSTEMIC TRANSITION AND ORGANIZATIONAL CHANGE

The previous section reviewed the literature on CE and on CE in the pharmaceutical, highlighting both the opportunities and the gaps that remain. This review showed, on the one hand, that CE needs to be integrated into the pharmaceutical sector more systemically, and on the other hand, that several structuring elements of CE, such as principles, frameworks, tools, and indicators, can serve as a foundation for such integration. Importantly, what emerged from this analysis is that defining how the CE and associated principles can be integrated within an organization is crucial and lies not only on what needs to be done, but also on how to do it. Indeed, strategies may articulate what should be achieved through goals, key performance indicators, and integration models, but the persistent challenge lies in how these ambitions can be embedded into organizations, through decision-making processes, governance mechanisms, and dynamic capabilities. In other words, systemic integration requires bridging between the development of structuring elements (e.g., strategies, frameworks, indicators) and their institutionalization across the organization (e.g., stakeholders, processes, culture, behaviors).

To explore how this bridging can occur, the following section turns to the literature on strategic management and organizational change management, examined through the lenses of organizational learning, capability, and maturity (Figure 28). The reviews conducted here followed a semi-systematic approach (Snyder, 2019), aimed at identifying and synthesizing key themes rather than exhaustively covering all publications. Several thematic reviews and conceptual contributions were used as entry points, and backward and forward snowballing was applied to trace the most relevant and connected works. This process consolidated recurring dimensions across the literature, which are presented under four interrelated perspectives:

- **Corporate strategy:** the role of strategic management, planning and strategic thinking in defining direction.
- **Organizational Learning (OL)**: the mechanisms by which knowledge and experience are transformed into routines.
- **Organizational Change Management (OCM)**: the processes and enablers of transformation.
- **Capabilities and maturity**: the means to institutionalize sustainability and evaluate progress.

Together, these perspectives provide the conceptual foundations for systemic integration. They highlight the key elements: strategic management, organizational learning, organizational change management, and capability development, that the literature identifies as essential for integrating new concepts or approaches such as environmental sustainability into organizations. By synthesizing these dimensions, this section structures the basis upon which systemic integration can be understood and conducted, before turning later in the thesis to how these insights can be applied within the pharmaceutical sector.

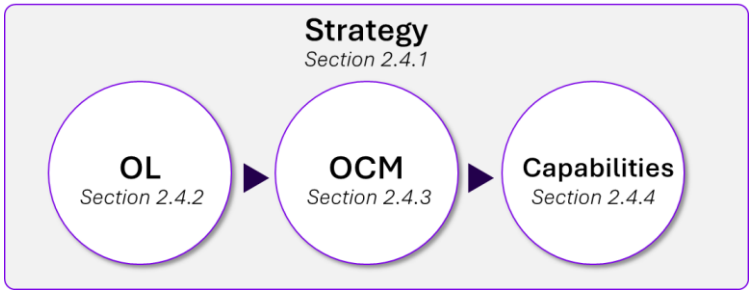

Figure 28. Structure of Section 4

2.4.1. Strategies as a foundation for systemic integration

This PhD is situated within the broader field of corporate strategy, and more specifically within strategic management, strategic planning and strategic thinking (Pieroni, 2020). Strategies are therefore a natural starting point for examining how environmental sustainability can be embedded in the pharmaceutical sector.
To structure this discussion, the section is organized into three parts: first, the general role of strategies in guiding organizational direction; second, the ways in which strategies intersect with sustainability objectives; and third, the limitations of strategies when considered in isolation from organizational processes and capabilities.

2.4.1.1. The role of strategy in organizations

The concept of strategy has been central to management scholarship for decades, but its meaning has remained fluid. Early definitions emphasized the long-term orientation of strategy and its connection to organizational objectives. As summarized by Nickols (2016), Chandler (1962) described strategy as "the determination of the basic long-term goals and objectives of an enterprise, and the adoption of courses of action and the allocation of resources for carrying out these goals." In the same vein, Andrews (1980) characterized it as "the pattern of decisions" that shapes objectives, policies, and the scope of the organization's contributions. Nickols (2016) further notes that during the 1980s and 1990s, Porter emphasized competitive positioning, while Mintzberg highlighted emergent patterns of action. Mintzberg later articulated strategy as a plan, a pattern, a position, a perspective, or a ploy, reflecting the multiple functions that strategy can serve within organizations (Nickols, 2016).

Building on these definitional debates, Heracleous (1998) examined the introduction of the terms "strategic planning" and "strategic thinking" into the literature (Heracleous, 1998). He found significant confusion in their use, but also a broad consensus that planning is associated with analytical, programmatic, and convergent processes, whereas thinking involves more creative, synthetic, and divergent reasoning. According to Heracleous, both processes are necessary: strategic planning operationalizes existing strategies, while strategic thinking enables novel strategies that challenge prevailing assumptions. He proposed a dialectical view in which strategic planning and strategic thinking represent distinct but complementary modes of reasoning. To clarify the distinction, he drew on organizational learning theory: planning as single-loop learning, operating within existing assumptions, and thinking as double-loop learning, which questions and reshapes those assumptions. This perspective positioned effective strategic management as the interplay of convergent and divergent modes of thought (Figure 29) (Heracleous, 1998).

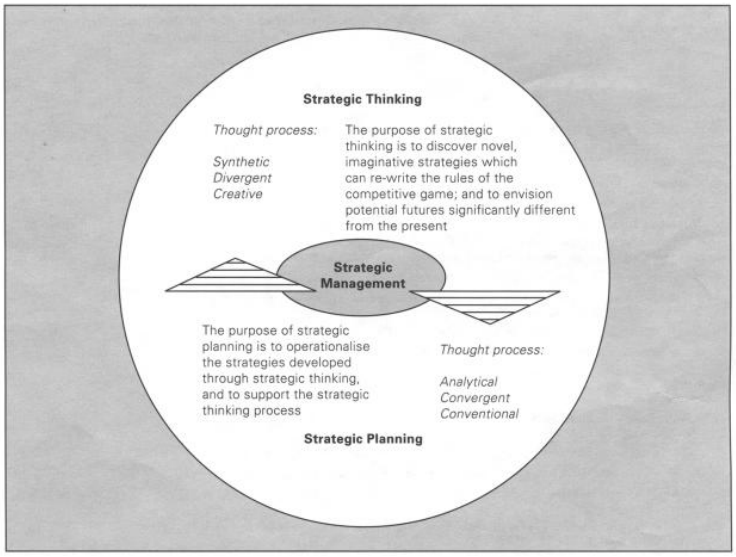

Figure 29. Strategic thinking and strategic planning (Source: Heracleous, 1998)

More recent contributions have sought to consolidate these distinctions into a clearer framework. Nickols (2016) reviewed the definitional evolution of strategy and synthesized it into a broad, practical formulation: strategy as a "general plan of action for achieving one's goals and objectives." Nickols (2016) proposes that these concepts are best understood as a set of "nested" elements (Nickols, 2016). Strategic management consists of strategy

formulation, strategic planning, and strategy deployment, which together aim to realize the intended goals (Figure 30). Overarching these, strategic thinking provides the creative and adaptive foundation, ensuring that planning and management are not reduced to routine exercises but remain aligned with broader purpose and evolving contexts. In this view, the objective is not to engage in strategic planning for its own sake, but to think and manage strategically.

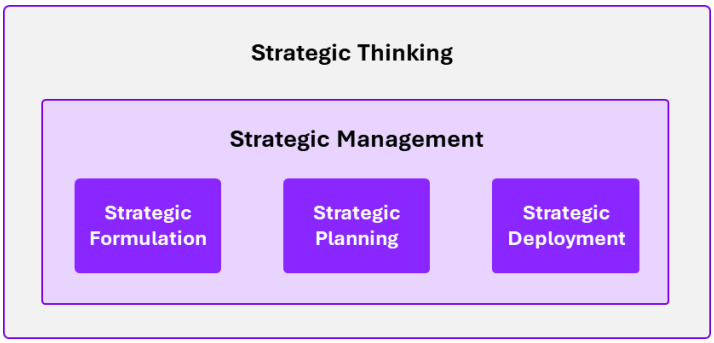

Figure 30. The "Nested" concepts related to strategy (adapted from Nickols, 2016)

This view aligns with Abraham (2012), who also distinguishes between planning (systematic process), thinking (creative generation of alternatives), and management (execution) (Abraham, 2012). The relevance of this distinction has been confirmed in the context of environmental sustainability, where Pieroni (2020) situates sustainability integration within corporate strategy, emphasizing that strategic planning structures the process while strategic thinking enables the generation of alternative business models for a CE (Pieroni, 2020).

These contributions illustrate that although the definitions of strategy have varied across time, there is convergence on three essential dimensions: setting direction and goals, framing and guiding decisions, and allocating resources. They also underscore that strategic management should not be reduced to formal planning exercises, but understood as a dynamic interplay between formulation, planning, deployment, and overarching strategic thinking.

2.4.1.2. Strategies and sustainability

Besides generic definitions of strategy, several contributions have examined how strategic management can specifically be mobilized to address sustainability. Placet et al (2005) argue that a sustainability-focused business strategy must rest on the three interdependent “cornerstones” of environmental stewardship, social responsibility, and economic prosperity. Their case study in the cement industry and the State of Arizona illustrates that such strategies cannot be generic. Rather, they require both innovations, often radical process, product, and business model innovation, and customization to the sectoral and regional context. Incremental improvements are unlikely to deliver the scale of change required; instead, sustainability strategies must open new pathways that reduce resource intensity, engage stakeholders, and reconfigure organizational value creation (Placet et al., 2005).

This emphasis on differentiated approaches is also reflected in the work of Baumgartner and Ebner (2010), who propose a typology of corporate sustainability strategies (Baumgartner and Ebner, 2010). They distinguish between four archetypes: introverted strategies, focused mainly on compliance; extroverted strategies, oriented toward external legitimization; conservative strategies, emphasizing efficiency and internal optimization; and visionary strategies, which adopt a holistic and proactive approach to sustainability. Each strategy type corresponds to different maturity levels across economic, ecological, and social dimensions, ranging from rudimentary compliance with regulation to sophisticated integration and leadership. Importantly, their framework highlights that sustainability strategies must also align with a firm’s competitive strategy. When designed coherently, they can reinforce cost leadership, product differentiation, or hybrid approaches; when misaligned, they risk remaining rhetorical or superficial (Baumgartner and Ebner, 2010).

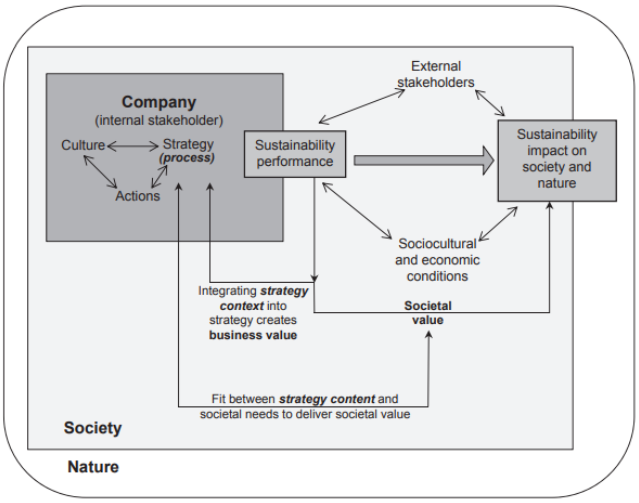

Fig. 3. Strategic perspectives integrated into a corporate sustainability impact chain.

Figure 31. Strategic perspectives integrated into a corporate sustainability impact chain (Source: Baumgartner and Rauter, 2017)

Further refinement has been provided by Baumgartner and Rauter (2017), who argue that sustainability cannot remain confined to abstract strategic declarations but must be integrated into organizational activities, routines, and processes (Baumgartner and Rauter, 2017). They conceptualize strategy through three interrelated dimensions: process, context, and content (Figure 31). The process refers to how strategies are constructed and implemented; the context encompasses the internal and external conditions, such as regulation, resource scarcity, or stakeholder pressures, that shape strategic choices; and the content represents the substantive outputs of strategy, namely goals, activities, and their implications for the organization and its stakeholders. Crucially, they argue that effective sustainability strategies must begin with clarifying the "why" (purpose), before defining the "what," "when," and "how" of strategic activities, ultimately embedding sustainability into operational management (Baumgartner and Rauter, 2017). As an example, Broman and Robert (2015) proposed the Framework for Strategic Sustainable Development (FSSD), which operationalizes sustainability strategies by combining a long-term perspective with actionable pathways (Broman and Robèrt, 2017a). Instead of extrapolating from current practices, the FSSD uses backcasting from sustainability principles to first define a desirable future state and then guide organizations in identifying the steps needed to achieve it (Figure 32). This framework illustrates how strategies can be both principled and adaptable, bridging high-level ambitions with context-specific implementation (Broman and Robèrt, 2017a).

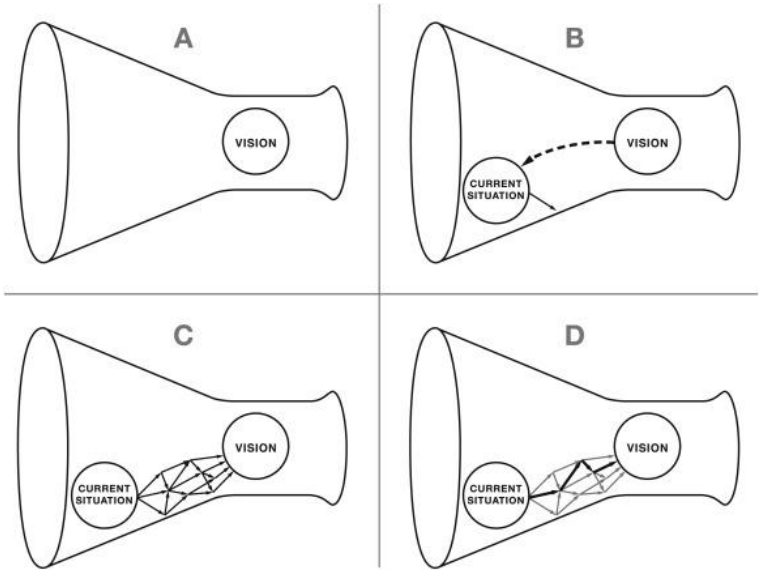

Figure 32. Funnel metaphor with ABCD-procedure of the FSSD (Source: Broman and Robert, 2017)

These publications underscore the importance of strategies for effective sustainability integration in organizations. However, they also highlight that strategies are not only about setting ambitions or principles, but about translating them into concrete profiles, maturity pathways, and organizational practices. In other words, they require both direction and depth: a clear purpose and vision (Placet et al., 2005), a structured profile that distinguishes orientations and levels of ambition (Baumgartner and Ebner, 2010), and integration into everyday decision-making and routines through the interplay of process, context, and content (Baumgartner and Rauter, 2017).

2.4.1.3. Why strategy alone is not enough

Strategies for sustainability provide purpose, orientation, and structured profiles of ambition, yet they do not guarantee effective implementation. Defining the why, the what, and the when of sustainability is a crucial step, but without a clear articulation of the how, strategies risk remaining aspirational (Baumgartner and Rauter, 2017). Many organizations struggle to move beyond high-level commitments because the concrete mechanisms that embed sustainability into everyday routines are missing.

This translation gap is consistently highlighted in the literature. Waas et al. (2014) distinguish between strategies, which describe a direction of travel towards a desired future, and decisions, which are the concrete choices that resolve uncertainty and enact the strategy. Without explicit mechanisms linking the two, strategies remain disconnected from practice and fail to generate measurable impact (Waas et al., 2014).

The reasons for this disconnection are well documented. Lozano (2012) emphasizes that organizational change is a complex and iterative process: new approaches must be embedded into existing processes, behaviors, and culture, rather than added as external layers. Strategies that remain confined to high-level plans often fail because they overlook these organizational dynamics (Lozano, 2012). In parallel, Teece (2018) underlines that strategies must be complemented by dynamic capabilities, defined as the organizational ability to sense opportunities, seize them, and reconfigure resources in response to evolving contexts. Without such capabilities, strategies risk remaining static and ineffective in turbulent environments (Teece, 2018).

Together, these insights suggest that while strategies are indispensable for setting direction, they are not sufficient to ensure systemic integration. What is required is a focus on the how, the organizational mechanisms that enable strategies to take root in everyday decision-making and resilient.

2.4.1.4. Synthesis on the role of strategies for environmental sustainability

In conclusion, strategies play a crucial role in framing sustainability ambitions and providing direction. They clarify why action is needed, what goals to pursue, and under which conditions these should be achieved. Different approaches highlight complementary dimensions: sustainability strategies must articulate a clear purpose and vision (Placet et al., 2005), be differentiated through profiles and maturity levels (Baumgartner and Ebner, 2010), and integrate process, context, and content to ensure coherence (Baumgartner and Rauter, 2017). The FSSD further exemplifies how such strategies can be operationalized through backcasting from sustainability principles (Broman and Robèrt, 2017a).

However, the literature also converges on the idea that defining strategies is not sufficient to achieve systemic integration. A strategy may outline the “why,” the “what,” and the “when,” but it often leaves open the crucial question of “how.” Without mechanisms that embed ambitions deeply into the organization, its processes, routines, decisions, and stakeholders, strategies risk remaining aspirational rather than transformative.

2.4.2. Organizational learning: building from experience

Strategies set purpose and direction for environmental sustainability, but they do not by themselves ensure systemic change. The persistent challenge is translating ambitions into organizational routines and practices. Organizational learning (OL) provides the mechanism for this translation, enabling organizations to absorb knowledge, adapt structures, and institutionalize new practices.

OL is not limited to setting objectives but unfolds as a continuous practice of action, reflection, and adaptation. As Serrat (2017) notes, strategizing depends on daily habits and must be refined through cycles of feedback and

iteration (Serrat, 2017). Concretely, OL involves knowledge acquisition, distribution, interpretation, and memory (Kloot, 1997), closely linked with knowledge management processes such as capturing, sharing, and reusing insights (Zils et al., 2023).

This perspective is particularly relevant for circular economy and sustainability transitions. Tools such as LCA and pilot projects can reveal opportunities, but without OL they remain disconnected experiments. Studies show that pilots only achieve systemic impact when lessons are captured, disseminated, and embedded into organizational routines (Boscherini et al., 2010; Zils et al., 2023). In this way, OL bridges strategic ambition, project experimentation, and lasting organizational change.

2.4.2.1. Foundations and practices of OL

Organizational learning has been described as a multidimensional process through which organizations acquire, interpret, and institutionalize knowledge. Early accounts identify four interrelated constructs: knowledge acquisition, information distribution, information interpretation, and organizational memory (Kloot, 1997; Williams, 2008). Knowledge acquisition refers to the mechanisms through which organizations gather insights, whether through projects, external scanning, or experimentation. Information distribution concerns the internal flows of knowledge across units and functions, ensuring that learning does not remain isolated. Information interpretation emphasizes the sense-making process: actors must not only receive data but also contextualize it and draw actionable meaning from it. Finally, organizational memory represents the institutionalization of knowledge into routines, databases, or cultural norms that preserve and transmit insights over time (Kloot, 1997; Williams, 2008). These constructs provide the foundation of OL and highlight that learning requires both cognitive and structural dimensions.
This perspective connects directly to the domain of knowledge management (KM), which operationalizes OL KM processes typically involve capturing, storing, sharing, retrieving, and reusing organizational knowledge (Nonaka et al., 2006). In this sense, KM can be seen as the operational arm of OL, providing methods and tools to leverage knowledge embedded in people and systems to support strategic goals and project execution. Among KM practices, lessons learned approaches are particularly significant. Originally conceived as a checklist of what went right or wrong in projects (Stewart, 1997), the concept has evolved to encompass both explicit and tacit dimensions of knowledge (Weber et al., 2001). Lessons learned now involve identification, validation, contextualization, and re-application to new contexts (Rowe, 2013).

Nevertheless, despite their apparent simplicity, lessons learned processes remain challenging in practice. Studies show that organizations often succeed in the identification stage, through reflection workshops, post-project reviews, or milestone assessments, but fail when it comes to dissemination and especially application (Duffield and Whitty, 2015; Williams, 2008). Barriers include cultural resistance, lack of incentives, inadequate systems for knowledge retrieval, and the inherently social nature of learning, which depends on trust and dialogue (Duffield and Whitty, 2015). As a result, valuable experiences frequently remain underutilized, and mistakes are repeated across projects. As Serrat (2017) highlights, overcoming these shortcomings requires a practice-oriented perspective. Strategy cannot remain at the formulation level: it must be navigated and enacted through iterative assessment, feedback, and adaptation (Serrat, 2017). Tools such as after-action reviews or retrospect make performance evaluation routine, by explicitly asking what was intended, what worked, and what should be done differently next time. In addition, Serrat emphasizes the value of codifying “good practices” and developing supporting infrastructures that ensure they can be disseminated and applied across contexts. This view directly links OL to strategic execution, since strategies that are not embedded in practice and continuously refined through learning risk remaining aspirational.

This challenge underscores a key point: organizational learning is not guaranteed by knowledge capture alone. It requires active processes that embed insights into organizational memory and routines, supported by both technical infrastructures (databases, portals, dashboards) and social infrastructures (communities of practice, mentoring, storytelling). Where these elements align, organizations are better equipped to transform isolated project experiences into systemic practices that inform strategy and build long-term capabilities.

2.4.2.2. Frameworks, models and practices of OL

The literature does not present a single unified model of organizational learning (OL) but rather a diversity of frameworks, practices, and enablers that explain how knowledge is generated, retained, and applied within organizations. Some key elements form the literature are summarized hereafter.

Early reviews highlighted the fundamental building blocks of OL. Kloot (1997) identified four major constructs: knowledge acquisition, information distribution, information interpretation, and organizational memory (Kloot, 1997). This conceptualization was later echoed in Williams (2008), who noted that while knowledge acquisition is a relatively mature area, interpretation and dissemination remain less developed, making the systemic integration of lessons into organizational routines particularly challenging (Williams, 2008).

Lessons learned process

A large share of the OL literature focuses on lessons learned processes, particularly in project-based organizations. According to Duffield and Whitty (2015), these processes typically involve three stages (Duffield and Whitty, 2015):

(1) **Identification**: capturing insights from projects through mechanisms such as after-action reviews, post-project appraisals, project milestone reviews, or audits. Typical questions at this stage include: What was supposed to happen? What actually happened? Why was there a difference? Who else needs to know this information?.

(2) **Dissemination**: codifying and transferring the identified lessons, often through knowledge databases, intranets, or training. Despite these tools, dissemination often remains inconsistent and fragmented.

(3) **Application**: the most challenging stage, as it requires embedding the lessons into decision-making and daily practices. The authors emphasize that this is where most organizations fail: lessons are captured but rarely implemented, due to cultural resistance, lack of incentives, or difficulties in transferring tacit knowledge.

The authors further highlight that while organizations often succeed in identifying lessons, the dissemination and especially the application stages fall short, preventing meaningful organizational learning from taking place.

Systemic framework

To overcome these gaps, several systemic frameworks have been proposed, such as the Syllk model (Figure 33) (Duffield and Whitty, 2015). The model draws on complex adaptive systems theory. Inspired by Reason's (1997) "Swiss cheese model," it conceptualizes OL across six organizational elements: learning, culture, social, technology, process, and infrastructure. Each element contains "holes" representing facilitators of learning (e.g., mentoring, communities of practice, knowledge databases, process guidelines, co-location of teams). For OL to be effective, these facilitators must align across the elements to enable the capture, dissemination, and application of lessons. The model highlights that OL is not solely about technical systems but depends equally on cultural and social factors that shape employees' willingness to share and apply knowledge.

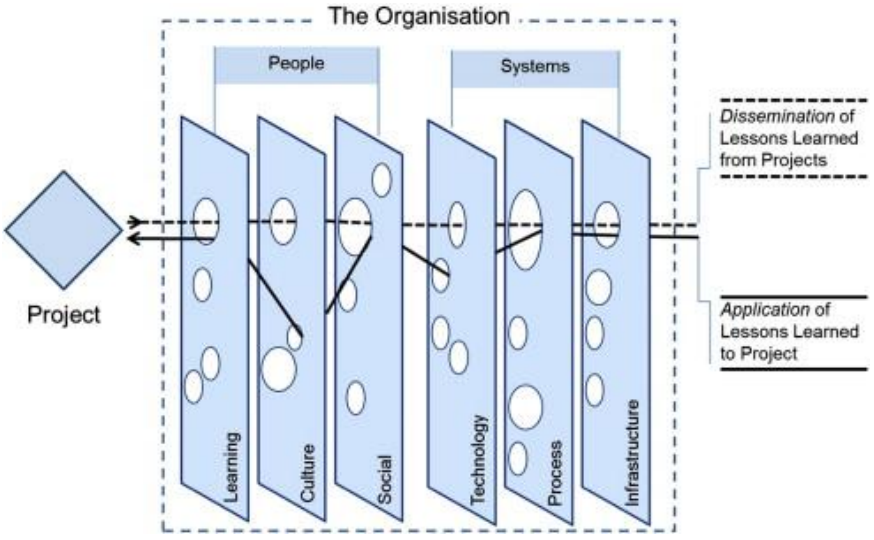

Figure 33. Sylk model (Source: Duffield and Whitty, 2015)

Key practices

In practice, OL is supported by a wide range of mechanisms that enable knowledge sharing and retention. Williams (2008) noted that practices such as post-project reviews, competence models, learning resource centers, and quality procedures are frequently used, but often inconsistently (Williams, 2008). Narratives and storytelling have been increasingly emphasized as effective tools to capture tacit knowledge and reflect the complexity of project outcomes. Communities of practice (CoPs) are also recognized as important enablers, providing social structures where tacit knowledge can be exchanged and contextualized (Williams, 2008). At the organizational level, culture and leadership are repeatedly identified as critical enablers. Studies highlight that "blame culture" remains one of the strongest barriers to OL, while supportive leadership, clear incentives, and visible links to organizational objectives foster knowledge sharing (Duffield and Whitty, 2015; Williams, 2008).

2.4.2.3. From pilot projects to organizational practices

Pilot projects are widely recognized as important vehicles for initiating change and experimentation within organizations (Boscherini et al., 2010). They provide a structured yet bounded environment in which new practices, technologies, or business models can be tested, validated, and refined before broader deployment. In the context of CE implementation, Zils et al. (2023) highlight that transformation typically progresses through three phases: the identification of opportunities, the initiation of pilot projects, and the implementation at scale (Figure 34). Pilots, therefore, serve as a critical intermediary step, demonstrating feasibility and building legitimacy. However, the authors stress that many organizations fail to progress beyond this stage, lacking a coherent pathway for scaling up and embedding the resulting insights into their operating models (Zils et al., 2023).

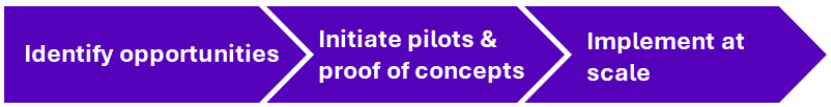

Figure 34.CE implementation journey (adapted from Zils et al., 2023)

This challenge is not unique to circular economy contexts. In health systems research, the SC4CCM program emphasized that scale-up alone is insufficient: interventions that succeed at pilot stage must be institutionalized into organizational practice to be sustained over time (SC4CCM, 2014). Institutionalization requires that the practices tested in pilots become embedded in the routines, governance mechanisms, and decision-making structures of the organization. Moreover, the process is rarely linear. Pilot-to-practice transitions are iterative, involving adaptation, feedback, and continuous improvement rather than a one-off scaling exercise.

Hussey et al. (2013) make a similar observation in the healthcare sector, where a proliferation of pilots has generated valuable insights but limited systemic impact (Hussey et al., 2013) . They note that pilots are often initiated rapidly, but without adequate attention to evaluation methods, contextual factors, and mechanisms for wider adoption. As a result, promising practices risk remaining confined to local experiments. The authors argue that pilots must be designed from the outset with a view to spread, incorporating considerations such as leadership engagement, infrastructure needs, data collection, and adaptability to different organizational settings. Not all pilots should be scaled indiscriminately; rather, careful selection and contextualization are essential to ensure meaningful and sustainable outcomes (Hussey et al., 2013).

Boscherini et al. (2010) further conceptualize pilot projects as "agencies for change" within organizations (Boscherini et al., 2010). Based on a multiple case study, they show that pilots can act as catalysts for organizational innovation when coupled with deliberate transfer mechanisms. These include championing by project leaders, institutionalization into permanent units, and the creation of standardized "boundary objects" (e.g., evaluation tools, IT systems) that facilitate diffusion across the organization. Without such mechanisms, however, pilots risk remaining isolated experiments with little systemic effect (Boscherini et al., 2010). Their analysis resonates with classic organizational change models, such as Lewin's "unfreeze–move–refreeze" process (Cummings et al., 2016), where pilots help to unfreeze established routines but must be followed by institutionalization to consolidate new practices.

In synthesis, the literature converges on the view that pilot projects represent an essential step in the trajectory of organizational learning. They provide evidence, build momentum, and reduce uncertainty, but their impact depends on the ability of organizations to capture, disseminate, and embed the knowledge they generate. The transition

from pilot to practice thus constitutes a critical link between high-level strategies and systemic integration. It illustrates how organizational learning unfolds in practice: not only through experimentation, but through the conversion of temporary initiatives into durable organizational capabilities.

2.4.2.4. Synthesis of organizational learning

Organizational learning (OL) is widely recognized as a key mechanism for adaptation and long-term performance, as it enables organizations to absorb knowledge, make sense of it, and embed it into routines (Duffield and Whitty, 2015; Kloot, 1997; Williams, 2008). In this context, OL is fundamental for moving from strategy to practice, providing the processes through which ambitions defined at the strategic level, together with their associated components and projects, can be conducted and successfully translated into systemic practices for the organization.

Pilot initiatives often serve as important entry points for integrating new concepts and approaches such as environmental sustainability, generating the experiences and insights that fuel learning. Nevertheless, without mechanisms to capture, disseminate, and institutionalize these lessons, such initiatives remain isolated, and their impact is limited, constraining the integration of sustainability. OL addresses this challenge by acting as a system of interlinked practices and enablers. Frameworks such as the Syllk model (Duffield and Whitty, 2015) emphasize the alignment of cultural, social, and technical elements, while mechanisms like lessons learned processes, communities of practice, and narratives illustrate how knowledge can be embedded and shared across the organization (Williams, 2008). Research on pilot institutionalization further shows that the real challenge is not generating knowledge but transforming it into scaled and standardized organizational practices (Boscherini et al., 2010; SC4CCM, 2014; Zils et al., 2023).

In conclusion, OL emerges as central to transforming experiences and knowledge from pilots or isolated projects into systemic practices, providing the connective tissue that links strategic intent with sustained organizational change.

2.4.3. Organizational Change management

Organizational learning (OL) has shown how organizations can capture and translate knowledge into practices, turning experiences into actionable lessons. However, the durability of these practices depends on more than knowledge capture. Embedding them into the fabric of an organization requires Organizational Change Management (OCM), the discipline concerned with shifting behaviors, culture, and structures so that new ways of working persist (Klein et al., 2022; Lozano, 2008). In this sense, OCM emerges as the next critical layer: it ensures that strategic ambitions and organizational learning are institutionalized into lasting routines and capabilities.

2.4.3.1. Foundations of OCM

Organizational change management (OCM) has been widely discussed as a necessary process for organizations to adapt to evolving environments and stakeholder expectations. Lozano (2008) describes organizations as complex systems composed of individuals and groups with mutual interdependencies (Lozano, 2008). On their road towards sustainability, these interactions shape how learning, feelings, and behaviors evolve, meaning that change requires congruent shifts at the level of individuals, groups, and the organization as a whole. A key challenge is that existing mental models strongly influence decision-making; unlearning old models and developing new ones becomes a critical step in enabling transformation (Lozano, 2008).

Alas (2007) conceptualizes organizational change as a stepwise process, drawing on two classical models (Alas, 2007). The first, developed by Lewin, consists of three stages: unfreezing, moving, and refreezing, while the second, from Tichy and Devanna, outlines three steps: recognizing the need for change, creating a vision, and institutionalizing it. These formulations highlight that change is not a singular action but a structured progression that requires both disruption of the status quo and stabilization of new practices (Alas, 2007). Importantly, the author emphasizes that the ability of organizations to learn continually is central to this process: responsiveness to stakeholder needs, the learning capacity of the organization, and its capacity for action are critical resources (Alas, 2007).

Hendry (1996) further note that initiating change is often the most difficult phase, since past experiences and established ways of working create inertia (Hendry, 1996). Organizational learning is therefore directly tied to change management: feedback processes and collective knowledge-sharing underpin the ability to recognize problems, anticipate shifts, and adjust behaviors. This view reinforces the argument that OCM and OL are intrinsically connected, learning provides the adaptive capacity that makes change possible, while change processes create the conditions for learning to occur.

2.4.3.2. Barriers and Enablers of OCM

Organizational change processes are rarely straightforward, as they are shaped by a balance of barriers and enablers that determine whether new approaches and practices can be effectively embedded. A recurrent challenge is organizational inertia: established mental models and routines often constrain the willingness or ability to change, making "unlearning of old models" a necessary but difficult step in transformation (Lozano, 2008). Resistance may also emerge from vested interests or from the familiarity of existing practices, which can discourage experimentation and adaptation (Lozano, 2008). Short-termism further compounds these difficulties, as financial logics tied to compensation systems, investor pressures, and reporting models tend to prioritize immediate results at the expense of long-term sustainability (Siegrist et al., 2019). The authors further relate that in mature industries, this inertia is reinforced, with firms often perpetuating business-as-usual approaches. Cultural fragmentation also acts as a barrier, as subgroups within organizations may hold conflicting values and perspectives that hinder the diffusion of shared sustainability-oriented practices (Siegrist et al., 2020).

At the same time, several enablers can help organizations overcome these obstacles (Figure 35). Leadership consistently emerges as one of the most decisive factors: active and supportive leaders can articulate a vision, mobilize resources, and build commitment around sustainability-related change (Millar et al., 2012). Structural adjustments also play a role, such as aligning reward systems with sustainability objectives and incentivizing potential change agents (Kiesnere and Baumgartner, 2019). Organizational culture is equally important: embedding sustainability values into corporate statements and guidelines, and fostering cross-departmental collaboration, helps integrate change beyond isolated units and promotes sustainability-oriented learning across the organization (Kiesnere and Baumgartner, 2019).

	System level		
	Individuals	***Groups***	***Organisational***
Barrier to change	• Misunderstanding/Lack of communication • Lack of trust • Threat to job status/Security	• Group culture • Ignoring institutions in the group • Individual – Group conflict	• Lack of strategy/long term plans (Managerial) • Bureaucracy/Patriarchal models (Organisational) • Lack of top management commitment/walking the talk (Managerial)
Strategy	• Negotiation • Manipulation • Participation	• Group participation in change • Individual – Groups interactions • Changing group values	• Developing new strategies, policies and frameworks (Managerial) • Identifying champions (Managerial) • Aggregation/Collaboration (Organisational)

Figure 35. Most commonly recognized barriers to change and strategies to overcome them (Source: Millar et al., 2012)

Overall, the literature shows that organizational change management operates at the intersection of these forces. Inertia, resistance, and short-term pressures can easily undermine change processes, but supportive leadership, aligned incentives, and collaborative cultures provide powerful counterbalances. Understanding and actively managing this tension is essential to design change processes that move beyond superficial adjustments and enable long-term institutionalization of new practices.

2.4.3.3. Organizational change for sustainability

Organizational change management for sustainability (OCMS) examines how organizations manage and implement change by addressing the social and human dimensions of transformation. Organizations are complex social systems, where individuals, groups, and structures interact in ways that shape behaviors, attitudes, and decision-making. Moving toward sustainability therefore requires alignment across these levels, often involving the unlearning of entrenched mental models and their replacement with new ones that support change (Lozano, 2008). As highlighted by Klein et al. (2022), OCMS emphasizes the importance of values, visions, culture, leadership, and learning capabilities in ensuring that sustainability principles are not only defined but embedded across organizational life (Figure 36) (Klein et al., 2022).

Influencing factors

Categories	Factors
Organisational culture	• Values and norms aligned with the changes
Governance system	• Collaboration, employee empowerment, stakeholder involvement • Leadership commitment

Factors addressed using organisational change strategies →

Strategies for organisational change

Categories	Strategies
Strategic initiatives	• Statements with vision and goals • Champions
Human Resource Management	• Training and awareness raising • Experts recruitment • Transversal teamwork
Communication and assessment	• Monitoring and assessment • Reporting

Figure 36. Influencing factors and Strategies for OCMS (Source: Klein et al., 2022)

Importantly, sustainability-oriented change is not limited to technical adjustments but involves a deeper paradigmatic shift. Desing et al. (2020) argue that sustainable resource management through circularity requires rethinking the way individuals, organizations, and governments consume, produce, and perceive their roles in society (Desing et al., 2020). In a similar vein, Hobson and Lynch (2016) contend that the CE agenda often overemphasizes technological fixes while overlooking human and social dimensions (Hobson and Lynch, 2016). They call for greater attention to the role of citizens and the social meanings of CE principles, underscoring that a truly circular society requires broad cultural engagement rather than purely technological interventions.

Barriers and drivers of transformation

Despite this recognition, significant barriers hinder the implementation of sustainability in practice. A central obstacle is short-termism: business executives often prioritize rapid financial returns, shaped by compensation systems, investor pressures, and reporting models, which undermines long-term sustainability integration (Siegrist et al., 2020). Institutional inertia also plays a role, particularly in mature industries, where entrenched ways of working resist transformation. Cultural fragmentation further complicates change, as subgroups within organizations frequently hold divergent values and perspectives. Embedding sustainability into performance evaluation and incentive systems has been suggested as a way to align values and gradually instill sustainability principles throughout the organization (Siegrist et al., 2020).

At the same time, a number of drivers and enablers have been identified. Sustainability-oriented change is often rooted in organizational and personal values, with culture and commitment providing the foundation for action (Diaz et al., 2021; Kiesnere and Baumgartner, 2019). Practical enablers include the adaptation of structures and reward systems, cross-departmental learning, and the active involvement of employees at all levels. Leadership is especially critical: active and supportive leaders can catalyze sustainability and circularity implementation, whereas their absence leads to cascading challenges such as poor training, lack of communication, weak stakeholder integration, and limited resources (Millar et al., 2012).

Models of sustainability-oriented change

Several authors have proposed structured models to guide organizations in embedding sustainability, moving beyond abstract principles to concrete roadmaps for transformation. Lozano (2017) introduced the notion of orchestrated change, emphasizing proactive, collaborative, and internally planned efforts that disrupt the status quo and progressively align organizational systems, operations, and strategies with sustainability principles (Lozano, 2018). This perspective highlights that sustainability-oriented change must be iterative and integrated across functions, rather than confined to isolated projects.

Building on a similar logic, Newman (2007) proposed a three-phase framework for embedding sustainability into organizations: Awakening, where sustainability enters the agenda through champions, committees, and pilot projects; Pioneering, where institutions demonstrate leadership, accountability, and broadened engagement through strategic planning; and Transformation, where sustainability becomes fully embedded into policies, structures, and decision-making . Transition phases between stages are marked by diffusion of responsibility and the identification of new leverage points. This model stresses that success lies not only in visible outputs, such as

renewable energy or waste initiatives, but in the deeper institutionalization of sustainability into governance, culture, and organizational routines (Newman, 2007).
More recently, Sancak (2023) proposed the Sequential Sustainability Transformation Model (STM), which adapts classical change management theory to sustainability transitions (Sancak, 2023). The STM identifies 50 sequential steps structured around change phases and mapped to ESG dimensions. Governance emerges as the dominant driver of transformation, particularly in the early stages, underscoring the role of leadership, accountability structures, and metrics as prerequisites for embedding sustainability. By linking sustainability change directly with ESG and regulatory frameworks, the STM provides both a practical roadmap for organizations and a theoretical contribution connecting change management research with sustainability transformation (Sancak, 2023).

Together, these models illustrate that sustainability transitions require more than general calls for cultural change: they demand structured processes, whether framed as iterative orchestration, phase-based progression, or sequential steps tied to governance. Each approach highlights that transformation occurs when sustainability moves from ad-hoc initiatives to institutionalized practices embedded across strategy, culture, and organizational systems.

Systemic and muti-scale perspectives

To ensure that change is long-lasting, organizational transformation must also be understood as a multi-scale process. Bögel et al. (2019) propose a heuristic that integrates drivers and barriers at three levels: the micro level of individuals, the meso level of organizations, and the macro level of the broader system (Bögel et al., 2019). This perspective emphasizes the need for coordination across multiple stakeholders and for a shift from short-term to long-term planning. Similarly, Lozano (2012) argues that sustainability-oriented change requires not only incremental adjustments in mental models, structures, and operations but also the development of shared visions and concrete pathways for implementation (Lozano, 2012).

Sectoral implications: the case of the pharmaceutical industry

In the pharmaceutical sector, the implications of OCMS are particularly salient. Cerf (2019) stresses that sustainability in pharma cannot be achieved through isolated initiatives; it requires a systemic approach that links environmental, economic, and health outcomes (Cerf, 2019). Using the SDG framework, Cerf shows that health goals (SDG 3) are deeply dependent on progress in environmental objectives (SDGs 6, 12, 13) and enabling infrastructures (SDG 9). For companies, this translates into embedding life-cycle thinking and circularity into governance, portfolio management, procurement, and operations, ensuring that actions in one area reinforce sustainability across the value chain. This “environment–economy–health nexus” reframes decision-making by placing environmental considerations on equal footing with cost, quality, and efficacy. Such integration moves the sector beyond ad-hoc projects toward systemic capabilities, consistent with the broader transition from strategy and learning to institutionalized practices developed later in this thesis.

2.4.3.4. Organizational change and systemic transformation

Organizational change initiatives often begin with pilots or isolated practices, but achieving long-term impact requires scaling and embedding these into systemic transformations. Change, in this sense, is not only about replicating projects but about reconfiguring organizational systems and routines to sustain new ways of working. This is where organizational learning and change management converge: knowledge generated through projects must be institutionalized, while change processes provide the structures, governance, and cultural shifts that allow this institutionalization to persist.

Research emphasizes that transformation requires moving beyond isolated tools and practices, toward more systemic mechanisms that can embed change across the organization. As Hendry et al. (1996) note, feedback loops and collective knowledge are central to this process, highlighting that organizational ideas and ways of working are inherently developed in interaction with others (Hendry, 1996) Similarly, Skerlavaj et al. (2007) show that organizations gain competitive advantage not merely by acquiring information but by transforming it into action (Škerlavaj et al., 2007). This underscores that employees are not passive recipients of change, but central actors whose engagement and empowerment are essential to translating knowledge into systemic outcomes.

The literature also stresses the importance of linking strategic and process change. According to Ford and Evans (2001), strategic change provides the long-term direction, while process change delivers the mechanisms and infrastructures for implementation (Ford and Evans, 2001). Both are complementary, and effective change requires self-assessment mechanisms to ensure alignment between operational processes and strategic ambitions. This dynamic reflects the bridge between strategy formulation, organizational learning, and capability building.

Scaling change to a systemic level, however, remains a complex challenge. Nystrom et al. (2014) argue that large-scale transformations in complex systems, such as health and social care, lack a blueprint (Nyström et al., 2014). Program management must navigate multidimensional strategies that consider governance, culture, stakeholder interactions, and contextual variability. This resonates with sustainability transitions more broadly: orchestrated, iterative, and collaborative approaches are required to move from isolated efforts to systemic integration (Klein et al., 2022; Lozano, 2018).

In this perspective, OCM provides the connective tissue between localized practices and systemic transformation. It emphasizes that projects, tools, and practices must evolve into dynamic capabilities embedded across the organization. This view directly sets the stage for the next section, which explores how capabilities and maturity models enable the institutionalization of sustainability within organizational systems.

2.4.3.5. Synthesis of Organizational Change Management

OCM emerges as a central mechanism for embedding sustainability into organizations. It highlights that change is not a single event but a structured and iterative process that requires alignment across individuals, groups, and organizational systems. For sustainability, this means moving beyond technical adjustments to shifts in culture, values, leadership, and governance, ensuring that sustainability principles are integrated into daily practices and long-term visions. OCM also provides the bridge between strategy and learning, institutionalizing the lessons generated by projects and pilots into enduring routines and structures. In doing so, it creates the conditions for organizations to move from isolated initiatives to systemic transformation, laying the groundwork for the development of capabilities and maturity that can sustain change over time.

2.4.4. Capabilities for environmental sustainability

Building on the role of OL and OCM, the next step in understanding how sustainability can be embedded in organizations is to examine the notion of capabilities. Whereas learning processes and change initiatives create the conditions for adaptation, capabilities represent the more stable yet evolving competences that allow organizations to consistently transform strategies into institutionalized practices. In recent decades, the concept of capabilities, particularly dynamic capabilities, has become central to organizational theory (Teece, 2018), and has increasingly been applied to sustainability. This section reviews the literature from five complementary angles. It first introduces the general concept of organizational capabilities, then explores how capabilities have been linked to sustainability. It next considers how learning and change processes translate into capabilities, before discussing the relationship between strategy and capabilities. Finally, it reviews maturity models as structured approaches to assess and guide capability development. A synthesis then draws the key insights that inform the capability framework developed in this thesis.

2.4.4.1. What are capabilities?

Within organizational theory, the concept of capabilities provides a lens for understanding how firms deploy resources and routines to achieve desired outcomes. At a basic level, capabilities can be defined as the coordinated set of tasks, processes, and competences that allow an organization to perform effectively (Hutchinson, 2024). They differ from resources in that they concern the ability to use and combine resources purposefully rather than the resources themselves.

A useful distinction is made between ordinary (or operational) capabilities and dynamic capabilities. Ordinary capabilities allow organizations to “make a living” in the short term, sustaining ongoing production and administration through established routines (Winter, 2003). In contrast, dynamic capabilities refer to the higher-order abilities of a firm to integrate, build, and reconfigure competences in order to respond to or shape rapidly changing environments (Teece, 2018, 2007). Dynamic capabilities (Figure 37) thus capture the essence of agility:

the ability to sense opportunities and threats, seize them through investments and innovation, and transform existing structures and processes accordingly (Teece, 2018). These capabilities are multi-faceted and path-dependent, emerging from both managerial decision-making and organizational routines.

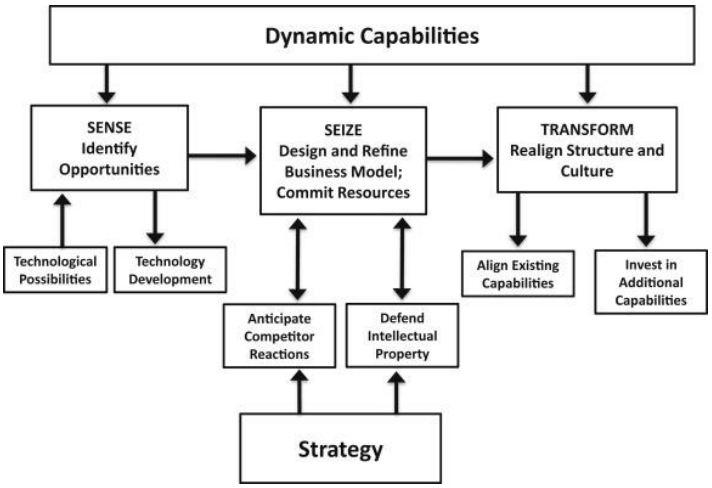

Figure 37. Dynamic capabilities and its structural elements (Source: Teece et al., 1997)

Project management research complements this perspective by emphasizing the role of capabilities as the building blocks that underpin best practices and translate strategy into action. In PMI's Organizational Project Management Maturity Model (OPM3), for instance, capabilities are defined as the specific knowledge, skills, and processes that must be in place for best practices to exist, evidenced through observable outcomes and measurable indicators (Fahrenkrog, 2004). This framing highlights capabilities as the operational link between high-level strategic intent and concrete organizational performance, reinforcing their role as the foundation of maturity and continuous improvement. Beyond their role in operational effectiveness, capabilities are inseparable from strategy. As Teece (2018) argues, strategy can be understood as a coherent set of analyses, policies, and actions to address high-stakes challenges, while dynamic capabilities provide the means to adjust and refine this strategy over time (Teece, 2018). Together, strategy and dynamic capabilities shape and renew business models, guiding organizational transformation and sustaining the resources and competences on which long-term performance depends.

In synthesis, capabilities function at multiple levels: they ensure operational performance in the present, provide the agility to adapt strategy to changing conditions, and establish the foundation for embedding best practices and long-term transformation across the organization, and are therefore essential for integrating environmental sustainability.

2.4.4.2. Capabilities for sustainable development

As presented in the previous sections of the context and of the State of the Art, sustainability presents organizations with unique challenges: it requires not only technical improvements in products and processes but also systemic shifts in culture, strategy, and governance.

Therefore, sustainability cannot be addressed through isolated skills or one-off initiatives, it requires a coherent system of capabilities that operate across strategy, culture, operations, and external relations. Amui et al. (2017) argue that sustainability must be conceived as a dynamic capability, continuously evolving, integrated with strategy and business models, and enabling firms to reconfigure resources and practices in response to environmental and societal challenges (Amui et al., 2017). This view emphasizes organizational learning, relationship building, and cross-functional integration as critical capabilities for aligning short-term actions with long-term sustainability goals.

Chen (2020) highlights that capabilities for circular and sustainable transitions must not only exist but also be sequenced within structured transition processes (Chen et al., 2020). Their framework shows how firms need to progress through stages of exploration, experimentation, and institutionalization, with specific capabilities (e.g., sensing opportunities, aligning stakeholders, embedding practices) being critical at each stage. This perspective complements Amui and Bezerra by underscoring that capabilities are dynamic not only in content but also in timing

and maturity, shaping the pathways through which organizations move from fragmented initiatives to systemic sustainability.

Bezerra et al. (2020) provide a more detailed map of what such organizational capabilities for sustainability (OCS) entail (Figure 38) (Bezerra et al., 2020). They identify seven interdependent domains:

- Collaborative capabilities (OCS1): building and managing stakeholder and inter-firm relationships to address sustainability collectively.
- Knowledge absorption and learning (OCS2): acquiring and applying sustainability-related knowledge internally and externally.
- Innovation and technology (OCS3): developing or adopting technologies and processes that enable sustainable products and operations.
- Alignment and motivation (OCS4): fostering internal enablers such as vision, leadership support, training, and employee motivation.
- Marketing and communication (OCS5): identifying sustainability-related market opportunities and communicating efforts transparently.
- Flexibility and adaptation (OCS6): enhancing resilience and reconfiguring resources to respond to sustainability challenges.
- Sustainable operations (OCS7): embedding eco-design, process improvements, and sustainable procurement into daily practices.

These domains highlight sustainability as a multi-level capability system, combining external orientation (collaboration, market communication, adaptability), internal enablers (learning, motivation, culture), and process execution (innovation, operations). Importantly, Bezerra et al. link these OCS categories to ten categories of corporate sustainability benefits (CSBs), ranging from support for environmental strategy and sustainable innovation to improved green supply chain management, adaptability, and overall firm performance. Collaboration, innovation, and operational capabilities emerge as cross-cutting levers with the broadest impact, while knowledge absorption and adaptability appear underexplored yet critical for resilience.

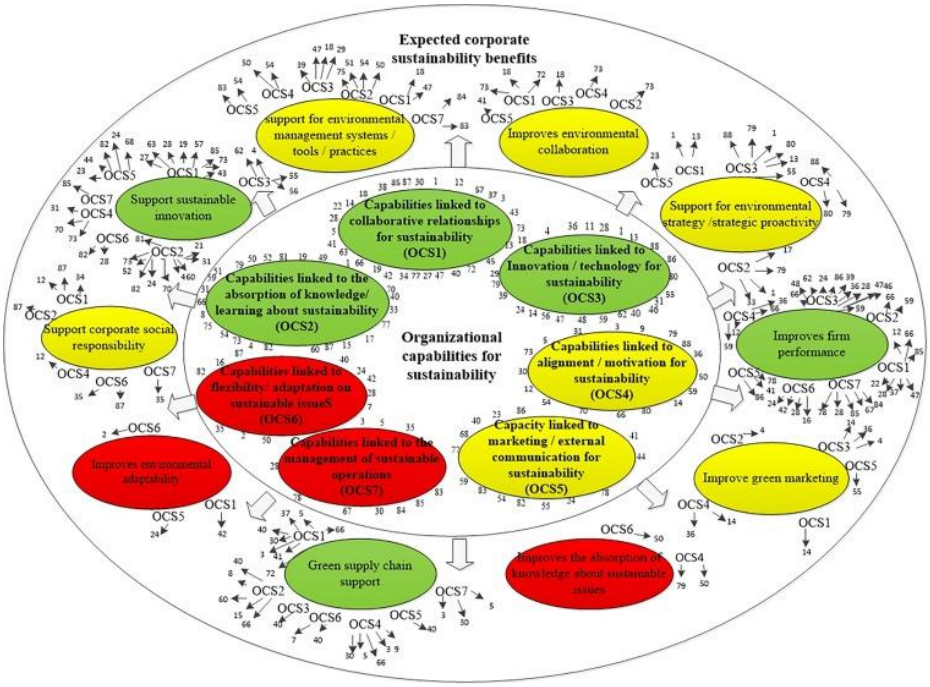

Figure 38. Relations between OCS and CSB (Source Bezarra et al., 2020)

Other contributions emphasize the strategic integration of sustainability into business capabilities. Annunziata et al. (2018) show that supplier collaboration, product innovation, and advanced technologies act as essential capabilities for embedding socio-environmental practices, with direct positive effects on economic performance (Annunziata et al., 2018). This confirms that sustainability-oriented capabilities are not ancillary but central to competitiveness, linking environmental and social outcomes to business success.

The literature on capabilities and sustainability demonstrates that organizational capabilities are the infrastructure through which sustainability can be operationalized. They translate values and strategies into repeatable practices, enable organizations to adapt dynamically to external pressures, and generate tangible benefits across strategic, operational, and reputational dimensions.

2.4.4.3. From organizational learning and change to capabilities

Organizational capabilities do not emerge in isolation, they are the result of cumulative processes of learning and change. In this sense, OL and OCM can be understood as the mechanisms through which organizations acquire, refine, and institutionalize the competences that later constitute capabilities.

Learning theories stress that knowledge creation and diffusion are inherently collective processes. As Hendry (1996) emphasized, knowledge, language, and thought evolve in interaction with others, and organizations intentionally develop new ideas and ways of working in conjunction with multiple actors (Hendry, 1996). Organizational learning therefore functions as a process of transforming information into action: firms that systematically acquire operational, tactical, and strategic information are better able to interpret and exploit it, strengthening their ability to recognize opportunities and adapt to external challenges (Škerlavaj et al., 2007). In this perspective, employees emerge as central stakeholders, since their ability and motivation to engage in learning processes directly condition the development of new organizational practices.

Different forms of learning play complementary roles in capability building. Adaptive learning enables organizations to cope with immediate challenges, but generative learning, creative processes that expand ways of seeing systems and designing responses, are essential for developing new and more advanced capabilities (Alas, 2007). At the individual level, the diversity of learning styles and the ability to acquire and use knowledge effectively also influence how organizational learning translates into collective capabilities (Duffield and Whitty, 2015).

Change management approaches reinforce this logic by showing how organizational transformation is structured around sequences of learning, alignment, and institutionalization. Klein et al. (2022) describe sustainability-oriented change as a staged process: establishing urgency, forming leading teams, building and communicating a vision, involving stakeholders, and monitoring progress (Klein et al., 2022). Each of these stages entails the acquisition and consolidation of new knowledge, practices, and routines, thus laying the groundwork for organizational capabilities. Similarly, Bögel et al. (2019) highlight that sustainability transitions require organizations to acquire new knowledge and capabilities at multiple levels: the micro level of individuals, the meso level of organizational structures, and the macro level of broader systems (Bögel et al., 2019).

In a similar way, eco-design integration studies confirm that capability development is often the missing link between pilots and systemic change. Brones et al. (2017) argue that while many companies experiment with tools and projects, the “soft side” of change, capacity building, culture, and multi-level governance, is critical for ensuring that learning is consolidated into long-term capabilities (Boks, 2006; Brones et al., 2017; Verhulst et al., 2007).

These perspectives indicate that learning processes (adaptive and generative), change processes (planned and iterative), and capability development are inseparable. OL provides the informational and cognitive foundations; OCM creates the conditions for diffusion and alignment; and capabilities represent the institutionalized outcomes of these processes. This progression illustrates why OL and OCM are often described as precursors or enablers of organizational capabilities, and why capability-building is increasingly seen as the bridge between temporary projects and systemic transformation.

2.4.4.4. Strategy and capabilities

Capabilities are not only essential for sustaining operations but also for enabling the translation of strategy into practice. In organizational theory, strategy provides the direction, the “what” and “why” while capabilities constitute the “how,” determining the extent to which strategic ambitions can be realized. Teece (2018) and Hutchinson (2024) both underline that capabilities operate as the connective tissue between high-level intent and

concrete organizational performance, ensuring responsiveness in turbulent environments (Hutchinson, 2024; Teece, 2018).

Teece (2018) emphasizes that dynamic capabilities and strategy must be understood as mutually reinforcing: strategy articulates responses to high-stakes challenges, while dynamic capabilities allow organizations to sense opportunities, seize them through reconfigured resources, and transform operations accordingly (Teece, 2018). In this view, capabilities are not peripheral enablers but core elements of strategic adaptation, ensuring that organizations can renew and refine their business models in line with environmental and market shifts.

From a project and portfolio perspective, Fahrenkrog et al. (2004) stress that strategies often fail not because they are ill-conceived, but because organizations lack the capabilities to implement them at the tactical level (Fahrenkrog, 2004). As an example, the OPM3 was developed precisely to address this gap by identifying best practices, mapping the capabilities required to achieve them, and linking these to observable outcomes and key performance indicators. This framing highlights that strategy alone cannot drive transformation: it must be coupled with a systematic process of capability development and assessment.

For sustainability, the implications are clear: strategic commitments, whether framed as corporate sustainability strategies, circular economy ambitions, or climate goals, require a parallel investment in capabilities such as collaboration, innovation, absorptive learning, and operational integration (Bezerra et al., 2020). Without such capability building, sustainability risks remaining symbolic or fragmented, with projects failing to scale into systemic practices.

In summary, capabilities and strategy are co-evolving dimensions of organizational transformation. Strategy defines the objectives and trajectory, while capabilities determine the organization's ability to act, adapt, and embed change over time. For sustainability, this interdependence is particularly critical: capabilities provide the foundation that transforms long-term visions into concrete practices, aligning strategic intent with organizational change and supporting the systemic integration of environmental sustainability across the organization.

2.4.4.5. Capability and maturity models

Maturity models emerged as structured pathways for organizational improvement. Rooted in quality management they describe how performance evolves through defined stages, from ad hoc and uncoordinated practices to disciplined, optimized, and continuously improving processes (Paulk et al., 1993; SEI, 2006). Each level represents a higher degree of institutionalization, where processes become more predictable, scalable, and effective. The underlying logic is that the quality of outcomes is directly tied to the maturity of the processes that generate them. Within this tradition, maturity models are tightly linked to capabilities. Capabilities describe what an organization is able to do, the skills, processes, and structures that enable performance, whereas maturity models describe how those capabilities develop over time through sequential adoption and institutionalization.

Generic models

One of the most influential models is the Capability Maturity Model (CMM), later refined into the CMMI (Paulk et al., 1993; SEI, 2006). The model rests on the premise that the quality of a product or system is determined by the quality of the processes used to develop and maintain it. It frames organizational capability through three dimensions: people, methods and procedures, and tools and technologies, all tied together by processes. CMM describes an evolutionary path from ad hoc, reactive practices to disciplined, predictable, and continuously improving processes. This progression is structured into five maturity levels, each underpinned by defined "Key Process Areas" that must be institutionalized before advancing further. Through this staged roadmap, organizations move from inconsistent and crisis-driven performance toward realistic planning, quantitative monitoring, and sustained improvement, ensuring that capability development is systematic, cumulative, and anchored in organizational structures.

Another widely recognized model is the Organizational Project Management Maturity Model (OPM3), developed by the Project Management Institute (Fahrenkrog, 2004). Its purpose is to help organizations translate strategy into results by systematically managing projects, programs, and portfolios. OPM3 is structured around four core components: Best Practices, the Capabilities required to achieve them, the Observable Outcomes that evidence

capability attainment, and the Key Performance Indicators (KPIs) used to measure outcomes (Figure 39). These elements are organized within a process architecture that combines PMBOK® process groups (initiating, planning, executing, controlling, closing) with four maturity stages (standardize, measure, control, continuously improve). Progression occurs through defined "pathways" that reflect interdependencies among capabilities and Best Practices, ensuring that maturity develops cumulatively and systematically. OPM3 thus provides both a diagnostic and an improvement roadmap: organizations can assess their current state, identify gaps, plan improvements, and embed practices before reassessing. In doing so, it offers a scalable and flexible mechanism for aligning project management practices with strategic objectives, embedding project-based thinking into organizational culture, and ensuring predictable and sustainable strategy execution.



Figure 39. Representation of a best practice, a capability, and outcome and a KPI (Source: Fahrenkrog et al., 2003)

These models illustrate how maturity frameworks not only map progression but also structure capability development. Effective models share common design features: they rely on clear definitions and consistent language, use observable indicators of performance, define proficiency levels to structure progression, and integrate assessment tools to evaluate maturity (INCIT, 2025). Their implementation typically follows a staged process of scoping, assessment, piloting, and scaling, thereby translating abstract maturity levels into concrete, observable pathways for organizational improvement.

Capability and maturity models for sustainability

In the field of sustainable development, capability and maturity models have been developed to adapt process–capability logic to the challenge of embedding environmental and social practices across products, organizations, and value chains. The underlying premise remains consistent with generic models; however, sustainability-specific models extend this logic by targeting sustainability and related concepts (DfS, eco-design, circular economy, etc.), thereby structuring the progression from ad hoc initiatives to systemic sustainability practices.

Eco-design and Eco-innovation

The Ecodesign Maturity Model (EcoM2) developed by Pigosso et al. (2013) (Pigosso et al., 2013). EcoM2 provides a structured roadmap that combines capability levels (institutionalization) with evolution levels (from awareness and pilot projects to integration and system innovation). It operationalizes this through a PDCA-inspired six-step method: (1) diagnosing the maturity profile, (2) proposing ecodesign practices and projects, (3) managing the portfolio of projects, (4) planning, (5) implementing, and (6) assessing results. EcoM2 distinguishes between managerial practices (integration into organizational structures and processes) and operational practices (technical aspects of design). By linking these practices to supporting tools and embedding them into iterative improvement cycles, EcoM2 enables both assessment and continuous improvement, making it a reference point in ecodesign integration.

Another example is the Eco-Innovation Maturity Model (Eco-Mi) which extends maturity logic to eco-innovation (Xavier et al., 2020). It is structured around four dimensions of innovation management, strategy, structure, resources, and culture, and encompasses 142 eco-innovative practices. Like EcoM2, Eco-Mi combines maturity levels (from non-application to holistic integration) with capability levels for each practice, thereby enabling organizations to systematize eco-innovation integration. Its focus on organizational enablers highlights the importance of culture, resources, and strategic alignment for advancing sustainability.

Circular Economy

Further models extend the approach beyond ecodesign and innovation. Uhrenholt et al. (2022) proposed a maturity model for circular economy transformation (CEMRM), structured along six dimensions (value creation, governance, people and skills, supply chain and partnerships, operations and technology, and products and materials) and six levels of maturity (none to regenerative) (Uhrenholt et al., 2022). Similarly, Jansen (2022) introduced a Circular Economy Capability Model structured into strategic, organizational, people, business development, and operational dimensions (Figure 40) (Jansen, 2022). These models illustrate how the capability–maturity logic can be applied to circular transformation, providing organizations with reference pathways for building CE-related competences across functions and ecosystems.



Figure 40. CE Capability Model (Source: Jansen, 2022)

Pharmaceutical focus

In the pharmaceutical industry, sector-specific frameworks remain scarce. A attempt was made in 2023, with DEimeter, which focuses on the integration of eco-design into drug development (Luu, 2023a). DEimeter evaluates organizational integration across three categories (leadership & tactical integration, training & resources, collaboration & communication) while also mapping the operational use of eco-design tools across the medicine development process (from early research to clinical phases). This dual perspective enables organizations to assess both organizational embedding and tool adoption, though its application remains exploratory and focused primarily on early development phases.

In summary, the capability/maturity models for sustainability presented here do not represent the exhaustive list of existing models in this field. Nevertheless, they illustrate how maturity logic can structure the progression from fragmented sustainability initiatives to systemic integration. They show that capabilities related to sustainability evolve through defined pathways, requiring alignment of strategy, organizational enablers, and operational practices.

Synthesis

Capability and maturity models play a central role in structuring organizational transformation. By mapping not only the practices an organization must adopt but also the sequential stages through which they become institutionalized, such models provide both an assessment baseline and a roadmap for improvement. In sustainability, they help organizations move from fragmented, tool-based initiatives to systemic, embedded practices that cut across functions and scales.

Despite the progress in generic and sustainability-oriented models, no capability or maturity framework has yet been established for environmental sustainability in the pharmaceutical industry. This absence is critical, given the sector's scale, regulatory complexity, and reliance on highly resource-intensive processes. Without such structured models, sustainability practices risk remaining ad hoc, scattered across pilot projects, and poorly integrated into governance, operations, and decision-making.

The urgency of this gap is reinforced by recent empirical findings. Vilochani et al. (2025) show that sustainable product development (SPD) practices in manufacturing firms remain at largely ad hoc or formalized levels, with very few practices consistently measured or continuously improved (Vilochani et al., 2025). Despite areas such as corporate sustainability strategy and performance reporting are relatively advanced, often driven by regulatory or reputational pressures, core practices tied to product requirements, data management, and eco-design integration remain weak. This demonstrates a persistent theory–practice gap: tools and concepts exist, but they are not systematically embedded into organizational capabilities and maturity pathways.

In the pharmaceutical context, the challenge is particularly true. As Cerf (2019) notes, achieving sustainability in pharma requires a systemic approach where life-cycle thinking and circularity are embedded into governance, portfolio management, procurement, and operations (Cerf, 2019). Actions in one area, such as clinical packaging or supplier engagement, must reinforce environmental and health objectives across the value chain. Recent research further highlights the relevance of a capability perspective for transformation in this sector. Robb et al. (2022) argue that pharmaceutical firms must enhance their innovation capability to adapt to rising R&D costs, stricter regulations, and the convergence of drug–device systems (Robb et al., 2022). Their findings stress the importance of non-technical enablers such as psychological safety, empowerment, and leadership style, in addition to technical expertise. Although their focus is innovation rather than sustainability, the underlying logic is the same: enduring transformation depends on building organizational capabilities that go beyond tools to become embedded in culture, structures, and practices.

In synthesis, the literature demonstrates both the value of capability and maturity models for supporting the systemic integration of environmental sustainability, and the absence of sector-specific applications for pharmaceutical sustainability.

2.4.5. Key gaps and needs for systemic transition and change management

The review of organizational learning (OL), organizational change management (OCM), and capability/maturity models highlighted the potential of these approaches to support the systemic integration of environmental. At the same time, several key gaps remain that limit their application to environmental sustainability, and more specifically to the pharmaceutical sector.

Weak institutionalization of learnings from projects

OL frameworks emphasize lessons learned, communities of practice, and knowledge-sharing mechanisms (Duffield and Whitty, 2015; Kloot, 1997; Williams, 2008), however many organizations fail to apply or scale this knowledge. Lessons are often identified but rarely disseminated or embedded into routines, meaning that pilots remain isolated, and their transformative potential is lost (Boscherini et al., 2010; Zils et al., 2023).

➔ *There is a need for mechanisms that ensure systematic capture, dissemination, and application of lessons so that pilots and isolated initiatives are transformed into standardized organizational practices.*

Limited integration between change processes and learning practices

OCM and OL are often studied separately, even though learning capacity is a precondition for change and change provides the conditions for learning (Hendry, 1996; Lozano, 2008). Few integrative approaches connect these two dimensions to support sustainability transitions.

➔ *There is a need for integrative frameworks that explicitly link OL and OCM, aligning feedback, cultural change, and capability-building with strategic sustainability objectives.*

Generic models, lack of sectoral adaptation

Capability and maturity models such as CMMI, OPM3, and EcoM2 demonstrate the value of structured pathways for embedding practices (Fahrenkrog, 2004; Paulk et al., 1993; Pigosso et al., 2013). However, these models are either generic or developed for specific manufacturing sectors. No dedicated capability model currently exists for embedding environmental sustainability in pharmaceutical product and process development (Cerf, 2019; Luu, 2023a).

➔ *There is a need for sector-specific capability and maturity models that translate sustainability principles into pharmaceutical decision points, governance structures, and operational practices.*

Low maturity of sustainability integration in practice
Empirical evidence shows that most companies, including those in manufacturing, remain at ad hoc or formalized levels of sustainable product development practice (Vilochani et al., 2025). Few practices are applied at measured or continuously improving levels, highlighting a persistent theory–practice gap.

➔ *There is a need for approaches that support the systematic progression from awareness and pilot projects toward institutionalized sustainability capabilities, with monitoring and iterative improvement.*

Fragmented treatment of stakeholders and cultural enablers
Although leadership, values, and culture are acknowledged as critical enablers (Kiesnere and Baumgartner, 2019; Klein et al., 2022; Lozano, 2012), they are often treated separately from operational and strategic dimensions. This fragmentation limits systemic uptake, particularly in pharmaceuticals where governance, compliance, and cross-functional collaboration are essential.

➔ *There is a need to integrate cultural and human dimensions with operational and strategic pathways, ensuring that leadership, employee engagement, and governance structures act together to enable systemic change.*

These gaps reveal that while OL, OCM, and capability models provide powerful conceptual tools, they have not yet been sufficiently integrated or adapted to the pharmaceutical context. Progress in this field depends on developing sector-specific frameworks that combine learning, change management, and maturity progression to enable the systemic integration of environmental sustainability in pharmaceutical product and process development.

2.4.6. Synthesis of systemic transition and organizational change

The literature converges on the view that systemic sustainability integration depends not only on defining what organizations should achieve but also on how ambitions are embedded into structures, processes, and culture. Strategies provide direction and purpose (Baumgartner and Ebner, 2010; Broman and Robèrt, 2017a; Placet et al., 2005), but without organizational learning and organizational change mechanisms they risk remaining aspirational. Organizational learning ensures that knowledge and experiences from tools and pilots are captured, disseminated, and embedded into routines (Boscherini et al., 2010; Kloot, 1997; Williams, 2008), while organizational change management addresses the behavioral, cultural, and governance shifts required to institutionalize new practices (Klein et al., 2022; Lozano, 2008). These perspectives collectively highlight that systemic integration requires bridging high-level strategies with day-to-day practices through iterative feedback, capability building, and stakeholder alignment.

Capabilities and maturity models provide the final layer of this bridge, translating learning and change into stable yet adaptive competences that allow organizations to consistently implement sustainability (Amui et al., 2017; Bezerra et al., 2020; Teece, 2018, 2007). Such models map progression from fragmented initiatives to institutionalized practices (Pigosso et al., 2013; Uhrenholt et al., 2022), however sector-specific frameworks remain scarce, especially for pharmaceuticals (Luu, 2023a). Overall, the evidence shows that strategies, learning, change, and capabilities must be understood as interdependent dimensions of systemic transition: strategies set direction, learning and change enable translation, and capabilities institutionalize practices over time. Together, they provide the conceptual foundations for structuring how environmental sustainability can move from isolated projects to systemic integration in the pharmaceutical industry.

2.5. PHARMACEUTICAL SECTOR AND ITS SPECIFICITIES

The pharmaceutical industry plays a pivotal role in modern societies by contributing simultaneously to public health, scientific progress, and economic development. Its primary mission is to improve human health and quality of life through the discovery, development, and distribution of medicines, making it a cornerstone of healthcare systems worldwide. Economically, the sector is one of the most research-intensive industries, generating substantial value in terms of employment, innovation, and global trade (EFPIA, 2024). Ethically, the sector carries a responsibility that extends beyond business imperatives: the long-standing principle of “first, do no harm” is

increasingly understood to encompass not only patient safety but also the environmental consequences of pharmaceutical activities (Soares et al., 2023).

At the same time, pharmaceuticals differ from other manufacturing sectors through several specificities that shape their operation and approach to sustainability. Medicines are developed and manufactured under stringent quality and safety requirements, governed by rigorous regulatory frameworks, and embedded within highly globalized supply chains. Their life cycle involves a wide network of stakeholders, ranging from researchers and regulators to healthcare providers and patients, that introduces systemic complexities and competing priorities (Luu, 2023a; K. Saha et al., 2025). These specificities constrain the direct application of generic eco-design or circular economy frameworks, underscoring the need for approaches that are tailored to the pharmaceutical context.

This section explores these dimensions in greater detail. First, the key specificities of the industry are examined, going through products and processes, to stakeholders, through regulations. Then, the environmental impacts of the sector are presented, which highlights why dedicated strategies are necessary to integrate sustainability into pharmaceutical activities.

2.5.1. Key specificities of the pharmaceutical industry

Compared to other manufacturing sectors, the pharmaceutical industry is marked by three defining specificities. First, the products and their development processes are highly complex. Second, the sector is governed by exceptionally stringent regulations. Third, a wide diversity of stakeholders is involved, adding further systemic complexity.

2.5.1.1. Pharmaceutical products

Pharmaceutical products are complex systems composed of multiple layers. At their core, they contain one or several active pharmaceutical ingredients (APIs) combined with excipients to form the semi-finished product. This is subsequently integrated into a sequence of packaging systems: the primary packaging, which directly protects the product, the secondary packaging, often referred to as consumer (patient) packaging, and the tertiary packaging, which ensures transport and distribution. For certain products, particularly injectables such as insulins or vaccines, the primary container (e.g., a glass cartridge) is incorporated into a delivery device, which is then placed in secondary packaging (Luu et al., 2022b).

Given the diversity of medicines, standardized classification systems have been created: two of the most widely used are the Anatomical Therapeutic Chemical (ATC) classification established by the World Health Organization, and the European Pharmaceutical Marketing Research Association (EphMRA) system (Luu, 2023a).

Active Pharmaceutical Ingredient (API)

The API, sometimes referred to as the “drug substance,” is the defining component of a medicine. APIs can be produced through chemical synthesis (small molecules) or derived from biological processes (large molecules). Chemical APIs are structurally simple, reproducible, and relatively straightforward to characterize, whereas biologics are derived from living organisms, making their final composition dependent not only on the genetic sequence but also on the manufacturing process. Consequently, biologics are structurally complex, highly sensitive to handling and storage conditions, and more prone to immunogenicity (IFPMA, 2022; Luu, 2023a).

Galenic Formulation

The galenic formulation, or drug product, defines the dosage form in which the API is delivered to patients. Four main families can be distinguished: solid, semi-solid, liquid, and injectable forms (Luu, 2023a).

- **Solid forms** (e.g., tablets, capsules, powders) involve steps such as grinding, granulation, and compression before packaging in blisters, bottles, or pill boxes.
- **Semi-solids** (e.g., ointments, gels, suppositories, patches) require mixing, sterilization, and filling into tubes or jars.
- **Liquids** (e.g., solutions, suspensions) rely on mixing, homogenization, and filtration before bottling.
- **Injectables** are the most demanding, requiring purified water, sterilization, sometimes lyophilization, and stringent filling and inspection before packaging in vials, syringes, or infusion bags.

Despite these differences, all dosage forms share common steps such as mixing, sterilization, filling, sealing, labeling, and inspection.

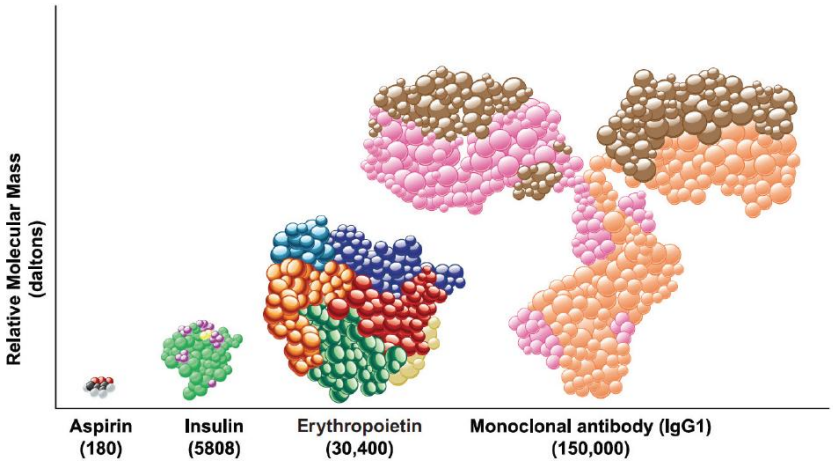

Figure 41. Comparison of the size and structure of biological medicines to small-molecules medicines (Source: IFPMA, 2024, from Mellstedt, 2013)

Despite chemistry historically dominating medicine development, biologics have expanded therapeutic possibilities in oncology, autoimmune, and genetic diseases (IFPMA, 2024, 2022). Their growing diversity, ranging from monoclonal antibodies and RNA therapies to mRNA vaccines and viral vectors, relies on advanced production technologies, including fermentation, cell culture, purification, inactivation, and flow chemistry (Luu, 2023a).

This evolution of the pharmaceutical landscape, shifting from chemistry-driven small molecules to increasingly complex biologics, has profound implications for manufacturing (Figure 41). Each class of API relies on distinct technologies, infrastructures, and expertise: chemical synthesis involves heating, mixing, and reagent-intensive processes, while biologics depend on fermentation, cell culture, purification, and strict sterility controls (Luu, 2023a). As companies progressively expand their biologics portfolios, the diversity of underlying processes grows, reinforcing the need for tailored strategies to address sustainability across different technological platforms.

Packaging and Devices

Pharmaceutical packaging is a regulated component of the medicine itself, ensuring stability, sterility, identification, and safe administration. Beyond protection, it enables traceability through labeling, serialization, and patient information leaflets. Packaging is commonly structured into three levels that together form the container closure system (Figure 42). Primary packaging refers to materials in direct contact with the drug, such as glass vials, blisters, bottles, pre-filled syringes, or cartridges. These materials must be inert and compatible with the medicine to avoid contamination or degradation. Secondary packaging includes non-contact components like cartons, labels, or patient information leaflets, providing additional protection and communication. Tertiary packaging refers to distribution and shipping elements such as pallets or corrugated boxes, which ensure physical protection during storage and transport (EFPIA, 2025). The performance of this system is critical to maintaining product quality and compliance throughout the supply chain.



Figure 42. Types of primary packaging (Source: EFPIA, 2025)

In addition to packaging, many medicines, particularly injectables and biologics, require drug delivery devices that facilitate safe and effective administration. These range from traditional devices such as syringes and infusion bags to self-administration systems like insulin pens and auto-injectors, which improve convenience and adherence (Figure 43). More recently, smart drug delivery systems have emerged, incorporating digital technologies to monitor dosing, provide reminders, and integrate with healthcare data platforms (Agnihotri et al., 2021; Gilero, 2020; MedTech Europe, 2015). These innovations blur the boundary between pharmaceutical and medical device industries, introducing new regulatory challenges and further diversifying the technological landscape of drug administration.



Figure 43. Example of insulin injection device (Source: DCA, Sanofi, 2018)

Life Cycle of a Medicine

Pharmaceuticals, like other products, follow a life cycle spanning raw material extraction, API synthesis, formulation, packaging, distribution, use, and end-of-life. Distribution typically involves factories supplying wholesalers, who then deliver to pharmacies or hospitals, although direct shipments also occur. For example, in France around 20% of output is delivered directly to hospitals (Mulcahy and Kareddy, 2022).

At the use stage, medicines may be administered in hospitals, in pharmacies (e.g., vaccines), or directly at home. The end-of-life of medicines is specific: while packaging and devices enter waste streams, APIs are metabolized in the body, generating excreted metabolites that often pass through wastewater treatment systems into the environment (Luu, 2023a).

2.5.1.2. Pharmaceutical development process

Pharmaceutical development is a structured, highly regulated, and resource-intensive process, designed to guarantee the safety, efficacy, and quality of medicines (Figure 44). Unlike most industrial products, pharmaceutical R&D is exceptionally long and risky, often spanning 10–15 years from discovery to market, with failure rates above 75% (Corr and Williams, 2009). This combination of long timelines, high attrition, and stringent requirements makes pharmaceutical processes fundamentally distinct from other manufacturing sectors.

The description that follows is primarily based on the detailed process analyses provided by Luu (2023) and Luu et al. (2024), complemented with additional references where relevant (Luu et al., 2022b; Luu, 2023a).



Figure 44. New product development process of a pharmaceutical (Source: Luu et al., 2024)

According to the International Council for Harmonization (ICH), the lifecycle of a medicinal product can be described through four overarching stages: pharmaceutical development, technology transfer, commercial manufacturing, and product discontinuation (ICH, 2008; Ramnarine et al., 2017). Within this framework, the development pathway follows a sequence of technical and clinical steps:

- Target identification and validation: Diseases are studied at the molecular level to define potential therapeutic targets.
- Lead discovery and preclinical testing: Candidate molecules are identified and evaluated in vitro (cell cultures), in vivo (animal models), and increasingly in silico (computational simulations) to assess toxicity, pharmacokinetics, and initial efficacy (Romasanta et al., 2020).
- Clinical trials: Human testing progresses through sequential phases.
    - Phase 1 assesses safety and metabolic profile in a small group of healthy volunteers, typically using preliminary formulations.
    - Phase 2a/2b determines efficacy and dose range in patients, often with formulations close to the final product.
    - Phase 3 evaluates safety and effectiveness on large patient populations, providing the evidence base for regulatory approval.
- Regulatory submission and approval: Dossiers are submitted to agencies such as the EMA or FDA, adapted to national and regional requirements. Successful evaluation leads to market authorization.

Once approved, the process enters technology transfer and commercial manufacturing, where production is scaled up to industrial level under Good Manufacturing Practices (GMP). Technology transfer, often initiated between phases 2b and 3, ensures that processes developed in R&D can be reproduced reliably at production sites (Ramnarine et al., 2017). Commercial manufacturing continues throughout the product's market life, involving quality control, potential site transfers, and supply chain optimization.

Finally, companies implement lifecycle management (LCM) strategies to maximize therapeutic and commercial value. This may include indication extensions, reformulations, or process improvements, always under regulatory oversight (Ellery and Hansen, 2012). Eventually, products are withdrawn when demand decreases, patents expire, or superior alternatives emerge.

Pharmaceutical development therefore combines two complementary perspectives: a stepwise progression from discovery to clinical validation, and a macro-process of industrialization (Figure 45). As described by Luu (2023), three macro stages can be distinguished (Luu, 2023b):

- **Discovery**, where APIs are synthesized and screened, though data on environmental performance remain uncertain and early design decisions can have long-term consequences.
- **Clinical manufacturing**, where pilot-scale production supports trials and product specifications (API, formulation, packaging) are defined.
- **Industrialization**, where large-scale GMP manufacturing is established, generating reliable data on materials, energy, emissions, waste, and end-of-life characteristics.

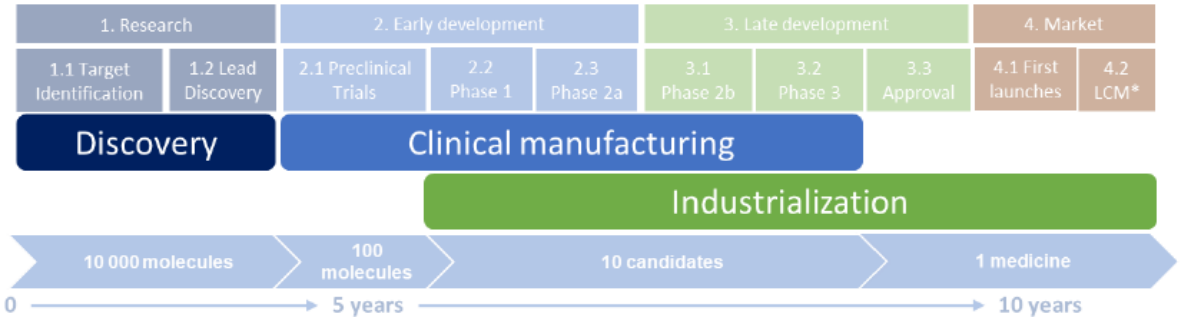

Figure 45. Overview of the R&D and Industrialization process (Source: Luu et al., 2022)

Although this overall structure applies to both small molecules and biologics, the latter introduce additional complexities. Biologics, derived from living systems, are more variable, sensitive, and process-dependent than chemically synthesized molecules. Their production requires advanced technologies such as fermentation, cell culture, and purification, alongside strict sterility and cold-chain requirements (Emara et al., 2019). In contrast, chemical APIs are based on reproducible synthesis routes, often with more standardized process control. The increasing share of biologics in pharmaceutical pipelines therefore translates into profound shifts in process technologies, infrastructures, and sustainability challenges (Luu et al., 2022b).

2.5.1.3. Regulatory framework

Ensuring patient safety is a core imperative of pharmaceutical product development (PDP), which explains why it is governed by stringent national and international regulations. Pharmaceutical regulation can be defined as "the combination of legal, administrative, and technical measures that governments take to ensure the safety, efficacy, and quality of medicines, as well as the relevance and accuracy of product information" (Rägo and Santoso, 2008). In practice, this includes activities spanning the entire product lifecycle, from premarket evaluation and inspection of manufacturing facilities to control of labeling, promotional activities, and post-marketing surveillance (Olson, 2014).

Pharmaceuticals are among the most heavily regulated goods globally, reflecting their direct link to the human right of access to safe and effective medicines (Lezotre, 2014). Regulatory systems, however, have developed unevenly across regions. While some countries have robust infrastructures, many low-resource settings lack effective oversight, creating disparities in drug quality and patient safety (Pezzola and Sweet, 2016). These differences are compounded by globalization, rising R&D costs, and public demands for transparency, which together increase the complexity of regulatory environments and push for international cooperation and harmonization (Lezotre, 2014).

The creation of the International Council for Harmonization (ICH) has been a landmark step in reducing duplication and aligning requirements across the U.S., EU, and Japan. Common technical guidelines, such as the harmonized framework on stability testing (Adlerberg, 2022; WHO, 2018), allow data generated in one region to be accepted in others, streamlining approval and accelerating patient access (Vogel, 1998). Still, convergence toward global norms is incomplete, with significant variation in how regulations are enforced across developing countries (Pezzola and Sweet, 2016).

Regulations also shape industry strategy and associated opportunities. For instance, European price regulation and health technology assessment mechanisms (e.g., AMNOG in Germany) contain costs but may dampen R&D investment, leading firms to relocate activities to less regulated markets such as the U.S. (Eger and Mahlich, 2014). Comparative analyses across Europe show that countries balance patient access and affordability in different ways, using combinations of marketing authorization, price controls, generic substitution, and reimbursement systems (Panteli et al., 2016). Although these mechanisms secure short-term sustainability of pharmaceutical financing, their long-term impacts on innovation and patient outcomes remain uncertain.
Concrete examples further illustrate how regulations constrain design flexibility. Single-use technologies in sterile manufacturing reduce cleaning requirements and water use but generate substantial waste; yet regulatory concerns about sterility limit adoption of more circular solutions (ISPE, 2018). Similarly, strict end-of-life requirements mandate the incineration of medicines and vaccines to eliminate health risks, restricting options for reuse or

recycling (K.L. Ang et al., 2021; EFPIA, 2020; Macneill et al., 2020). Therefore, regulations prioritizing safety and patient safety often restrict the introduction of more sustainable practices (EFPIA, 2020).

In summary, pharmaceutical regulation is a defining specificity of the sector. It safeguards patient safety and product quality but also profoundly influences development timelines, industrial strategies, and the scope for environmental innovation. Understanding this regulatory environment is therefore critical for identifying both the constraints and the levers available to integrate sustainability into pharmaceutical product and process development.

2.5.1.4. Pharmaceutical stakeholders

Understanding the stakeholder landscape is essential to capture the systemic complexity of the pharmaceutical sector. Medicines, like all manufactured goods, follow a complete life cycle, from raw material extraction to production, distribution, use, and end-of-life. However, because of their critical societal role, pharmaceutical products involve a particularly dense and regulated network of stakeholders. These actors not only influence product development and market access but also shape norms, practices, and opportunities for sustainability integration.

Building on the analysis and network proposed by Luu (2023), stakeholder roles can be grouped into eight main families (Luu, 2023b):

- **Healthcare Professionals (HCPs)**: Prescribers, pharmacists, and nurses, who act as key intermediaries in medicine use. Increasingly, they express interest in environmental impacts; for example, 85% of surveyed French medical interns reported interest in environmental training.
- **Patients and the Public**: End-users of medicines and broader societal actors whose expectations drive transparency, safety, and, increasingly, sustainability.
- **Pharmaceutical Industry**: Developers, manufacturers, and marketers. While some companies adopt life cycle approaches or eco-design, many remain focused on green chemistry initiatives.
- **Public Authorities**: Regulators, ministries, and health agencies (e.g., EMA, FDA, ANSM), which establish the legal and administrative frameworks governing pharmaceuticals.
- **Purchasers and Payers**: National health systems, insurers, and mutual organizations, whose reimbursement decisions influence market access and incentives for innovation.
- **Research Actor**s: Academic laboratories and contract research organizations (CROs), often involved in discovery, clinical trials, and knowledge generation.
- **Societal Groups**: NGOs, citizen groups, and think tanks (e.g., Health Care Without Harm, Shift Project) that advocate for environmental and social responsibility in healthcare.
- **Suppliers**: Providers of raw materials, equipment, logistics, and technologies, whose practices strongly affect the sector's environmental footprint.

Building on this mapping, other perspectives highlight the interdependence of these stakeholder groups around patient care. For example, Tan et al. (2020) propose a multistakeholder model in which optimal outcomes emerge from the interaction of patients, healthcare professionals, pharmaceutical and biotech companies, regulators, academic researchers, payers, and technology providers (Tan et al., 2020). In this view, patients and families are positioned at the center, with all other actors contributing resources, expertise, and data to support personalized and effective treatments (Figure 46). The model underscores that pharmaceutical companies are not isolated innovators but rather bridging actors that connect discovery, development, regulation, and care delivery.

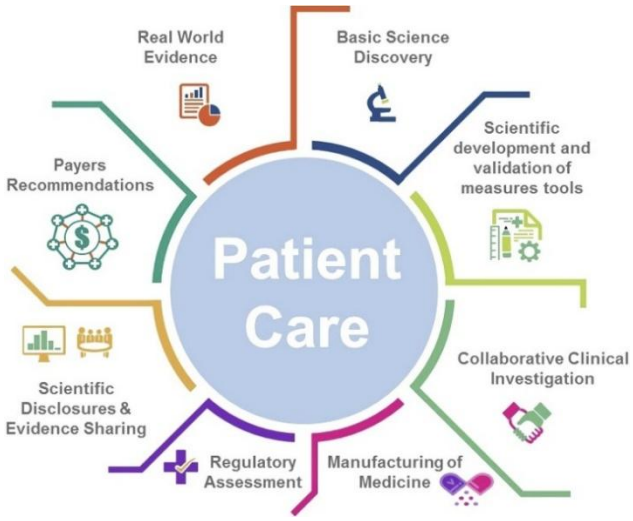

Figure 46. Multi-stakeholders model (Source: Tan et al., 2020)

By being part of the broader healthcare system, the pharmaceutical industry interacts, directly or indirectly, with all stakeholder families identified above. These actors must be considered not only during the development of medicines but also when seeking to integrate environmental sustainability into products and processes. Within the industry itself, the network of internal stakeholders is equally extensive. Pharmaceutical companies comprise a wide range of functions, each with specific responsibilities and influence over product development and sustainability-related decisions. These include functions such as research and development, clinical trials, regulatory affairs, quality assurance, manufacturing, pharmacovigilance, medical affairs, risk management, marketing, sales, data science, and supply chain management. The multiplicity of these internal actors adds another layer of complexity, as sustainability objectives must be coordinated across diverse expertise, priorities, and organizational silos.

In this context, the systemic integration of environmental sustainability requires both active engagement with external stakeholder families and effective alignment within the pharmaceutical industry itself, where decision-making authority is distributed among many specialized functions.

2.5.1.5. Synthesis of pharmaceutical specificities

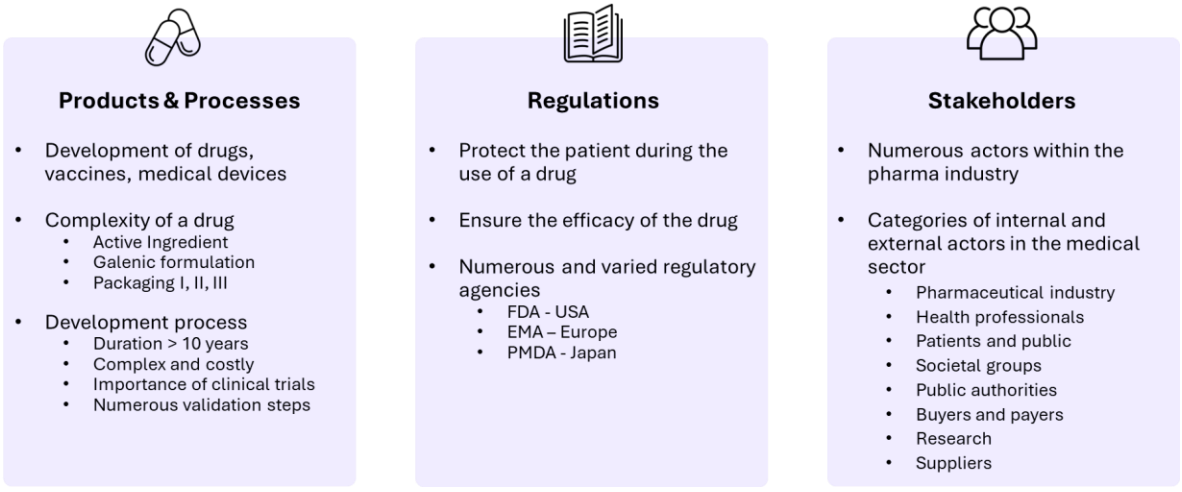

Figure 47. Overview of the specificities of the pharmaceutical industry

2.5.2. Environmental impacts of the pharmaceutical sector

Because pharmaceuticals are embedded within broader healthcare systems, it is not always straightforward to separate the environmental impacts directly attributable to pharmaceutical companies from those arising from healthcare more generally. Yet, understanding this distinction is essential: situating pharmaceuticals within the

larger healthcare footprint helps clarify the scale of the challenge and the specific stakes of integrating environmental sustainability in this sector.

This section therefore examines the environmental impacts at two levels. First, it reviews the impacts associated with healthcare systems as a whole. Second, it focuses more specifically on the environmental footprint of the pharmaceutical industry itself.

2.5.2.1. Environmental impacts of the healthcare sector

For clarity, the impacts of healthcare systems are presented by category.

Climate impacts (GHG emissions)

Healthcare systems are increasingly recognized as significant contributors to environmental pressures worldwide. Recent estimates suggest that the sector is responsible for around 4.5% of global greenhouse gas (GHG) emissions, underlining the urgency of decarbonization and resource efficiency in health-related activities (Eckelman et al., 2020). Using a multiregional input–output model, Pichler et al. (2019) estimated that healthcare was responsible for 4.4% of global GHG emissions in 2014 (≈1.6 Gt CO_2), comparable in scale to the food sector (Pichler et al., 2019). The analysis across 36 countries showed large variations in per capita footprints, from 1.51 tCO_2 in the United States to 0.06 tCO_2 in India, and identified energy system characteristics, economic energy intensity, and healthcare expenditure as the main drivers of differences.

Beyond carbon, healthcare contributes to a wide range of environmental impacts. Lenzen et al. (2020) estimated that the sector accounts for 1–5% of global impacts, depending on the indicator, including particulate matter formation, NOx and SO_2 emissions, nitrogen pollution, malaria risk, and scarce water use (Lenzen et al., 2020). The main sources are concentrated in hospitals, ambulatory services, and medical retail, with supply chain emissions driven largely by electricity and heating (38%), transport (22%), and pharmaceuticals and chemicals (10%) (Pichler et al., 2019).

Recent narrative reviews have reinforced these findings, framing healthcare as both a driver and a victim of climate change. Or and Seppänen (2024) estimate that the sector is responsible for about 5% of global GHG emissions, making it comparable in scale to energy-intensive industries such as construction and transport (Or and Seppänen, 2024). They highlight that pharmaceuticals and medical products account for up to one-third of the sector's emissions, often surpassing the direct energy use of hospitals, and that the majority of emissions arise from supply chains (Scope 3). Their analysis emphasizes that targeted mitigation strategies, ranging from energy efficiency and procurement reform to waste reduction and low-carbon medical products, are essential to curb this footprint and deliver co-benefits in terms of cost savings, resilience, and patient outcomes (Or and Seppänen, 2024).

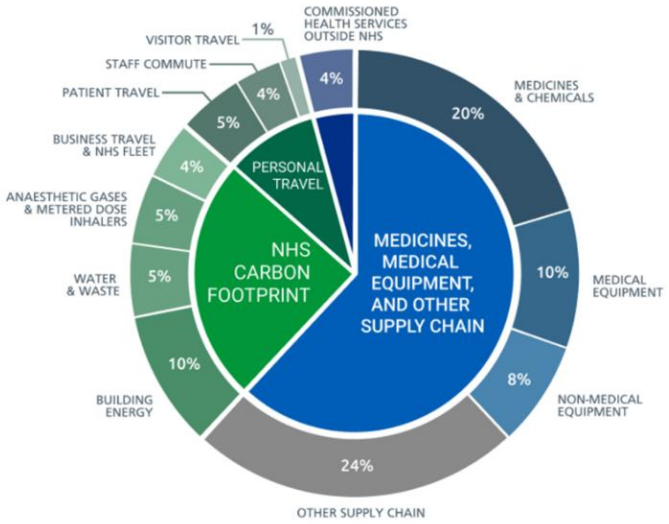

Figure 48. Sources of carbon emissions by proportion of NHS Carbon Footprint Plus (Source: NHS, 2020)

Within this overall footprint, pharmaceutical products represent a major hotspot (Figure 48). According to Lenzen et al. (2020), the pharmaceutical sector accounted for approximately 15% of healthcare-related GHG emissions in 2015, corresponding to 36.5 Mt CO_2-eq when including categories such as "medical and pharmaceutical products" and "pharmaceutical companies" (Lenzen et al., 2020). National assessments provide complementary evidence. In Canada, pharmaceuticals contributed about 3% of total healthcare GHG emissions between 2009 and 2015 (Eckelman et al., 2020). In the United Kingdom, the NHS reported that "medicines and chemicals" were the second largest contributor to emissions, representing 20% of the total (NHS, 2020). In France, the Shift Project (2021) estimated that pharmaceuticals represented 33% of healthcare-related GHG emissions, based on emission factors from ADEME (The Shift Project, 2025, 2023).

Although methodologies vary, from multiregional input–output modeling to economic allocation, the results converge on a common finding: pharmaceutical products consistently emerge as a structural contributor to the healthcare sector's environmental footprint. This applies both upstream, through resource- and energy-intensive manufacturing, and downstream, through distribution, use, and end-of-life management. These findings reinforce the case for systematically embedding environmental considerations into pharmaceutical product and process development, from the earliest design stages to market deployment.

Resource use (energy and water)

Beyond emissions, healthcare facilities are characterized by intensive resource consumption. In the United States, healthcare facilities consume over 836 trillion BTUs annually, a demand approximately 2.5 times higher than commercial buildings of comparable size (Zadeh et al., 2016). Hospitals are the second most energy-intensive building type per square meter, after food services. The associated costs are substantial, estimated at USD 6.5 billion annually, and representing roughly 15% of healthcare industry profits (Zadeh et al., 2016). These figures highlight the dual challenge of rising operating costs and environmental impacts.

Water use represents another critical dimension. Healthcare facilities consistently rank among the top ten users of water in the commercial building sector. Although national-scale figures remain scarce, the role of hospitals as hotspots of water demand is well established, particularly due to sterilization, sanitation, and heating, ventilation, and air conditioning (HVAC) systems (Zadeh et al., 2016).

Overall, these patterns underscore the resource intensity of healthcare infrastructure. High levels of energy and water use are structurally linked to the mission of hospitals, ensuring sterility, patient safety, and continuous service delivery, but they also amplify the sector's environmental burden. Improving resource efficiency in healthcare facilities is therefore an important lever for reducing the environmental footprint of the sector.

Waste and circularity challenges

Healthcare activities generate substantial amounts of solid waste, creating both environmental and public health risks. Globally, healthcare waste is estimated to represent around 4% of total solid waste, of which approximately 15% is classified as hazardous (Govindan et al., 2022). Hazardous fractions include infectious, pharmaceutical, and chemical residues, while the majority is non-hazardous and comparable to municipal waste. However, poor segregation practices often lead to contamination of non-hazardous streams, inflating costs and risks, especially in developing regions where waste management infrastructure is limited.

The generation of healthcare waste is rising by 2–3% annually, making the sector one of the fastest-growing sources of solid waste worldwide (Figure 49) (Ranjbari et al., 2022). While 75–90% of waste is non-hazardous, the remaining 10–25% requires specialized treatment. Hazardous disposal is estimated to be ten times more costly than non-hazardous waste, emphasizing the need for accurate segregation at the source. In practice, however, incineration remains the dominant treatment method globally, despite well-documented environmental concerns such as the release of toxic residues, persistent organic pollutants, and heavy metals in ash.

Recent work has highlighted the potential for circular economy strategies in healthcare waste management. Voudrias (2018) identifies multiple avenues including waste prevention, source reduction, environmentally preferable purchasing, safe reuse, recycling, and the reprocessing of selected single-use devices (E.A. Voudrias, 2018). For example, reusable sharps containers in a 1,000-bed hospital were shown to reduce waste by 15.5 tons per year while saving approximately USD 175,000. FDA-regulated reprocessing of certain devices (e.g., catheters,

laparoscopic instruments) has also demonstrated cost savings of 40–60% compared to new purchases, while diverting significant volumes of waste from incineration. Recycling initiatives targeting operating room materials (blue wrap, PVC tubing, metals) and composting of food waste offer further opportunities for impact reduction.

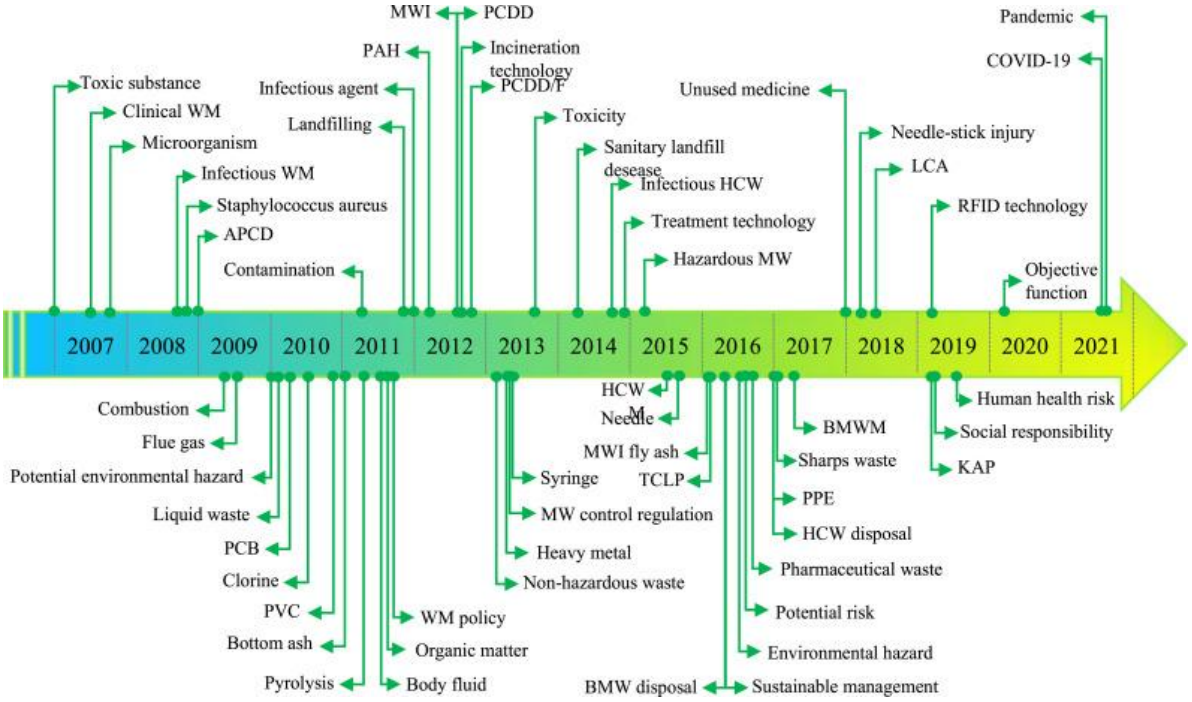

Figure 49. Timeline of dominant HealthCare Waste (HCW)-related subject areas of research (Source: Ranjbari et al., 2021)

Nevertheless, opportunities for circularity remain uneven. Hazardous and infectious wastes, including pathological residues and contaminated materials, have limited alternatives to incineration or landfilling. Regulatory, liability, and cultural barriers also restrict reuse and recycling practices. As Govindan et al. (2022) note, unlocking circularity in healthcare waste requires systemic approaches, including reverse logistics networks, improved waste segregation, and stronger governance frameworks (Govindan et al., 2022).

In summary, healthcare waste management illustrates the tension between patient safety and sustainability. Even though non-hazardous fractions could be managed through circular strategies, hazardous fractions remain tied to linear end-of-life pathways. Overcoming this challenge will require integrated governance, technological innovation, and collaborative efforts across the healthcare value chain.

Pharmaceutical and wastewater pollution

A distinct dimension of healthcare's environmental footprint relates to pharmaceutical residues in wastewater and the environment. Hospitals are major sources of pharmaceutical effluents, as most drugs are only partially metabolized and are excreted unchanged by patients. Studies indicate that hospital wastewater is 5–15 times more toxic than municipal sewage, with high loads of unmetabolized antibiotics, for example, up to 94% of clarithromycin and 67% of azithromycin excreted without transformation (Singh et al., 2021). These effluents contribute heavily to pharmaceutical loads in urban water systems, which conventional wastewater treatment plants are not equipped to remove effectively.

Industrial pharmaceutical manufacturing sites also represent critical hotspots, particularly in countries such as India and China. Extremely high concentrations of active pharmaceutical ingredients (APIs) have been reported in local water bodies, including ciprofloxacin at over 10 mg/L and oxytetracycline at around 600 mg/L, levels far exceeding environmental safety thresholds (Singh et al., 2021). Beyond hospitals and industry, households and livestock also contribute significantly to pharmaceutical pollution, as a large fraction of consumed antibiotics is excreted unchanged.

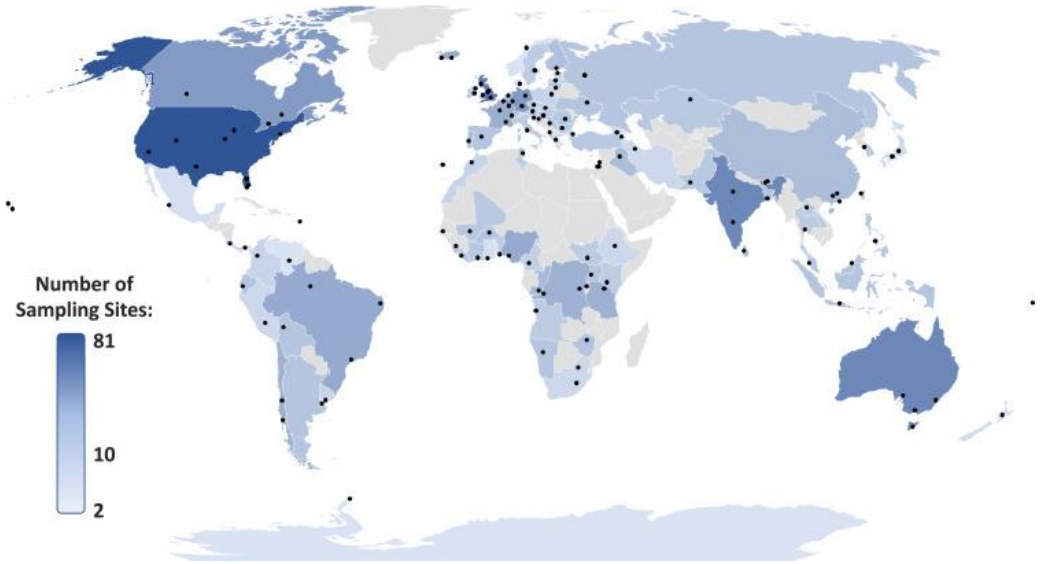

Figure 50. Locations of studied rivers for API detection (Source: Wilkinson et al., 2022)

At the global level, Wilkinson et al. (2022) conducted the first comprehensive study of API pollution across 258 rivers in 104 countries, covering over 1,000 sampling sites (Figure 50) (Wilkinson et al., 2022). Their results confirmed that pharmaceutical contamination is ubiquitous, with compounds such as carbamazepine, metformin, and caffeine detected at more than half of sites worldwide. The most contaminated sites were located in low- and middle-income countries, particularly in South Asia, sub-Saharan Africa, and South America, where weak wastewater infrastructure and pharmaceutical manufacturing drive high exposure levels. Importantly, API concentrations at over one-quarter of monitored sites exceeded safe thresholds for aquatic organisms or raised concerns for antimicrobial resistance, demonstrating that pharmaceutical pollution constitutes a global threat to ecosystems and human health.

The persistence and toxicity of these compounds amplify environmental and health risks. Pharmaceuticals, particularly antibiotics, are highly recalcitrant, with long half-lives, endocrine-disrupting effects, and chronic toxicity. Their continuous discharge fosters the spread of antibiotic-resistant bacteria (ARB) and antibiotic resistance genes (ARGs), now recognized as one of the most pressing global health threats.

Technological innovations are emerging to mitigate these risks. Advanced oxidation processes, ozonation, and UV treatment have shown effectiveness but remain costly and energy-intensive. Nanomaterials such as activated carbon, biochar, graphene, and TiO_2 catalysts offer promising alternatives, achieving >90% removal efficiency in laboratory conditions and enabling regeneration or valorization of waste streams (Singh et al., 2021). These technologies open possibilities for circular approaches, such as transforming pharmaceutical wastewater into secondary resources for energy or material recovery.

In summary, these findings position pharmaceuticals as not only a major driver of healthcare's carbon footprint but also a critical source of persistent pollutants in aquatic ecosystems. Addressing these challenges requires combined action across pharmaceutical manufacturing, hospital infrastructure, and wastewater treatment systems, with governance frameworks that balance safety, affordability, and sustainability.

2.5.2.2. Environmental impact overview of the pharmaceutical industry

As highlighted in the previous section, pharmaceutical products consistently represent a major contributor to the environmental footprint of healthcare systems, accounting for 10–33% of sectoral GHG emissions depending on the country and methodology (Eckelman et al., 2020; Lenzen et al., 2020; NHS, 2020; The Shift Project, 2025, 2023). Beyond their role within healthcare supply chains, the pharmaceutical industry itself has a distinct environmental profile, shaped by the specificity of its products, processes, and regulatory requirements. As one of the structural hotspots of healthcare systems, the pharmaceutical industry has a distinctive environmental footprint that spans manufacturing processes, product use, and end-of-life phases. Impacts are not limited to carbon emissions but extend to persistent chemical pollution, resource use, and waste generation.

Greenhouse gas emissions and energy intensity

The pharmaceutical sector is among the most carbon-intensive industries. Recent analyses show that its CO_2 emissions are 13% higher than those of the global automotive industry, despite generating substantially lower revenues (Russo et al., 2023). This disproportionate intensity reflects the sector's reliance on energy-intensive manufacturing processes, stringent sterility and quality requirements, and globalized supply chains. With the growing shift toward biologics, which depend on fermentation, bioreactors, and cold chain logistics, energy demand is expected to increase further. More broadly, climate change and the health sector's contribution to it are interlinked: rising emissions contribute to the spread of vector-borne diseases and other climate-sensitive health burdens (Ogden and Gachon, 2019).

Pharmaceutical pollution and ecotoxicity

Active Pharmaceutical Ingredients (APIs) have specific environmental risks due to their persistence, bioactivity, and potential to disrupt aquatic and terrestrial ecosystems. APIs enter the environment through manufacturing effluents, patient excretion, and improper disposal of unused medicines. Once released, they can accumulate in water bodies, promoting ecotoxic effects and antimicrobial resistance (Wilkinson et al., 2022). Household disposal practices, such as flushing medicines or discarding them with regular waste, exacerbate the problem and remain widespread despite regulatory guidance (OECD, 2022). Recent global monitoring studies confirm that API residues are now detectable in rivers on all continents, with concentrations in many locations exceeding ecological safety thresholds (Wilkinson et al., 2022).

Waste generation and material flows

The pharmaceutical industry also generates large and growing volumes of waste. Increasing demand, complex multi-layered packaging, and reliance on single-use technologies (SUTs) in sterile and biologics manufacturing all contribute to this footprint (Kenny and Priyadarshini, 2021). While SUTs reduce cleaning requirements and water consumption (Budzinski et al., 2022a), they produce significant plastic waste streams that are currently managed almost exclusively through incineration, given regulatory constraints on sterility and contamination risks. Packaging, particularly for injectables and combination products (e.g., prefilled syringes, insulin pens, autoinjectors), adds further challenges due to the mix of plastics, glass, and metals.

2.5.2.3. Life Cycle Assessments in the pharmaceutical industry

Environmental Life Cycle Assessment (LCA) is a widely recognized analytical tool for evaluating product sustainability, linking environmental performance to functionality and identifying hotspots across the life cycle (Curran, 2013; Jolliet et al., 2019). In pharmaceuticals, LCA has attracted growing attention over the past two decades as both academics and industry seek to quantify and mitigate the sector's environmental footprint. A series of literature reviews has documented this evolution, each emphasizing different aspects of the field.

The first systematic review of pharmaceutical LCAs was conducted by Jiménez-González and Overcash (2014), who considered both pharmaceuticals and related chemical processes (Jiménez-González and Overcash, 2014). Their study highlighted two critical barriers: (i) the generation of reliable inventory data, complicated by the diversity of reagents, solvents, and intermediates in pharmaceutical production, and (ii) the application of LCA results in decision-making. They also presented early examples of corporate adoption at companies such as Pfizer, AstraZeneca, and GSK, where LCA was applied to compare chemical synthesis routes, evaluate material choices, and optimize formulated products. Despite these advances, they concluded that LCA was not yet embedded as a routine business process, with adoption uneven and largely project-driven.

In addition, Emara et al. (2019) examined methodological aspects in greater detail, focusing on modeling approaches and the quantification of API emissions (Emara et al., 2019). They found that most studies adopt cradle-to-gate boundaries, concentrating on API production while neglecting downstream phases such as use and end-of-life. This omission is particularly significant, as APIs and their metabolites are often released into the environment post-consumption. Emara et al. also underscored the lack of API-specific data in commercial databases, which limits the robustness of emission modeling and environmental fate characterization.

More recently, Sabour et al. (2023) conducted the first bibliometric and social network analysis of pharmaceutical LCAs, covering 207 publications from 2000 to 2022 (Sabour et al., 2023). Their study revealed strong growth

since 2010, with peaks in 2018 and 2020, and confirmed the cross-disciplinary nature of the field, spanning environmental science, chemical engineering, energy, and pharmacology. Keyword clustering highlighted a shift from early emphasis on green chemistry and energy efficiency toward recent focus on carbon footprinting, wastewater treatment, toxicity, APIs, and packaging. Geographically, 47 countries contributed, led by the USA, UK, Germany, Spain, China, and India, though most studies remained single-country with limited international collaboration. Importantly, Sabour et al. also documented industry engagement, with case studies from Pfizer, Novartis, AstraZeneca, and GSK applying LCA for solvent selection, hotspot identification, and enterprise-level footprinting. Despite these advances, they stressed that adoption remains fragmented, hindered by methodological inconsistencies, restricted data access, and supply chain complexity.

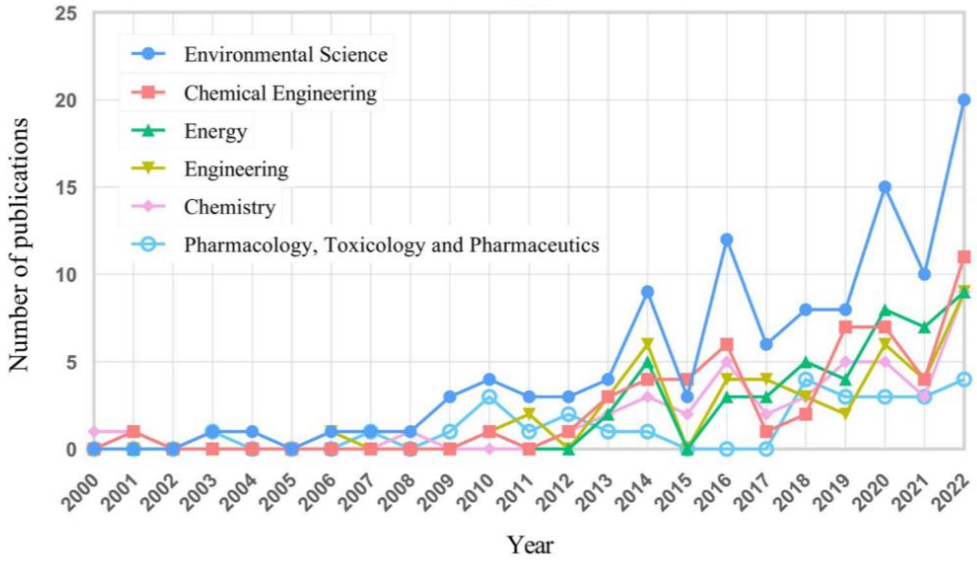

Figure 51. Annual evolution of the top six Scopus subject categories represented in pharmaceutical LCA publications between 2000 and 2022 (Source: Sabour et al., 2023)

Figure 51 illustrates the evolution and multidisciplinary nature of pharmaceutical LCA research. Although environmental science has grown rapidly since 2009, reflecting LCA's evaluative focus, strong contributions from chemical engineering, chemistry, and pharmacology highlight the continued integration of technical and medical expertise.

Finally, Chen et al. (2024) provided a structured categorization of 37 pharmaceutical LCAs, emphasizing life cycle coverage (Chen et al., 2024). They found that 54% focused on production processes, especially API synthesis and optimization; 27% addressed use and end-of-life stages; and 19% examined packaging and transportation. Only about 20% were cradle-to-grave assessments, confirming that downstream phases remain underrepresented. Chen et al. also highlighted the growing regulatory pressure for life cycle information, which is beginning to stimulate more comprehensive assessments.

A recent milestone is the creation of the Pharma LCA Consortium (2023), which brings together major pharmaceutical companies to address the methodological inconsistencies identified in the literature. The consortium is developing sector-specific Product Category Rules (PCRs) and co-creating with NHS England and BSI the forthcoming international standard PAS 2090, intended to provide a unified framework for assessing and comparing the environmental impacts of medicines (SMI and PEG, 2025). This coordinated initiative signals a growing strategic interest in LCA across the pharmaceutical sector.

In conclusion, these reviews reveal a field in transition: pharmaceutical LCAs have grown rapidly in number, scope, and thematic diversity, with rising attention to toxicity, wastewater treatment, and packaging alongside traditional carbon footprinting. However, most remain process-oriented and partial, with downstream phases, data quality, and methodological harmonization as persistent gaps. Early reviews emphasized the need for data and decision-making relevance (Jiménez-González and Overcash, 2014), later reviews pointed to modeling challenges and overlooked life cycle stages (Emara et al., 2019), while recent analyses highlight rapid growth, emerging

themes, and regulatory drivers (Chen et al., 2024; Sabour et al., 2023). Together, they illustrate both the progress made and the distance yet to travel before LCA becomes a routine and strategic tool for sustainable pharmaceuticals.

Illustrative outcomes of pharmaceutical LCA

Beyond methodological reviews, individual case studies provide concrete evidence of environmental hotspots. For example, Sharma et al. (2022) compared two dosage forms of paracetamol (tablet vs. syrup) and showed that syrup production contributed up to 90% of climate change impacts and dominated eight out of eleven endpoint categories, underscoring how galenic formulation strongly influences results (Sharma et al., 2022). At a larger scale, Piffoux et al. (2024) estimated the carbon footprint of over 12,000 oral medicines in France using a hybrid LCA approach, finding an average of 8.5 $kgCO_2$-eq per box, with corporate activities (34.5%), API synthesis (28.5%), and manufacturing (25.5%) as the main contributors (Piffoux et al., 2024). Their analysis highlighted that innovative and orphan drugs tend to have the highest footprints, linked to complex APIs and high R&D overheads. Similarly, Ma et al. (2025) assessed aspirin production and found that packaging accounted for ≈84% of total impacts, far exceeding API (11–22%) and formulation stages (≈7%). Substituting PVC/aluminum with PET or PE, or switching to bottle packaging, reduced impacts and costs significantly, showing the potential for material and design innovations (Ma et al., 2025).

These results do not provide an exhaustive view of existing pharma-LCAs, but they confirm that pharmaceutical manufacturing processes, packaging systems, and product design choices are decisive drivers of environmental impacts, complementing the trends identified in literature reviews.

2.5.2.4. Synthesis of the pharma-related environmental impacts

The literature confirms that the healthcare sector is a substantial contributor to global environmental impacts, responsible for around 5% of global GHG emissions (Eckelman et al., 2020; Or and Seppänen, 2024; Pichler et al., 2019) alongside other pressures such as water use, air pollution, and solid waste generation (Govindan et al., 2022; Ranjbari et al., 2022; E.A. Voudrias, 2018; Zadeh et al., 2016). Within this footprint, pharmaceuticals consistently emerge as a structural hotspot, contributing between 10% and 33% of healthcare-related emissions depending on the study and national context (Eckelman et al., 2020; Lenzen et al., 2020; NHS, 2020; The Shift Project, 2025, 2023). The pharmaceutical industry itself amplifies these challenges through its carbon-intensive manufacturing processes (Russo et al., 2023), reliance on solvents and single-use technologies (ISPE, 2018; Kenny and Priyadarshini, 2021), extensive packaging requirements (EFPIA, 2025), and the release of APIs into the environment (OECD, 2022; Wilkinson et al., 2022).

In parallel, the application of LCA in the pharmaceutical sector has expanded considerably. While early work emphasized production processes with cradle-to-gate boundaries (Emara et al., 2019; Jiménez-González and Overcash, 2014), more recent studies have broadened to include toxicity, wastewater treatment, and packaging (Chen et al., 2024; Sabour et al., 2023). The number of publications has grown steadily since 2010, reflecting increasing academic and industrial attention, but significant challenges persist: downstream phases such as use and end-of-life remain underrepresented, inventory data are often scarce or inconsistent, and the integration of LCA into business decision-making remains limited.

Opportunities

Taken together, these insights suggest that while pharmaceuticals are a critical driver of healthcare's environmental footprint, they also present significant opportunities for sustainable development. Several avenues are highlighted in the literature:

- **Integration of sustainability:** embedding environmental considerations into product and process design stages is essential, since early decisions lock in the majority of a product's footprint (Chen et al., 2024; Luu et al., 2022b).
- **Organizational strategies**: companies are encouraged to invest in sustainable supply chains, adopt standardized sustainability criteria, and promote staff training and incentives. At the public health level, monitoring the environmental impacts of drug production is expected to become a future priority (Russo et al., 2023).

- **Sustainable design frameworks**: eco-design, Design for Sustainability (DfS), and approaches such as Sustainability by Design (SbD) adapt principles from Quality by Design (QbD) to integrate life cycle thinking, LCA, and green chemistry into product development (Barle et al., 2023).

Besides general strategies, the literature also identifies when and how sustainability can be embedded during the pharmaceutical product development process. Luu et al. (2022) mapped eco-design opportunities across the R&D timeline (Figure 52), showing that qualitative approaches are feasible during early research (e.g., API ecotoxicity profiling), while quantitative tools such as LCA become possible in early development once data on formulation, galenic form, and manufacturing emerge (Luu et al., 2022b).

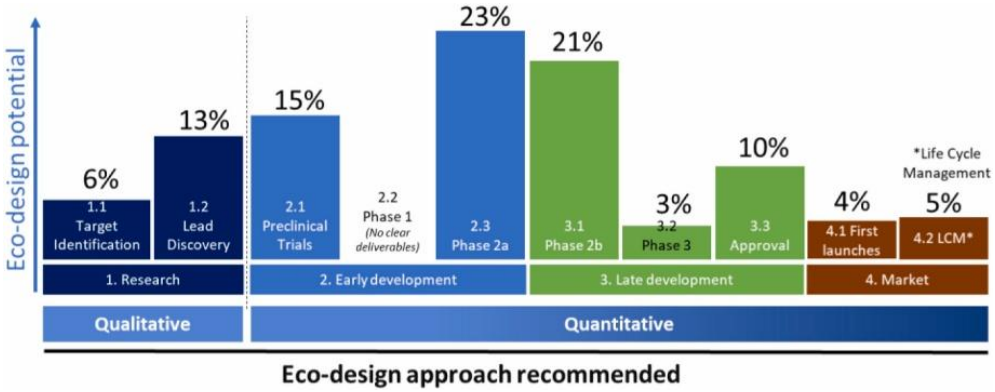

Figure 52. Eco-design potential per steps of the pharmaceutical development (Source: Luu et al., 2022)

Importantly, in pharmaceuticals the design of manufacturing processes begins in parallel to clinical phases 2a–2b, since scalable and validated production is a prerequisite for regulatory approval. This overlap makes the transition between phases 2a and 2b a critical window, where both product and process choices remain flexible enough to integrate environmental considerations. In contrast, later phases allow only incremental optimization, while post-market changes are largely limited to packaging refinements.

A similar perspective is offered by the SbD framework (Barle et al., 2023), which emphasizes aligning sustainability efforts with the drug development cycle (Figure 53). It illustrates how different workstreams, ranging from product eco-design to operational footprint reduction and supplier engagement, can deliver improvements at different development stages.

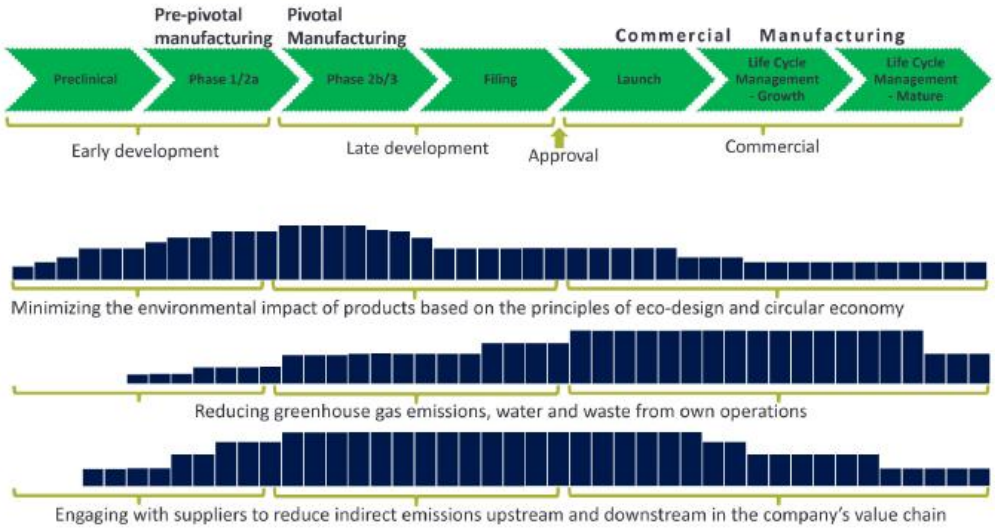

Figure 53. Drug development process with sustainability workstreams (Source: ISPE, 2023)

In summary, these opportunities illustrate how LCA, eco-design, and organizational change can be combined to advance sustainability in pharmaceuticals. However, the literature also stresses that realizing this potential requires

overcoming persistent limitations. The following section therefore turns to the key gaps and needs that remain barriers to the systemic integration of sustainability in the pharmaceutical industry.

2.5.3. Key gaps and needs related to the pharmaceutical industry

The literature on pharmaceuticals and sustainability points to persistent gaps that emphasize the need for a systemic integration of environmental sustainability in the sector.

Fragmented LCA landscape
Although the number of pharmaceutical LCAs has increased, most adopt cradle-to-gate boundaries and focus narrowly on production processes, overlooking downstream phases such as use, excretion, and end-of-life (Chen et al., 2024; Emara et al., 2019; Jiménez-González and Overcash, 2014). Data scarcity, particularly for APIs and biologics, further constrains robust modeling.

➔ *There is a need to strengthen and harmonize LCA practices, expand scope, and develop approaches that provide a more comprehensive picture of impacts*.

High impacts of processes and technologies
Studies confirm that pharmaceutical industries generate significant environmental burdens through energy-intensive manufacturing and API synthesis (Govindan et al., 2022; Kenny and Priyadarshini, 2021; Piffoux et al., 2024; Sharma et al., 2022).

➔ *There is a need to embed environmental considerations into product and process design, to support transitions toward circular and sustainable manufacturing models*.

Pharmaceutical specificities
The sector's defining characteristics: stringent regulations, stakeholder diversity, and complex products and processes, make sustainability integration particularly challenging and limit the direct transfer of generic frameworks (EFPIA, 2025, 2024, 2020; Luu, 2023b).

➔ *Dedicated approaches are needed that align regulatory imperatives with environmental goals and explicitly account for the specificities of pharmaceutical industries, including their products and process development*.

Organizational and systemic fragmentation
Pharmaceutical companies operate within dense healthcare systems while internally spanning numerous specialized functions, which complicates the integration and institutionalization of environmental sustainability (EFPIA, 2025, 2020).

➔ *There is a need to structure how environmental sustainability can be integrated across these elements, ensuring coherence between internal functions, governance levels, decision-making processes, and stakeholder relationships*.

Overall, these gaps show that advancing environmental sustainability in the pharmaceutical sector is not optional but a necessity, given its significant environmental impacts. While increasing use of LCA has improved knowledge of where impacts occur, critical gaps remain in scope, harmonization, and integration into decision-making. Addressing these requires not only more comprehensive LCAs but also practical guidance on reducing impacts, frameworks that reconcile regulatory, technological, and stakeholder constraints, and organizational strategies that support the integration of environmental sustainability in the pharmaceutical industry. Reducing the environmental footprint of pharmaceuticals is not only a matter of quantifying impacts, but also of identifying leverage points where sustainable practices can be embedded into product development and manufacturing.

2.5.4. Synthesis of the pharmaceutical sector and specificities

The review highlights the pharmaceutical industry as a sector that is both structurally complex and environmentally intensive. Its products range from chemically synthesized small molecules to biologics derived from living systems, each relying on distinct technologies, infrastructures, and quality controls (IFPMA, 2024; Luu, 2023a). Development pathways are unusually long, resource-intensive, and tightly regulated (Corr and Williams, 2009; Luu et al., 2022b), conditions that constrain flexibility and make the integration of environmental sustainability

more challenging than in most other manufacturing industries. In parallel, the sector is embedded in a dense stakeholder network, including regulators, payers, healthcare professionals, suppliers, and patients, that shapes both product development trajectories and sustainability agendas (K. Saha et al., 2025; Tan et al., 2020).

From an environmental perspective, healthcare systems account for approximately 4–5% of global GHG emissions (Eckelman et al., 2020; Or and Seppänen, 2024; Pichler et al., 2019), with pharmaceuticals consistently identified as a major hotspot contributing between 10% and 33% of this footprint depending on context (Eckelman et al., 2020; Lenzen et al., 2020; NHS, 2020; The Shift Project, 2025, 2023). The industry's environmental profile extends beyond carbon, encompassing high energy and water demand (Zadeh et al., 2016), reliance on single-use technologies (Budzinski et al., 2022a; Kenny and Priyadarshini, 2021), complex packaging systems (EFPIA, 2025; Ma et al., 2025), and the release of persistent APIs into aquatic environments (OECD, 2022; Wilkinson et al., 2022). These features make pharmaceuticals both a significant source of environmental pressures and a priority sector for sustainable transformation.

LCA has become a key tool for evaluating the impacts of pharmaceuticals. Despite early work focused mainly on production and cradle-to-gate boundaries (Emara et al., 2019; Jiménez-González and Overcash, 2014), more recent studies extend to toxicity, wastewater, and packaging (Chen et al., 2024; Sabour et al., 2023). Nevertheless, adoption remains fragmented, with persistent data gaps, especially for biologics and API emissions, and limited integration into decision-making.

In conclusion, the literature underscores both the urgency and the opportunity of embedding sustainability into pharmaceutical design and manufacturing. It clearly identifies where major impacts occur and highlights leverage points ranging from early R&D choices to manufacturing processes and packaging design (Ma et al., 2025; Piffoux et al., 2024; Sharma et al., 2022), while also exposing the structural barriers, regulatory, organizational, and systemic, that hinder their systematic consideration.

2.6. RESEARCH GAPS AND OPPORTUNITIES

The reviews across design sciences, sustainability-oriented design, circular economy, organizational transformation, and the pharmaceutical sector highlight persistent gaps that limit the systemic integration of environmental sustainability. Four overarching gaps can be identified across the literature:

Fragmentation of approaches

Design for Sustainability, eco-design, and Circular Economy each provide valuable principles, frameworks, and tools, but they remain poorly connected and often redundant (Faludi et al., 2020; Saidani et al., 2019). Existing contributions tend to be either too generic to guide implementation in specific sectors or too narrow to address systemic challenges. This lack of coherence constrains their ability to structure action in complex, highly regulated contexts such as pharmaceuticals. There is therefore an opportunity to consolidate and align these approaches into integrative frameworks that can be tailored to the sector's specific needs.

Limited translation from pilots to systemic practice

Pilot projects are widely used to explore innovative solutions for environmental sustainability, but they frequently remain isolated experiments with little long-term embedding (Boscherini et al., 2010; Zils et al., 2023). Although organizational learning literature has long emphasized the importance of capturing and disseminating lessons (Kloot, 1997; Williams, 2008), practical mechanisms for transforming temporary initiatives into institutionalized practices are underdeveloped. Strengthening the role of pilots as steppingstones toward systemic change, by ensuring that insights are systematically captured and embedded, represents an important opportunity for advancing institutionalization of sustainability in practice.

Insufficient integration of organizational and cultural enablers

The literature tends to privilege technical levers such as eco-design tools, cleaner processes, or waste treatment technologies, while giving less attention to governance, leadership, capabilities, or cultural change (EFPIA, 2020; Klein et al., 2022; Lozano, 2008; Luu, 2023a). This imbalance prevents sustainability from being embedded in

everyday decisions and weakens systemic uptake. Future approaches must therefore combine technical, strategic, and cultural dimensions in order to connect environmental objectives with organizational routines and behaviors.

Sector-specific constraints

Long and costly development cycles, stringent regulatory requirements, and complex stakeholder networks, make the transfer of generic sustainability frameworks difficult (Chen et al., 2024; Jiménez-González and Overcash, 2014; Luu, 2023a). The absence of sector-specific adaptations limits the industrial relevance of existing approaches. Addressing this gap requires tailoring sustainability frameworks to the pharmaceutical context, balancing regulatory compliance and patient safety with the need to improve environmental performance.

2.7. SYNTHESIS OF THE STATE OF THE ART

The integration of environmental sustainability into industrial practices has generated a wide body of research, drawing from design sciences, eco-design, sustainability-oriented frameworks, and more recently the Circular Economy. Each of these domains has contributed valuable principles, methods, and tools. However, as the review shows, their translation into practice remains fragmented, with limited adaptation to the pharmaceutical context. Despite the availability of hundreds of methods, most are generic, redundant, or confined to environmental efficiency, leaving unanswered the question of how to achieve systemic integration in highly regulated and complex industries (Ceschin and Gaziulusoy, 2020, 2016; Faludi et al., 2020; Rossi et al., 2016).

Organizational perspectives, such as learning, change management, and capability development, underline the importance of cultural and institutional enablers for embedding sustainability. However, they too remain insufficiently mobilized in the pharmaceutical sector. Pilot projects proliferate but rarely evolve into standardized practices (Boscherini et al., 2010; Zils et al., 2023), while governance, leadership, and stakeholder alignment are often sidelined in favor of technical substitutions (EFPIA, 2020; Klein et al., 2022; Lozano, 2008). The pharmaceutical industry itself amplifies these challenges: long development cycles, strict regulatory demands, and persistent data gaps constrain flexibility and hinder experimentation (Chen et al., 2024; Jiménez-González and Overcash, 2014; Luu, 2023a). As a result, sustainability advances in pockets of activity, but without the coherence and institutionalization required for complete and long-term transformation.

These findings resonate directly with the broader stakes identified in the contextual chapter. At the societal level, the paradox between the life-saving mission of pharmaceuticals and their environmental burdens highlights the urgency of reconciling health and sustainability imperatives (Eckelman et al., 2020; Soares et al., 2023). At the scientific level, the lack of tailored approaches underscores the need to clarify pathways, levers, and methodological adaptations capable of supporting systemic integration (Ceschin and Gaziulusoy, 2020; Pigosso et al., 2013). At the industrial level, the persistence of fragmented initiatives reveals the importance of translating conceptual advances into actionable frameworks that fit the realities of pharmaceutical development (Brones and Carvalho, 2015; EFPIA, 2025, 2024, 2020; IFPMA, 2024).

In this light, the state-of-the-art exposes both the maturity and the limitations of current knowledge. Although robust foundations exist, important debates remain open, scholars of design and sustainability continue to question how diverse approaches can be consolidated into coherent strategies rather than remaining fragmented (Faludi et al., 2020; Saidani et al., 2019). Research on organizational change and learning highlights the persistent difficulty of moving from isolated initiatives to systemic practices that endure over time (Boscherini et al., 2010; Köhler et al., 2019). Finally, work on dynamic capabilities and sustainability emphasizes the need to better understand how organizations can build and institutionalize the capabilities required for long-term systemic integration (Amui et al., 2017; Bezerra et al., 2020). These broader debates frame the unresolved issues to which this research seeks to contribute, providing the foundation for the problem statement and research orientation developed in the following chapter.

Résumé en français -Chapitre 2 : État de l'art

Ce chapitre a pour objectif d'explorer les fondements, développements et lacunes qui structurent l'intégration systémique de la soutenabilité environnementale dans les organisations, et plus spécifiquement dans l'industrie pharmaceutique. Il s'articule en cinq sections, allant des sciences de la conception jusqu'aux spécificités du secteur pharmaceutique, en passant par le Design for Sustainability (DfS), l'économie circulaire (EC) et la transformation organisationnelle.

Sciences de la conception et ingénierie : La formalisation des sciences de la conception, née dans les années 1960, a évolué de modèles linéaires et mécanistes (analyse-synthèse-évaluation) vers des approches itératives et interdisciplinaires, sous l'influence de Simon (rationalité limitée) et de la notion de « wicked problems » (Rittel et Webber). Trois notions structurent la discipline : la conception scientifique, la science de la conception, et la science de la conception comme objet d'étude. Les théories de conception se répartissent en trois familles complémentaires : les théories scientifiques formelles (GDT, Axiomatic Design), les modèles méthodologiques (Systematic Design, Stage-Gate) et les modèles créatifs/cognitifs (C-K Theory, Design Thinking, TRIZ). Cette pluralité constitue un terreau fertile pour l'intégration de la soutenabilité, qui nécessite à la fois rigueur méthodologique et exploration créative.

Design for Sustainability et éco-conception : Le DfS a évolué du « green design » vers des cadres systémiques intégrant les dimensions environnementale, sociale et économique, à travers quatre niveaux d'innovation (produit, produit-service, spatio-social, socio-technique) définis par Ceschin et Gaziulusoy. L'éco-conception, souvent approchée par l'Analyse de Cycle de Vie (ACV), reste l'approche la plus opérationnalisée mais demeure centrée sur l'efficience environnementale. Malgré plus de 600 méthodes et outils recensés, leur adoption industrielle reste limitée et fragmentée, freinée par leur complexité et leur déconnexion des réalités d'entreprise (Faludi et al., 2020). Les modèles d'intégration distinguent une dimension verticale (macro, méso, micro) et transversale (gestion du changement, culture, communication), soulignant l'importance des facteurs « soft » souvent négligés.

Économie circulaire et application pharmaceutique : L'EC, popularisée par la Fondation Ellen MacArthur, s'appuie sur des cadres tels que les frameworks en « R » (3R à 9R), le diagramme papillon, ou ReSOLVE. Malgré la prolifération d'indicateurs (plus de 350 recensés), leur fragmentation et le biais persistant vers le recyclage (au détriment des boucles courtes comme la réutilisation) limitent leur efficacité. Une revue systématique et une analyse bibliométrique menées dans ce chapitre montrent que la recherche sur l'EC appliquée à la pharma et à la santé reste embryonnaire (16 publications seulement contre plus de 2000 pour l'EC en général en 2024), concentrée sur la gestion des déchets, et peu connectée aux enjeux amont (conception, achats) ou aval (fin de vie). Trois revues consolidées (Ang et al., 2021 ; D'Alessandro et al., 2024 ; Saha et al., 2025) confirment un déséquilibre structurel : les études pharmaceutiques privilégient les boucles courtes (chimie verte), tandis que les études sur la santé se concentrent sur la gestion des déchets hospitaliers, laissant les boucles intermédiaires et les leviers organisationnels largement sous-explorés.

Transition systémique et changement organisationnel : Cette section montre que la stratégie seule ne suffit pas : elle doit être complétée par l'apprentissage organisationnel (capture et diffusion des enseignements issus de projets pilotes), la gestion du changement (dépassement de l'inertie, alignement culturel) et le développement de capacités dynamiques. Des modèles de maturité génériques (CMMI, OPM3) et spécifiques à la soutenabilité (EcoM2, Eco-Mi, CEMRM) illustrent comment structurer la progression d'initiatives ponctuelles vers des pratiques institutionnalisées. Toutefois, aucun modèle de capacité ou de maturité dédié à la durabilité environnementale n'existe à ce jour pour l'industrie pharmaceutique, une lacune renforcée par des données empiriques montrant que la plupart des entreprises manufacturières restent à un stade ad hoc de développement durable des produits (Vilochani et al., 2025).

Spécificités du secteur pharmaceutique : L'industrie pharmaceutique se distingue par la complexité de ses produits (petites molécules vs biologiques), de ses processus de développement (10 à 15 ans, taux d'échec supérieur à 75%), de son cadre réglementaire extrêmement strict, et de la diversité de ses parties prenantes (huit familles identifiées, allant des professionnels de santé aux autorités publiques). Sur le plan environnemental, le

secteur de la santé représente environ 4 à 5% des émissions mondiales de GES, les produits pharmaceutiques contribuant à hauteur de 10 à 33% de cette empreinte selon les études. Les impacts s'étendent au-delà du carbone : pollution des eaux par les résidus pharmaceutiques (détectés dans des rivières de 104 pays), consommation énergétique et hydrique élevée, génération de déchets liée aux technologies à usage unique. L'ACV s'est développée comme outil d'évaluation mais reste fragmentée, majoritairement centrée sur la production (cradle-to-gate), avec des données lacunaires notamment pour les biologiques.

Synthèse et lacunes de recherche

Quatre lacunes transversales émergent de cette revue : (1) la fragmentation des approches (DfS, éco-conception, EC) qui restent mal articulées entre elles ; (2) la difficulté de transformer les projets pilotes en pratiques systémiques pérennes ; (3) l'insuffisante prise en compte des leviers organisationnels et culturels au profit des solutions techniques ; (4) l'absence d'adaptation sectorielle des cadres génériques de durabilité au contexte pharmaceutique. Ces constats font écho aux enjeux sociétaux, scientifiques et industriels identifiés au chapitre 1, et posent les bases de la problématique de recherche développée au chapitre suivant.

Chapter 3. Research Question & Hypotheses

The preceding chapters established the broader context of this work: the urgent environmental challenges that frame sustainability transitions, the specific constraints of the pharmaceutical sector, and the current state of scientific knowledge with its persisting gaps. Together, these elements underline the need for structured approaches that can enable a more systemic integration of environmental sustainability into pharmaceutical product and process development.

Building on this foundation, the present chapter defines the scientific orientation of the thesis. It begins by formulating the central research question that crystallizes the problem at stake and provides a unifying thread for the investigation. The chapter then introduces the hypotheses and associated sub-research questions that give structure and direction to the inquiry. Finally, it presents the methodological framework and research methods mobilized, explaining how they support both scientific rigor and industrial relevance.

In this way, the chapter establishes a bridge between the contextual and theoretical background developed so far and the empirical studies that follow. It marks the transition from identifying challenges and gaps to defining a coherent research path, moving step by step from the problem to the guiding question, to the hypotheses, and finally to the methodology through which the thesis is carried out.

3.1. PROBLEMATIC STATEMENT

Human activities have led to growing environmental degradation, primarily driven by unsustainable production and consumption patterns (Richardson et al., 2023; Rockström et al., 2009; UNEP, 2012). These pressures have prompted international, European, national and local strategies to mitigate impacts and reduce the burden on ecosystems (e.g., SDGs, European Green Deal) (EC, 2019a; UN, 2015b). As a result, companies are increasingly expected to reduce their environmental footprint and align with sustainability goals. Pharmaceutical companies, while committed to protecting human health and delivering societal value, are also part of this dynamic. As manufacturing actors, they contribute to environmental impacts and are subject to environmental and institutional pressures (Eckelman et al., 2020; Wilkinson et al., 2022). Their primary mission remains the delivery of safe and effective medicines, but this mission must increasingly be achieved without compromising the environment (Mackenzie and Jeggo, 2019).

Eco-design and Circular Economy (CE) are widely recognized as key strategies to support environmental sustainability (Ceschin and Gaziulusoy, 2016; Pigosso and McAloone, 2017b). They provide actionable frameworks to reduce environmental impacts, resource use, emissions, or waste across product life cycles. In this thesis, environmental sustainability is therefore approached primarily through the combined lenses of eco-design and CE. Design science reviews highlight three areas as particularly critical for CE: product, service, and system design (with strong emphasis on PSS); design methods and tools; and Design for X approaches (Pigosso and McAloone, 2017b). These insights reinforce the idea that eco-design does not stand apart from CE but rather constitutes one of its methodological foundation (Brones and Carvalho, 2015).

The phenomenon under investigation in this thesis is the difficulty of integrating environmental sustainability into pharmaceutical products and process development, thereby leading to significant environmental impacts. The sector presents unique challenges: its activities are highly regulated, development cycles are long and complex, and organizational structures are often fragmented across functions (e.g., R&D, Manufacturing, Procurement) (EFPIA, 2020, 2024; ISPE, 2018; Luu et al., 2022b). These factors make integration particularly difficult, resulting in isolated or project-based actions that remain disconnected from systemic change (K.L. Ang et al., 2021; Krishnendu Saha et al., 2025).

This situation reflects a broader research problem observed in the literature: despite the availability of numerous Design for Sustainability (DfS) approaches, methods, and tools (e.g., LCA, green chemistry) (Pigosso et al., 2015; Rossi et al., 2016), their adoption remains fragmented (Chen et al., 2024; Jiménez-González and Overcash, 2014; Luu et al., 2022b; Luu, 2023a). Scholars emphasize three recurring challenges: (1) the need for well-defined strategies to drive sustainability integration (Lozano, 2008; Newman, 2007), (2) the consolidation of fragmented approaches and pilot projects into coherent and standardized practices (Boscherini et al., 2010; Zils et al., 2023), and (3) the development of organizational capabilities to institutionalize sustainability over time (Amui et al.,

2017; Bezerra et al., 2020; Pigosso et al., 2013; Teece, 2018; Uhrenholt et al., 2022). These limitations are particularly acute in pharmaceutical industries, where regulatory and organizational constraints amplify the barriers to integration.

The core research problem is therefore not the absence of methods or tools, but the lack of structured approaches that enable the systemic integration of environmental sustainability within pharmaceutical organizations. This thesis seeks to understand and design the conditions, mechanisms, and organizational levers that can transform organizational practices and support the transition toward sustainability.

The central research question guiding this work is therefore as follows:

How can the systemic integration of environmental sustainability be structured in the pharmaceutical industry?

This research question comprises several key terms that need to be clarified. **Structuring** refers to the intentional development of an organized, reproducible approach that enables implementation. **Systemic integration** implies the embedding of environmental practices across organizational functions and decision-making levels, rather than through isolated or ad hoc initiatives. **Environmental sustainability** encompasses the reduction of environmental impacts (e.g., emissions, waste, resource use) throughout the life cycle of products and processes. Finally, the **pharmaceutical industry** refers to the research, development, and manufacturing of medicinal products within a highly regulated, complex environment, along with its stakeholders.

3.2. HYPOTHESES

To answer this research question, our approach is built around two complementary axes of resolution, aligned with both prior work and existing approaches.

3.2.1. Key observations and resolution axes

The pharmaceutical sector is structurally complex, involving a wide range of functions and stakeholders (e.g., R&D, manufacturing, regulatory, quality, procurement). This complexity, combined with strict regulatory requirements, makes it difficult to coordinate and implement environmental approaches such as Circular Economy (CE) and Eco-design (ED).

Collaboration is a critical enabler of circular practices, but it is often hindered by regulatory constraints, confidentiality concerns, and market competition. Internally, drivers and barriers for CE are not always identified or shared across the organization, which prevents the development of aligned strategies or structured roadmaps. At the same time, while a wide range of tools, metrics, and practices exist (e.g., LCA, PCF, MCI), guidance on their effective selection and application to pharmaceutical contexts remains limited.

Pharmaceutical development processes generate environmental impacts, both through the activities they involve and through early decisions that determine the future footprint of products and processes. However, sustainability is rarely embedded at this stage, despite the decisive influence these choices have on downstream impacts. As a result, existing practices and tools often remain fragmented, context-specific, or insufficiently embedded in broader strategic and organizational frameworks.

These observations converge on a recurring difficulty: translating environmental ambitions into structured and scalable action in pharmaceutical organizations. To address this challenge, this thesis develops along two complementary resolution axes.

- The **strategic axis** addresses the need for a structured Circular Economy strategy, tailored to the specificities of the pharmaceutical sector, and capable of fostering collaboration, alignment, and the emergence of circular initiatives.

- The **organizational axis** focuses on the need to transform isolated projects into standardized practices, and to institutionalize the environmental sustainability strategy and its components as organizational capabilities, thereby supporting the systemic and long-term integration of sustainability.

Grounded in earlier work on eco-design integration and extended through new industrial projects, this research leverages CE and ED as two complementary operational levers to support the broader goal of environmental sustainability.

3.2.2. Strategic axis: toward a Circular Economy in the pharmaceutical industry

The first resolution axis focuses on the strategic integration of CE principles within the pharmaceutical sector. Existing literature and industrial experience highlight that the absence of well-defined strategies hampers coordination, prevents alignment across functions, and limits the capacity to mobilize collaboration around common sustainability goals. A structured CE strategy, tailored to pharmaceutical specificities, is needed to provide direction, foster internal and external collaboration, and align stakeholders around shared objectives.

Hypothesis 1 (H1): "*A structured Circular Economy strategy, enabling internal and external collaboration and alignment, can foster the emergence and reinforcement of circular initiatives in the pharmaceutical sector, ultimately contributing to the reduction of environmental impacts across the organization*".

This hypothesis is supported by two sub-research questions (SRQ):

- **SRQ1.1**: *What are the key elements of a CE strategy in the pharmaceutical sector, and how can they be effectively implemented?*
- **SRQ1.2**: *To what extent can a CE strategy be effectively applied in pharmaceutical contexts, and how do collaboration mechanisms influence its implementation and outcomes?*

Together, these SRQs address both the design of a CE strategy adapted to pharmaceutical constraints and the conditions for its successful deployment.

3.2.3. Organizational axis: embedding Environmental Sustainability as a capability

The second resolution axis addresses the organizational dimension of sustainability integration. In the pharmaceutical sector, environmental initiatives are often limited to pilot projects or stand-alone practices, without mechanisms for scaling or long-term embedding. More fundamentally, the challenge is not only to consolidate validated projects into standardized practices but also to manage the broader organizational change required for their adoption. Regulatory complexity, functional silos, and established routines often act as barriers, making it difficult for sustainability to move beyond isolated efforts.
Achieving systemic integration therefore requires both the translation of projects into durable practices and the institutionalization of the environmental sustainability strategy through organizational capabilities. This implies developing the structures, culture, and governance mechanisms that enable sustainability to become cross-functional, long-term, and embedded in everyday decision-making.

Hypothesis 2 (H2): "*Systemic integration of environmental sustainability in the pharmaceutical industry can be achieved by consolidating validated projects into standardized practices and institutionalizing the sustainability strategy as enduring organizational capabilities, thereby enhancing the environmental performance of products and processes*."

This hypothesis is explored through two complementary sub-research questions (SRQs):

- **SRQ2.1**: *How can validated environmental projects be consolidated and standardized into practices that support systemic integration across pharmaceutical product and process development?*
- **SRQ2.2**: *How can the environmental sustainability strategy and its components be institutionalized across organizational functions to develop durable capabilities?*

Together, these SRQs address both the operational transformation of projects into practices and the organizational embedding of sustainability as a lasting capability.

3.2.4. Synthesis of the hypotheses

Given the exploratory and qualitative nature of this research, and its foundation in an inductive approach, the work adopts sub-research questions (SRQs) rather than sub-hypotheses. This choice reflects the need to investigate complex organizational dynamics and design frameworks through contextual understanding rather than confirmatory testing.

The two hypotheses are complementary and converge toward the overarching research objective: enabling the systemic integration of environmental sustainability in the pharmaceutical industry. Each addresses a different but interconnected resolution axis: the strategic deployment of CE (H1) and the organizational institutionalization of environmental sustainability as a capability (H2). Together, they provide a coherent structure to investigate how sustainability can be operationalized across decision levels and functions.

Building on strategic insights from the literature, effective sustainability strategies are understood to require a clear articulation of the **why** (purpose), before defining the **what** (methods and tools), the **when** (decision points), and the **how** (implementation pathways) of integration (Baumgartner and Rauter, 2017). Earlier studies on eco-design integration in pharmaceuticals have already clarified several of these dimensions: the why of reducing environmental impacts, the what through methods such as LCA and green chemistry, and the when by identifying early development stages as critical leverage points (Luu et al., 2022b; Luu, 2023a). Extending this logic to the CE, the present research addresses these same dimensions while advancing further toward the how. Specifically, it examines how strategies for environmental sustainability can be institutionalized within pharmaceutical organizations (Figure 54).

The resulting hypotheses and SRQs therefore reflect a dual ambition: first, to define the strategic elements required for CE in the pharmaceutical industry, and second, to enable the transformation of strategies and projects into systemic practices and capabilities. In this way, the thesis bridges earlier eco-design integration efforts with broader CE-oriented strategies, and ultimately with the institutionalization of environmental sustainability.

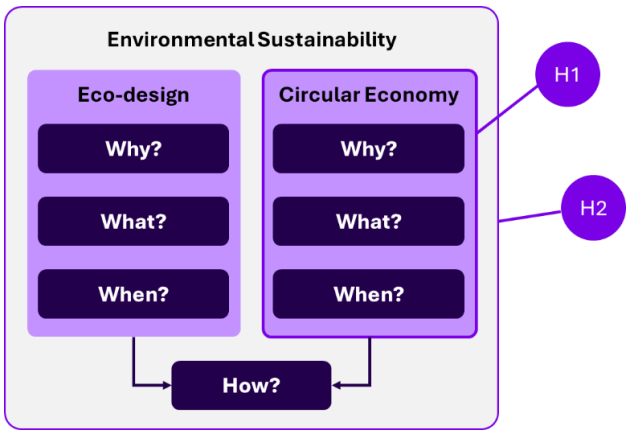

Figure 54. Overall structure of hypotheses and their relation in the broader environmental sustainability strategy

3.3. RESEARCH METHODOLOGY

This section explains the research methodology followed during this thesis, the research structure deployed to answer the research question and hypotheses, and finally introduces the methods applied during the research.

3.3.1. Design Research Methodology

The methodological framework adopted in this thesis is the Design Research Methodology (DRM) (Blessing and Chakrabarti, 2009a). The strength of the DRM lies in its ability to provide a structured approach for conducting rigorous and applicable research in the field of design. It offers a set of methods and guidelines to support the planning and implementation of design-oriented research.

Therefore, the DRM was chosen for this work as it aligns with both the exploratory nature of the research and the industrial context in which it was conducted. It supports iterative processes, enabling adaptations based on findings from the field, and promotes the use of empirical data to understand current practices, identify needs, and evaluate improvements. This makes it especially suitable for applied research that aims to deliver both scientific contributions and practical outcomes.

The DRM is composed of four main stages: *Research Clarification, Descriptive Study I, Prescriptive Study, and Descriptive Study II*. Each stage has been tailored to the context of this thesis and is detailed in the following sections. Figure 55 illustrates how the research questions and hypotheses are structured across the different DRM phases, and how these phases and the industrial projects conducted are linked.

3.3.1.1. Research clarification

The Research Clarification (RC) phase aims to define the initial need and the research problem. At this stage, the objective is to gather early evidence or indications that support the assumptions and help formalize a concrete research goal. This exploratory phase was primarily based on a literature review, used to identify relevant gaps and refine the direction of the study. In this thesis, the exploratory literature review focused on several core topics:

- Design for Sustainability and Eco-design
- Circular Economy
- Organizational learning, organizational change, and capabilities
- Pharmaceutical product development

This work helped shape the overall structure of the research project: refining its scope, identifying key gaps, and defining the research objectives, hypotheses, and methodological orientation.

3.3.1.2. Descriptive Study I

Building on the clarified research goal, the Descriptive Study I (DS-I) stage aims to provide a detailed description of the current situation in order to identify the key factors that should be addressed to overcome the previously identified challenges. The objective is to understand the phenomenon under investigation, along with its causes, influencing elements, and contextual characteristics. This understanding lays the groundwork for the development of a potential support. In the context of the Design Research Methodology, a support refers to any means, such as methods, tools, guidelines, knowledge bases, or procedures, that can help improve design activities for a specific purpose (Blessing and Chakrabarti, 2009a).

In this thesis, the DS-I stage was approached through two complementary paths, conducted in parallel. First, a review-based investigation was carried out to consolidate findings from the literature and identify influencing factors. Second, empirical studies were performed using a qualitative approach, in collaboration with the industrial partner, to explore the research phenomena in real settings and refine the understanding of current practices, barriers, and opportunities.

3.3.1.3. Prescriptive Study

The Prescriptive Study (PS) stage focuses on the development of a support to address the practical problems identified in the previous stages and improve the current situation. In line with the DRM framework, this phase involves the conceptualization, description, elaboration, and realization of supports that can be tested for their potential to meet the defined design requirements.

In this thesis, three prescriptive studies were carried out, each aiming to provide a tailored response to specific aspects of the research problem:

1. *Development of a CE strategy and integration model for the pharmaceutical industry*, to structure strategic CE implementation and stakeholder alignment.
2. *Development of a transition framework for project-to-practice transformation*.
3. *Development of a Capability Model and Application method for capability building and institutionalization*.

These supports were designed to be applicable in real industrial contexts and adaptable to the constraints and complexity of the pharmaceutical sector.

3.3.1.4. Descriptive Study II

The Descriptive Study II (DS-II) stage focuses on the evaluation of the proposed support to assess how effectively it addresses the research and practical problems identified, and to what extent it improves the existing situation. Additionally, this stage supports the assessment of the support's applicability, usability, and usefulness. Empirical studies are often conducted at this stage to evaluate the use and performance of the support in real-world settings where the phenomenon occurs.

Two main descriptive studies were conducted as part of this thesis. First, the CE strategy was evaluated through the outcomes of circular initiatives implemented within the pharmaceutical context. Then, the Transition framework, developed to expand the positive impacts of previously isolated initiatives, was evaluated through two applications: a portfolio Life Cycle Assessment (LCA) of insulin products, and the development of a guide for environmentally sustainable manufacturing processes.

3.3.1.5. DRM application in the thesis

The application of DRM in this thesis reflects both its iterative logic and its adaptability to real-world constraints. The four stages were not followed in a strictly linear manner but rather as overlapping cycles, with empirical findings continuously feeding back into the design and refinement of supports (Figure 55).

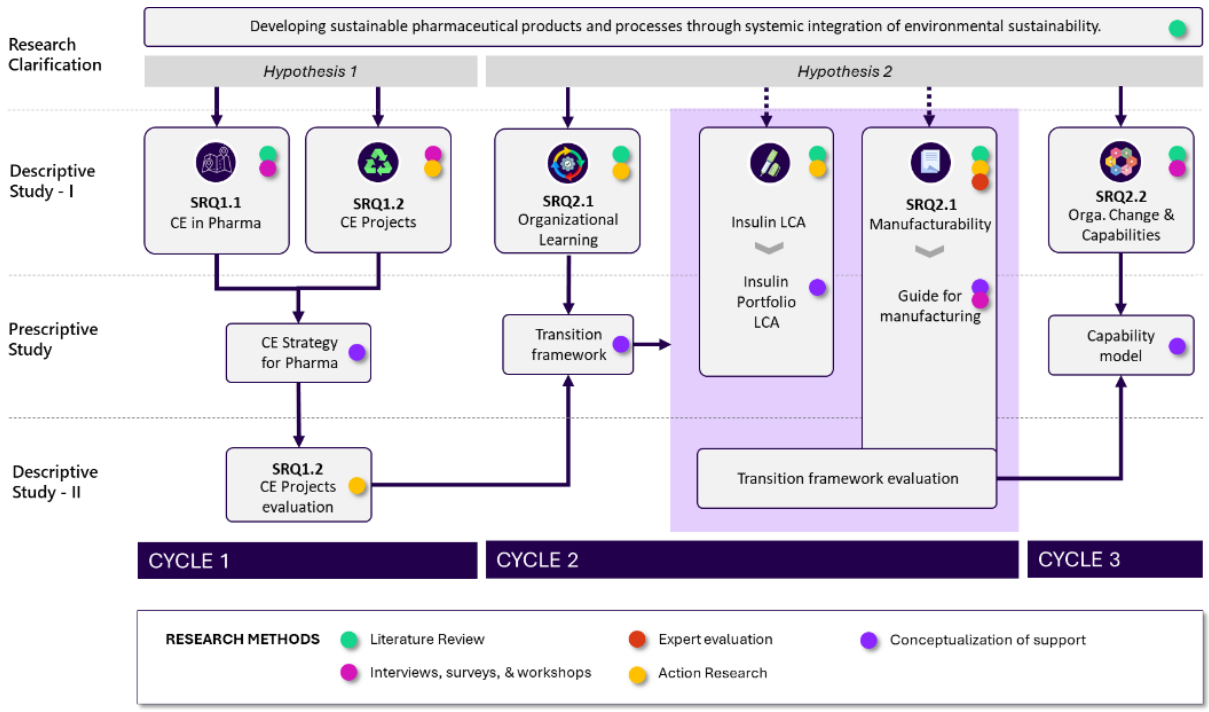

Figure 55. Application of the DRM throughout the research: Hypotheses, Sub-Research Questions (SRQ), and results according to the DRM stages

- **Research Clarification (RC)** consolidated the environmental, industrial, and scientific contexts through targeted literature reviews and exploratory interviews. This provided the basis for identifying research gaps and refining the main research question and hypotheses.

- **Descriptive Study I (DS-I)** deepened the understanding of the pharmaceutical context by characterizing drivers, barriers, and stakeholder perspectives. It combined systematic literature analyses with empirical studies of current practices, highlighting the fragmentation of sustainability initiatives and the need for structured integration.
- **Prescriptive Study (PS)** focused on the development of three supports tailored to the pharmaceutical sector: (1) a CE strategy and integration model, (2) a transition framework for transforming isolated projects into systemic practices, and (3) a capability model for embedding sustainability as an organizational capability.
- **Descriptive Study II (DS-II)** evaluated these supports in practice. The CE strategy was assessed through circular initiatives piloted with industrial sites; the systemic transition framework was validated through a portfolio LCA of insulin products and a guide for manufacturing processes; and the capability model was examined through first steps of application.

This mapping shows how the DRM structure ensured coherence between the exploratory phases, the design of prescriptive outputs, and their evaluation in industrial settings. By embedding empirical projects within this framework, the research combined methodological rigor with practical relevance, thereby addressing both academic and industrial stakes.

3.3.2. Research methods

The methodological orientation of this thesis is strongly applied, situated at the intersection of design research and industrial practice. Consequently, the research combined multiple qualitative and quantitative methods to explore current practices, design new supports, and evaluate their application in real pharmaceutical contexts. The purpose of this section is not to detail each method exhaustively, but rather to provide an overview of the methods employed and their alignment with the DRM framework.

Five families of research methods were mobilized during this doctoral thesis:

- **Literature reviews**: conducted primarily during the RC and DS-I phases, to map the state of knowledge, identify gaps, and clarify the research problem. These included systematic and semi-systematic reviews of DfS, CE, organizational learning, change, capabilities, and pharmaceutical sustainability.

- **Interviews, surveys, and workshops**: used to capture stakeholder perspectives, identify drivers and barriers, and co-develop prescriptive outputs. These methods were central to DS-I and PS and provided empirical grounding for the design and refinement of supports.

- **Action research and case studies**: carried out in collaboration with the industrial partner, to test circular initiatives, develop pilot projects, and evaluate the implementation of proposed frameworks This iterative engagement, aligned with PS and DS-II, followed an action research logic in which change and knowledge creation occurred simultaneously through cycles of implementation, observation, and reflection with stakeholders (Coughlan and Coghlan, 2002).

- **Conceptualization of supports**: central to PS, where insights were translated into actionable artefacts (models, methods, frameworks). The supports were developed using knowledge gathered during the DS-I stages, systematized and combined with creative exploration. Co-design sessions with stakeholders ensured clarity, feasibility, and alignment with pharmaceutical constraints.

- **Expert evaluations**: applied in the later stages to validate the consistency, completeness, and usability of the developed supports, and to strengthen the scientific robustness of the findings.

This multi-method approach reflects the iterative and adaptive nature of the DRM. Literature reviews and qualitative inquiries provided the foundation for problem exploration (RC, DS-I); action research and case studies enabled prescriptive development and real-world testing (PS, DS-II); conceptualization activities ensured that supports were co-designed and context-specific; and expert evaluations reinforced their academic and practical

validity. Taken together, these methods created a complementary and coherent research design, balancing conceptual rigor with practical applicability.

3.4. SYNTHESIS OF CHAPTER 3

This chapter has defined the scientific orientation of the thesis. It first articulated the central research question: How can the systemic integration of environmental sustainability be structured in the pharmaceutical industry? To address this question, two complementary hypotheses were formulated. The first emphasizes the strategic dimension, proposing that a tailored Circular Economy strategy can foster collaboration and alignment to enable circular initiatives. The second emphasizes the organizational dimension, arguing that systemic integration requires consolidating projects into standardized practices and embedding sustainability as an enduring capability. Each hypothesis was further specified through sub-research questions to guide the inquiry in a structured way.

To investigate these questions, the chapter introduced the Design Research Methodology (DRM) (Blessing and Chakrabarti, 2009a) as the overarching research framework. Its iterative and flexible structure provided coherence across the different phases of the work, from clarifying the problem and describing the current situation, to developing prescriptive supports and evaluating them in practice. Within this framework, a multi-method approach was mobilized, including literature reviews, empirical studies, action research, conceptualization of supports, and expert evaluations.

In summary, the research question, hypotheses, and methodology provide a coherent roadmap for the thesis. They establish the link between the contextual and theoretical background and the empirical studies that follow. The next two chapters present the experimental core of the work: Chapter 4 develops a Circular Economy strategy and explores collaborative initiatives in the pharmaceutical sector, while Chapter 5 addresses the systemic transition and organizational change required to embed environmental sustainability as a lasting capability. These two chapters serve to test and validate the hypotheses and sub-research questions, thereby providing the empirical foundation for the contributions of the thesis.

Résumé en français - Chapitre 3 : Question de recherche et hypothèses

Ce chapitre définit l'orientation scientifique de la thèse en formulant la question de recherche centrale, les hypothèses associées, ainsi que le cadre méthodologique mobilisé pour y répondre.

Énoncé de la problématique : Les entreprises pharmaceutiques, tout en assurant leur mission de santé publique, contribuent aux impacts environnementaux en tant qu'acteurs industriels et sont soumises à des pressions réglementaires et institutionnelles croissantes. L'éco-conception et l'économie circulaire (EC) constituent les deux leviers privilégiés dans cette thèse pour aborder la soutenabilité environnementale, ces approches étant complémentaires plutôt que concurrentes. Le phénomène étudié est la difficulté d'intégrer la soutenabilité environnementale dans le développement des produits et procédés pharmaceutiques, difficulté exacerbée par la forte réglementation du secteur, la longueur des cycles de développement, et la fragmentation organisationnelle entre fonctions (R&D, manufacture, achats). Le problème de recherche ne réside donc pas dans l'absence de méthodes ou d'outils, mais dans le manque d'approches structurées permettant une intégration systémique de la soutenabilité.

Question de recherche centrale : Comment structurer l'intégration systémique de la soutenabilité environnementale dans l'industrie pharmaceutique ?

Hypothèses et axes de résolution : deux axes complémentaires structurent la réponse à cette question

- **Axe stratégique (H1) :** Une stratégie d'économie circulaire structurée, favorisant la collaboration et l'alignement internes et externes, peut favoriser l'émergence et le renforcement d'initiatives circulaires dans le secteur pharmaceutique, contribuant ainsi à la réduction des impacts environnementaux de l'organisation. Cette hypothèse est déclinée en deux sous-questions de recherche portant sur les éléments clés d'une stratégie d'économie circulaire adaptée au secteur pharmaceutique (SRQ1.1) et sur les mécanismes de collaboration influençant sa mise en œuvre (SRQ1.2).
- **Axe organisationnel (H2) :** L'intégration systémique de la durabilité environnementale dans l'industrie pharmaceutique peut être atteinte en consolidant les projets validés en pratiques standardisées et en institutionnalisant la stratégie de durabilité sous forme de capacités organisationnelles durables. Cette hypothèse est déclinée en deux sous-questions portant sur la consolidation des projets validés en pratiques (SRQ2.1) et sur l'institutionnalisation de la stratégie à travers les fonctions organisationnelles (SRQ2.2).

Ces deux hypothèses sont complémentaires : la première porte sur le déploiement stratégique de l'EC, la seconde sur l'institutionnalisation organisationnelle de la soutenabilité comme capacité. Elles s'inscrivent dans la continuité de travaux antérieurs sur l'éco-conception (qui avaient clarifié le pourquoi, le quoi et le quand de l'intégration) en visant à approfondir le comment.

Méthodologie de recherche : Le cadre méthodologique retenu est la Design Research Methodology (DRM), structurée en quatre phases itératives :

1. **Research Clarification (RC)** : revue de littérature exploratoire sur le DfS, l'éco-conception, l'EC, l'apprentissage organisationnel, le changement organisationnel, les capacités, et le développement pharmaceutique, permettant d'affiner la problématique et les hypothèses.
2. **Descriptive Study I (DS-I)** : caractérisation approfondie du contexte pharmaceutique (facteurs, freins, parties prenantes) combinant analyses de littérature et études empiriques.
3. **Prescriptive Study (PS)** : développement de trois supports adaptés au secteur pharmaceutique : (1) une stratégie et un modèle d'intégration de l'EC, (2) un cadre de transition pour transformer les projets isolés en pratiques systémiques, et (3) un modèle de capacités pour l'institutionnalisation de la soutenabilité.
4. **Descriptive Study II (DS-II)** : évaluation de ces supports dans des contextes industriels réels, la stratégie d'EC via des initiatives circulaires pilotées sur sites industriels ; le cadre de transition via une ACV de portefeuille d'insulines et un guide pour le développement de procédés de fabrication soutenables ; le modèle de capacités via ses premières applications.

Cinq familles de méthodes de recherche ont été mobilisées : revues de littérature, entretiens/enquêtes/ateliers, recherche-action et études de cas, conceptualisation de supports, et évaluations par experts. Cette approche multi-méthodes combine rigueur conceptuelle et applicabilité pratique, en cohérence avec la nature itérative de la DRM.

En conclusion, ce chapitre établit le pont entre le contexte théorique développé précédemment et les études empiriques à venir. Le chapitre 4 développera la stratégie d'économie circulaire et les initiatives collaboratives (testant H1), tandis que le chapitre 5 abordera la transition systémique et le changement organisationnel nécessaires à l'institutionnalisation de la durabilité comme capacité durable (testant H2).

Chapter 4. Circular Economy Strategy & Collaborative Projects

This chapter presents the design and evaluation of a Circular Economy strategy tailored to the pharmaceutical sector, directly addressing **Hypothesis 1**: *A structured Circular Economy (CE) strategy, enabling internal and external collaboration and alignment, can foster the emergence and reinforcement of circular initiatives in the pharmaceutical sector, ultimately contributing to the reduction of environmental impacts across the organization.*

Building on the conceptual foundations, context, and research gaps identified in the previous chapters, this chapter operationalizes H1 through two sub-research questions:

- **SRQ1.1**: *What are the key elements of a Circular Economy strategy in the pharmaceutical sector, and how can they be effectively implemented?*
- **SRQ1.2**: *To what extent can the designed Circular Economy strategy be effectively applied and generate value in pharmaceutical contexts, and how do internal–external collaboration mechanisms influence its successful implementation and outcomes?*

The chapter is organized into two main parts (Figure 56). Part A addresses SRQ1.1 by drawing on literature analysis, empirical investigation, and industry-specific insights to design a CE strategy adapted to pharmaceutical constraints and opportunities. Part B addresses SRQ1.2 by applying the designed strategy to a set of case studies and related projects, assessing its applicability, usability, and usefulness, and exploring the role of collaboration in enabling or hindering successful implementation.

Together, these two parts provide an integrated view of both the conceptual design and the practical performance of the CE strategy, generating evidence to support H1 and laying the groundwork for Chapter 5, which focuses on systemic integration and capability building.

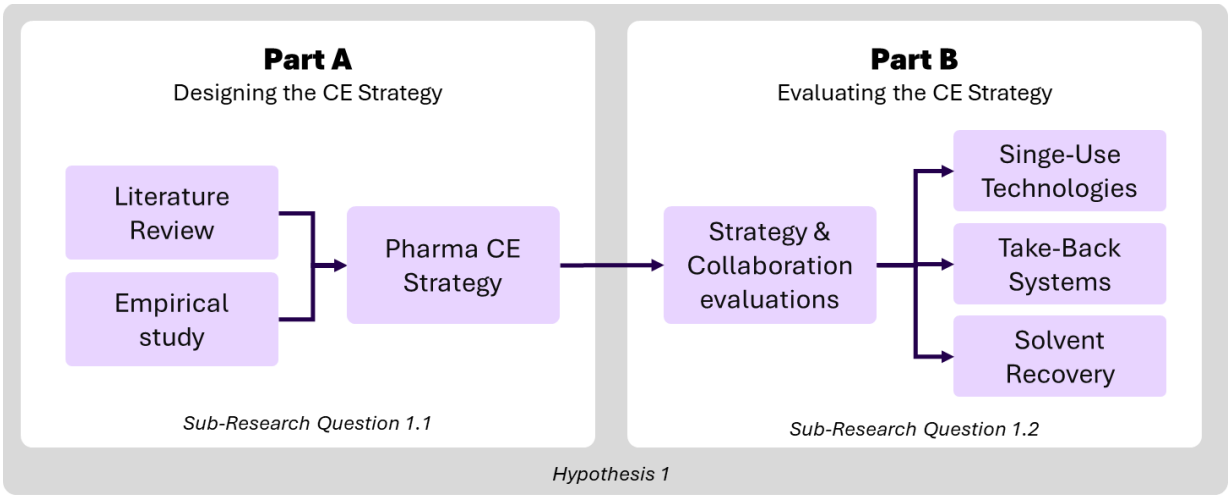

Figure 56. Structure of Chapter 4 and logical flows

PART A: DESIGNING THE CE STRATEGY

Integrating new approaches and concepts, such as Circular Economy (CE), within organizations requires more than isolated initiatives; it demands a structured and strategic response. At the corporate level, the shift toward CE must be anchored in both strategic planning (to define objectives, indicators, and roadmaps) and strategic thinking (to envision how circularity can transform operations, governance, and culture).

This first part of Chapter 4 is therefore dedicated to the design of a comprehensive CE strategy tailored to the pharmaceutical sector. It builds upon the results of the systematic literature review and empirical study, aiming to move from scattered practices and conceptual ambiguity to a structured framework that can support systemic implementation.

By addressing the core dimensions of CE, such as guiding principles, organizational integration, performance indicators, and implementation tools, this section provides the foundational components necessary to answer Sub-

Research Question 1.1: *"What are the key elements of a Circular Economy strategy in the pharmaceutical sector, and how can they be effectively implemented?"*

4.1. CONTEXT

The transition toward more sustainable industrial systems increasingly relies on the Circular Economy (CE) as a framework for decoupling economic growth from resource consumption and environmental degradation. By promoting strategies such as waste prevention, resource efficiency, and closed-loop systems, the CE provides a practical pathway to operationalize sustainable development. Within this context, design sciences act as key enablers for creating sustainable products and processes, notably through Design for Sustainability (DfS) approaches, such as eco-design. Eco-design plays a pivotal role by embedding environmental considerations into the earliest stages of product and process development, ensuring that sustainability is built in rather than added on. The strong link between eco-design and the circular economy is widely recognized, with institutions such as the French Agency for Ecological Transition (ADEME) identifying eco-design as one of the core pillars of a circular economy. Similarly, the Ellen MacArthur Foundation emphasizes that design underpins all three circular economy principles: eliminating waste and pollution, circulating products and materials, and regenerating nature (EMF, 2013b). Design determines how products, services, and systems are created, shaping the material environment to meet human needs and aspirations. By enabling repair, reuse, remanufacturing, or recycling, design unlocks new value for companies and consumers (or patients). As a result, the boundaries between the circular economy and design for sustainability are not always clear, as both aim for similar objectives and often overlap in practice.

Despite the increasing maturity of CE concepts in other industrial sectors, the pharmaceutical industry has remained comparatively underexplored in this respect. Several structural factors explain this gap. First, pharmaceutical products and their development processes are inherently complex, involving long timelines, multiple decision gates, and diverse product categories and specificities (e.g., monoclonal antibodies, viral and bacterial vaccines, mRNA vaccines). Second, the sector is subject to stringent regulations to ensure patient safety, product efficacy, and quality, which can limit flexibility in product or process redesign. Third, the value chain is highly fragmented and involves a diverse range of internal and external stakeholders, from research partners and suppliers to regulators, healthcare providers, and patients. For example, several key functions are directly involved in the development and manufacturing of a drug, including quality assurance, clinical operations, chemistry manufacturing and control, production, and others. These specificities create a complex environment, making the integration of environmental sustainability approaches such as the circular economy particularly challenging.

Within the pharmaceutical sector, eco-design initiatives began several years ago, primarily through the application of Life Cycle Assessment (LCA) to pharmaceutical products. This focus on product-level assessments has progressively built awareness and technical capability within organizations, increasing eco-design maturity. However, while LCA provides robust environmental performance data, CE implementation requires complementary action at multiple organizational levels, including manufacturing, supply chain, and stakeholder engagement. It also requires local adaptation, as the feasibility and impact of circularity measures are often context dependent.

At Sanofi, where this research takes place, given Sanofi's global footprint, with over 60 manufacturing sites and 20 R&D facilities across multiple countries, coordinating circular initiatives demands clear corporate strategy, based on corporate-level strategic planning and strategic thinking to ensure alignment across regions, business units, and sites. Without a shared vision, consistent metrics, and coordinated implementation, efforts risk remaining fragmented and less impactful.

In this context, the objective of this study is to determine whether CE and its principles can be effectively applied in the pharmaceutical sector and, if so, how these principles can be structured in an effective strategy. The focus is on defining the strategic and operational levers needed to support the CE transition within pharmaceutical industries and to identify synergies between circular economy and existing eco-design actions.

4.2. MATERIAL AND METHODS

The research follows the Design Research Methodology (DRM) and focuses here on two stages: the Descriptive Study I (DS-I) and the Prescriptive Study (PS). The DS-I stage aims to develop a detailed understanding of the existing situation, identifying key influencing factors, barriers, and opportunities relevant to integrating CE principles in the pharmaceutical context. This involves combining insights from the literature with internal empirical data to build a comprehensive description of the current state. Building on this, the PS stage defines the desired situation and explores potential improvement scenarios. It focuses on the systematic development of a corporate CE strategy, leveraging the factors identified in DS-I to propose structured support, such as an integration model, key performance indicators, and roadmaps, that can be implemented and tested within the organization.

4.2.1. Literature Review

A Systematic Literature Review (SLR) was conducted to assess the current state of knowledge regarding the integration of CE principles within the pharmaceutical sector. The review followed a structured and transparent protocol to ensure reproducibility. This protocol involved the formulation of research questions, the development of keyword strategies, and the application of defined inclusion and exclusion criteria.

The review aimed to address the following research questions:

- To what extent has the circular economy been implemented in the pharmaceutical sector?
- How can circular economy be integrated within pharmaceutical companies?
- Which circular principles are most commonly applied in the pharmaceutical sector, and at which stages of the value chain?

Accordingly, the analysis focused on identifying existing frameworks, models, indicators, types of circular loops (e.g., reuse, recycling, remanufacturing), as well as reported barriers and enablers to CE adoption in the pharmaceutical industry. These findings provided a theoretical foundation for the study and supported the identification of knowledge gaps and the contextualization of the subsequent empirical investigation.

The literature search was conducted primarily through Scopus, PubMed, and Google Scholar, using the following query: *("circular economy" OR "circular" OR "circularity" OR "waste management") AND ("pharmaceutical*" OR "pharmaceutical industry" OR "pharmaceutical sector" OR "healthcare" OR "drug manufacturing" OR "drug development" OR "medicine" OR "vaccine" OR "medical device")*

Only peer-reviewed research articles, review papers, and conference proceedings published in English, from 2000 to 2025, were included in the final selection.

4.2.2. Empirical data collection and analysis

To complement the insights from the SLR, an empirical investigation was carried out at Sanofi, and across pharmaceutical companies, to explore how circular economy principles are currently integrated within the companies' operations. The empirical data collection comprised three main components: (1) a review of internal documentation, (2) a benchmark of CE in the top-20 pharmaceutical companies, and (3) a combination of survey and semi-structured interviews. This mixed-method approach enabled a comprehensive understanding of both strategic intents and operational practices related to CE in the pharmaceutical sector.

4.2.2.1. Internal documentation review

The first component of the empirical phase involved a qualitative review of internal documents made available by Sanofi. These included corporate sustainability reports, internal policy guidelines, product design protocols, and technical documentation related to product development. The objective was to assess the extent to which eco-design principles, such as resource efficiency, substitution of hazardous materials, and lifecycle thinking, were embedded in current design processes.

This review enabled the identification of existing frameworks, tools, or assessment criteria used within Sanofi to support eco-design efforts. The analysis also sought to map out the level of formalization and alignment with CE principles in upstream stages of the pharmaceutical value chain, such as R&D and manufacturing process design.

4.2.2.2. Benchmarking circular commitments and maturity in pharma

As part of the empirical investigation, a benchmarking analysis was conducted to assess the CE commitments and maturity across leading pharmaceutical companies. This component aimed to complement the internal data and site-level insights with an external, industry-wide perspective.

The analysis focused on the top 20 pharmaceutical companies, selected based on global market rankings. For each company, publicly available documentation was collected and reviewed, including Universal Registration Documents (URD), annual Corporate Sustainability Reports (CSR), Environmental, Social, and Governance (ESG) disclosures, and other relevant CE-related content available through company websites.

The purpose of this analysis was to identify:

- The strategic positioning of CE within each company's sustainability agenda
- Types of CE language and principles referenced (e.g., reuse, eco-design, zero waste, cradle-to-cradle)
- The scope and depth of commitments (e.g., targets, indicators, value chain coverage)
- The potential maturity level of CE implementation based on disclosed actions and indicators

It is important to note that this benchmarking exercise relied exclusively on self-reported and publicly disclosed information, which may vary in completeness, accuracy, and timeliness across companies. The analysis was conducted using documents primarily published in 2022-2023 and thus reflects the state of circular economy disclosure at that time.

4.2.2.3. Survey and semi-structured interviews

The third component involved collecting primary data through a targeted survey and a series of semi-structured interviews with key sites from the different business units of Sanofi. Figure 57 represents the process from site selection to the data analysis.

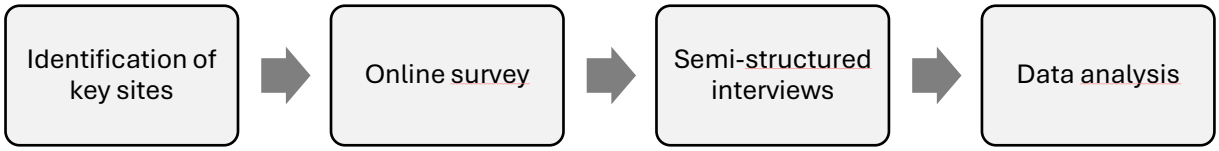

Figure 57. Process followed for the survey and semi-structured interviews at Sanofi

Identification and selection of relevant sites

Given the large number of operational sites within the organization, a selection process was conducted to identify the most relevant sites for inclusion in the empirical investigation. The objective was to ensure representative coverage across all Global Business Units (GBUs), while capturing variation in CE implementation practices. At the time of the study, Sanofi comprised four primary GBUs: Specialty Care, General Medicines, Vaccines, and Consumer Healthcare (CHC). Each unit is responsible for different product types and therefore likely faces distinct challenges and opportunities in implementing CE principles, particularly regarding waste management.

To inform the selection, the company's internal waste management reporting tool was used to extract relevant data for the year 2022. The data included: (1) the total quantity of waste generated per site, (2) the proportion of waste treated through various pathways (e.g., incineration, recovery, recycling)

A comparative analysis was conducted within each GBU to evaluate the sites according to both the volume of waste produced and the extent of circular actions already in place. Based on this dual-criterion analysis, the 10 most relevant sites per GBU were identified, resulting in a total of 30 sites selected for participation in the next stages of the research (survey and interviews). Sites from the CHC business unit were ultimately excluded, as this GBU was scheduled for divestment in 2024. It is important to note that the corporate waste management reporting

tool primarily provided a high-level overview of waste flows and treatment methods. Even though it enabled site comparisons and trends identification, it did not offer detailed insights into specific practices, technologies, or decision-making processes. Therefore, in order to gain a more comprehensive understanding of how circular economy principles were actually implemented at the operational level, it was necessary to supplement this analysis with surveys and semi-structured interviews.

This selection strategy ensured that the sample included sites with varying maturity levels in CE implementation, thus enabling a richer and more diverse data collection.

Online survey

The survey was developed using Microsoft Forms and distributed via email to selected site contacts. Its purpose was to collect structured data on waste types, current management practices, and existing CE initiatives, such as waste reduction, reuse, and recycling. The survey aligned with Sanofi's broader environmental strategy, which emphasizes the adoption of circularity principles, specifically, the transformation of waste into resources.

This survey acted as a preliminary diagnostic tool, with three key objectives:

- To map the diversity of waste management practices across different sites.
- To identify ongoing or planned CE initiatives.
- To gather operational feedback and perspectives on implementation challenges and opportunities.

The questionnaire targeted site-level stakeholders involved in waste and environmental management, including environmental and waste managers. Respondents were informed that participation was voluntary, the survey would take approximately 10 minutes to complete, and all responses would remain confidential, accessible only to the Eco-Design and Circular Economy team conducting the research. Both closed and open-ended questions were included to allow for standardization as well as site-specific elaboration. The survey included four main sections included in Table 7 below.

Table 7. Structure and key questions of the survey

Section	Questions
1. General information	• What Sanofi site do you work at? • What is your role within Sanofi? • What department do you work in?
2. Main categories of waste	• What are your 3 main categories of waste? • For each category, please estimate the annual quantity (kg/year).

3. Circular practices for each waste category	*Repeated for each of the three waste categories*
	For each category, do you have a plan to:
	• Reduce: Yes/No
	  ○ If yes, please describe the plan.
	  ○ If no, please explain why.
	• Reuse: Yes/No
	  ○ If yes, please describe the plan.
	  ○ If no, please explain why.
	• Recycle: Yes/No
	  ○ If yes, please describe the plan.
	  ○ If no, please explain why.

4. Additional information	• Are there any other ongoing or planned CE-related projects on your site (Reduce, Reuse, Recycle)? • What is the estimated budget allocation for these initiatives (CAPEX/OPEX)? • Who are the key site contacts for CE and waste management? • Do you have any additional comments or suggestions?

This design allowed for both quantitative comparisons across sites and the collection of qualitative insights specific to operational contexts. The responses were compiled and structured into a review table, which facilitated a preliminary analysis of trends, gaps, and areas of interest. This analysis served as a foundation for the subsequent interview phase, allowing for a more targeted and efficient interview process focused on clarifying, deepening, and contextualizing key survey findings.

Semi-structured interviews

Following the collection and preliminary analysis of survey data, semi-structured interviews were conducted with selected site representatives. These interviews served two key purposes:

- **Strategic alignment**: to align corporate-level and site-level stakeholders by presenting aggregated waste management results and introducing the shift from a waste management focus to a CE.
- **Survey follow-up:** to review and deepen the understanding of the survey responses, clarifying specific points and addressing any gaps or inconsistencies.

Each interview lasted a minimum of 30 minutes, with the option to extend the duration if necessary to allow for deeper discussion. The interviews were conducted online and involved site environmental and waste managers or relevant stakeholders involved in CE and waste-related activities. The structure and content of the interviews are summarized in Table 8 below:

Table 8. Structure of the semi-structured interviews

Section	Content	Duration
1. Introduction	Establish contact, introduce the role of the CE team, and provide context for the interview. As this year marked the introduction of CE efforts, building connection and shared understanding was essential.	5 minutes
2. From waste management to CE	Present Sanofi's evolving strategy to transition from traditional waste management to a more circular approach. This included a discussion of global aggregated waste data (2019–2030 glidepath), and an invitation for open dialogue around feasibility, barriers, and strategic ideas from the sites.	5 minutes
3. Survey review and deep dive	Review of previously collected survey data using a standardized summary table. This section allowed clarification of responses, collection of more detailed information, and discussion of site-specific interpretations of CE practices. Although key terms were defined in the survey, the interviews allowed further explanation and ensured consistency in understanding.	20 minutes

This qualitative phase enriched the findings from the survey and documentation review by capturing contextual factors, practical constraints, and site-specific innovation opportunities. The flexible structure of the interviews allowed for dynamic discussion while maintaining a consistent focus across all participating sites.

Data analysis

The data collected from the internal reporting tool, surveys, and semi-structured interviews were consolidated and analyzed using a mixed-methods approach. For each of the 30 selected sites, a structured summary document was developed, integrating both quantitative and qualitative insights. These documents provided a holistic view of each site's practices and maturity level in relation to circular economy implementation.

Each site summary included the following sections:

- General site information
- Top three waste streams, including volumes
- CE practices currently in place or planned for each waste stream, categorized by CE principles (e.g., reduce, reuse, recycle)
- Other CE-related projects
- Next steps, identifying priority areas for further action, potential support needs, or follow-up actions

In addition to site-level documentation, an aggregated analysis was conducted by GBU. This step enabled the identification of common trends, specific challenges, and varying degrees of circularity across the four GBUs. The comparative analysis supported the synthesis of insights and provided the foundation for the development of a company-wide CE strategy.

4.2.3. Conceptualization of supports

The insights derived from the literature review and the empirical data analysis (DS-I) were consolidated to inform the development of a corporate-level CE strategy. This step corresponds to the Prescriptive Study (PS) stage of the DRM, where the goal is to define a desired future state and to conceptualize potential solutions based on prior findings.

The outcomes of the DS-I stage led to the development of a draft CE integration framework, composed of several core elements: (1) key elements for circularity at Sanofi, (2) relevant indicators, and (3) supporting tools, including those for performance monitoring and decision-making.

This conceptual framework was refined through iterative feedback loops, including discussions with internal experts. These exchanges ensured alignment with both corporate sustainability priorities and site-level operational constraints. To facilitate validation and adoption, the proposed strategy and indicators were presented during regional waste committee meetings, where site-level waste and environmental managers convene quarterly. These sessions enabled direct feedback, clarification of expectations, and initial steps toward dissemination.

Although the strategy was developed at the corporate level, its role was not to enforce specific actions at the site level, but rather to:

- Provide a clear strategic direction for CE implementation,
- Identify priority areas for transformation,
- Foster a shared understanding of the shift from traditional waste management to a circular economy approach.

4.3. RESULTS

This section presents the key outcomes of the research conducted. It begins by summarizing the main findings from the literature review, with a focus on the current state of CE integration within the pharmaceutical industry. It then outlines the insights derived from the empirical investigation carried out at Sanofi, including the review of internal documentation, survey responses, and semi-structured interviews.

Finally, these findings are consolidated and synthesized to support the development of a CE strategy, incorporating strategic pillars, indicators, tools, and a roadmap aimed at guiding pharmaceutical industry's transition to circular economy.

4.3.1. Insights from the Pharma-CE literature review

The comprehensive analysis of CE in pharmaceuticals is presented in the State-of-the-Art (Section 3.6). This subsection synthesizes only the insights most relevant for informing the design of a CE strategy.

The literature consistently highlights that while CE principles hold promise for reducing environmental impacts and supporting SDGs (3, 7, 12, and 13), their application in pharmaceuticals remains fragmented and uneven (K.L. Ang et al., 2021; D'Alessandro et al., 2024; Krishnendu Saha et al., 2025). A clear polarization exists across the life cycle: pharmaceutical-focused studies concentrate upstream on raw materials and manufacturing, notably through green chemistry and solvent recovery (K.L. Ang et al., 2021; EFPIA, 2020; Massot et al., 2023; Zuin, 2016), whereas healthcare research emphasizes downstream distribution, use, and end-of-life management, such

as device reuse or hospital waste treatment (Govindan et al., 2022; MacNeill et al., 2020; E.A. Voudrias, 2018; Wuyts et al., 2020).

Building on the mapping presented in the State-of-the-Art, Figure 58 highlights the resulting upstream bias of pharmaceutical CE research compared with the downstream orientation of healthcare CE literature.

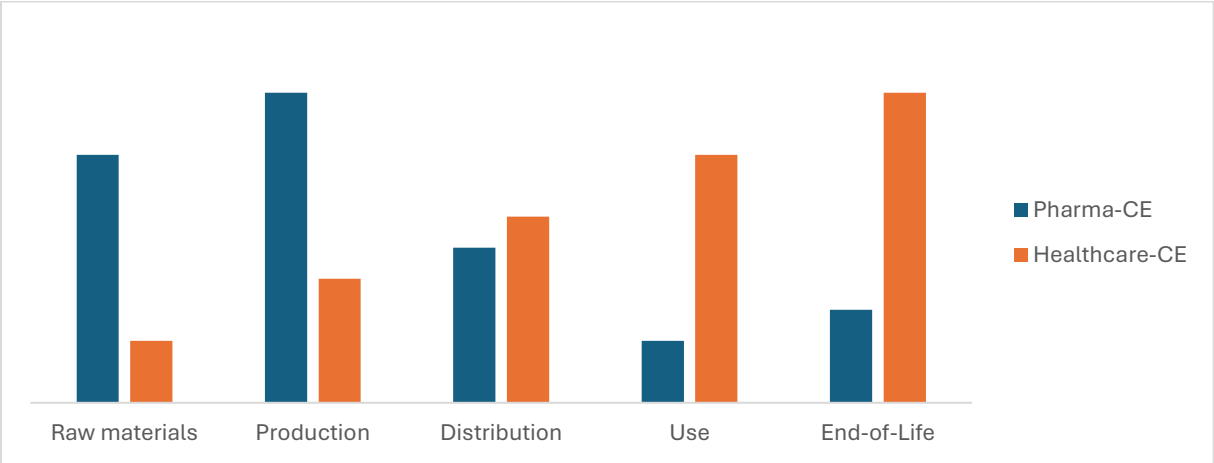

Figure 58. Qualitative distribution of CE literature across life-cycle stages in healthcare vs pharmaceuticals

Beyond this polarization, the field is dominated by technical innovations, greener synthesis routes, material substitution, recovery processes, with limited integration of systemic enablers such as governance, procurement, or regulatory adaptation (K.L. Ang et al., 2021; D'Alessandro et al., 2024; Ranjbari et al., 2022). Saha et al. (2025) describe this as a "post-waste" orientation, where interventions primarily address end-of-pipe challenges rather than preventive or systemic levers (Krishnendu Saha et al., 2025).

The concentration of pharmaceutical CE research in the production stage is largely explained by this end-of-pipe orientation. In this sector, "post-waste" strategies typically address post-industrial waste generated during manufacturing (e.g., solvent recovery, wastewater treatment), rather than post-consumer waste such as expired medicines or take-back schemes. By contrast, healthcare CE research emphasizes downstream stages, focusing on post-consumer waste from distribution, use, and end-of-life (e.g., hospital waste streams, single-use devices). This divergence helps explain the polarized life-cycle focus observed between the two domains.

Promising strategies have nonetheless been identified, including bio-waste valorization, sustainable packaging, and device reprocessing. Yet most remain isolated pilot efforts, constrained by regulatory hurdles, economic barriers, and operational inertia (MacNeill et al., 2020). Recent reviews converge on the need for four underdeveloped but essential pillars: sustainable product design, waste management, policy and economic frameworks, and stakeholder engagement (Krishnendu Saha et al., 2025).

In summary, the literature suggests that advancing CE in pharmaceuticals requires moving beyond lab-scale innovations toward systemic transformation. Opportunities lie in aligning CE with regulatory frameworks (e.g., GMP, EMA, FDA), developing new business models (e.g., take-back schemes, circular procurement), leveraging digital enablers (e.g., IoT, CE metrics), and fostering stakeholder engagement and co-creation across the value chain. These insights form the foundation for the strategy proposed in the following sections.

4.3.2. Empirical study

4.3.2.1. Internal documentation review

Sanofi's environmental sustainability approach has progressively matured over the past decade, with eco-design emerging as one of its most advanced and structured pillars. Framed within the broader Planet Care strategy, Sanofi has embedded environmental objectives across its operations, with major targets such as achieving carbon neutrality by 2030 and net zero by 2045. Despite themes such as climate mitigation, water conservation, and

ecotoxicology are extensively addressed in public reporting, the concept of CE was not explicitly framed or labeled as such in the earlier stages of the company's sustainability discourse.

Eco-design: a structured trajectory

Sanofi's eco-design journey began with the integration of Life Cycle Assessment (LCA) into product development as early as 2016, with early applications on key products such as Cerezyme and Dupixent. By 2021, a more formal methodology was established, and in 2023, the company scaled its efforts significantly, launching the Eco-Design Digital Intelligence (EDDi) LCA tool, aligning practices with ISO 14040/44, and initiating large-scale upskilling across R&D, manufacturing, and supply chain functions.

By 2024, Sanofi had completed 27 LCAs, including for seven of its top-selling products, leading to quantifiable improvements such as an 80% reduction in climate impact for Cerezyme and a 60% reduction in water use for Dupixent (Sanofi, 2025d).

A major milestone was reached with the 2025 commitment that all new medicines and vaccines would follow an eco-design approach, with the goal of expanding this methodology to top-selling products by 2030. This trajectory reflects not only technical capability but also growing organizational maturity, with eco-design now embedded in processes such as R&D stage-gate reviews.

Eco-design and Circular Economy: converging strategies

Due to its maturity, eco-design served as both an operational and conceptual foundation for the company's emerging approach to circular economy. Although the term "circular economy" did not appear prominently in Sanofi's strategy before 2024, many eco-design initiatives already contributed to circular outcomes. Actions such as solvent recovery, waste minimization, PVC-free packaging, or packaging downsizing supported resource efficiency and material circularity, even if not yet framed within a CE vocabulary.

As highlighted in the state-of-the-art review (Chapter 2, Section 2.3.4), the boundaries between eco-design and CE are often fluid. In Sanofi's case, circularity was not distinct from eco-design; rather, the two were deeply intertwined. The company's investment in eco-design tools, indicators, and training has laid the groundwork for CE thinking, even before it became a central strategic element and narrative.

4.3.2.2. Benchmarking pharmaceutical companies

The results of the benchmarking were categorized in two parts, the first one focuses on qualitative insights, and the second one on CE targets and ambitions.

Qualitative insights

The qualitative review of public disclosures by major pharmaceutical companies revealed a strong and growing engagement with CE, even when these were not always explicitly labeled as such. Across the sector, companies are implementing a wide array of initiatives aimed at reducing resource use, minimizing waste, and promoting reuse and recycling. These actions often go beyond compliance, reflecting a proactive approach to environmental stewardship and long-term value creation.

Several companies have advanced significantly in embedding CE principles into product and packaging development, particularly through eco-design strategies. Novo Nordisk, for example, launched its "Circular for Zero" framework, articulating four core design principles: designing for lifetime, sustainable material use, zero waste in production, and recyclability after use. Similarly, Biogen demonstrated strong integration of circular thinking through its "Healthy Climate, Healthy Lives" initiative, which includes a commitment to eliminate fossil-fuel-derived plastics by 2040 and the launch of reusable autoinjector prototypes. Biogen also applies CE practices across over 14 laboratories, embedding waste prevention both upstream and downstream in the value chain. AstraZeneca stands out for applying circularity across the full product lifecycle, from R&D to distribution, supported by initiatives such as the elimination of 200 tons of single-use plastic annually and the creation of a product sustainability index to drive prioritization.

Packaging is one of the most common entry points for CE practices. Companies like Johnson & Johnson, GSK, and Lilly have implemented packaging reuse, reduction, and recycling initiatives at scale. In the same spirit, Takeda introduced bio-based polyethylene (bio-PE) for packaging, receiving international awards for sustainable design.

Beyond packaging, many companies were moving upstream to address waste at the source. Gilead implemented Process Mass Intensity (PMI) reduction projects, reducing solvent waste by 88% per kg of active pharmaceutical ingredient. Additional initiatives included green waste reuse and advanced water recycling systems, reducing cooling tower water use by 44%. Pfizer applied green chemistry principles and deployed solvent recovery practices throughout its operations, benchmarking site-level CE performance to encourage continuous improvement. Bayer integrated CE across its value chain using the principles of Minimize, Recirculate, Regenerate, and Partner, recovering materials like solvents and catalysts for reuse. Merck has developed digital tools to operationalize CE, including a CE dashboard and the Progressive Materials Economy (ProMec) program to refine solvent recycling. Novartis has launched over 65 CE-related projects, spanning packaging recovery, green logistics, and collaborative eco-design pilots.

Governance and employee engagement are also key levers. Abbvie has developed a formal Sustainable Packaging Program based on CE principles, coupled with employee training on waste management. Takeda framed CE through three priorities: empowering employees, decarbonizing the value chain, and minimizing product impact through circularity.

Finally, cross-sector collaboration was proving essential in accelerating CE in pharma. Companies like Johnson & Johnson and GSK are active members of global initiatives such as the New Plastics Economy (UNEP/EMF) and CEFLEX. Others, including Novartis and Bayer, partnered with academic and industry networks to test eco-design solutions, recovery systems, and CE-aligned supply chain practices.

Synthesis of the qualitative insights collected

To consolidate the qualitative findings gathered from the public disclosures of pharmaceutical companies prior to and during 2023, a comparative mapping was developed to assess their maturity in CE implementation. The objective of this mapping was not to provide a fully exhaustive or rigorous evaluation but rather to offer a high-level, indicative overview of how CE is evolving across the sector and to position each company within a simplified maturity framework.

A five-level CE maturity scale was proposed, reflecting a progressive integration of circularity into corporate practices and strategy. The levels were defined as follows:

- **Level 1 – Initial**: no clear targets, limited or no evidence of circularity-related actions or commitments.
- **Level 2 – Emerging**: ad hoc initiatives in place; CE is mentioned in corporate strategies with limited alignment. Some goals are set, but concrete implementation is limited.
- **Level 3 – Developing**: multiple actions deployed across different functions; membership in CE alliances or external platforms. CE is often driven by development or operational teams.
- **Level 4 – Advanced**: a wide range of actions and targets implemented throughout the product and value lifecycle. Companies develop internal CE tools and publish externally to advance sector-wide learning.
- **Level 5 – Transformational**: CE is integrated across all business functions and value chains. All core principles of circularity are addressed, with novel business models developed to support a systemic shift.

The maturity positioning was assessed qualitatively, based on four key dimensions: the transparency of disclosure, the strategic coherence, the operational integration of CE actions, and the specificity and scale of implementation (Figure 59).

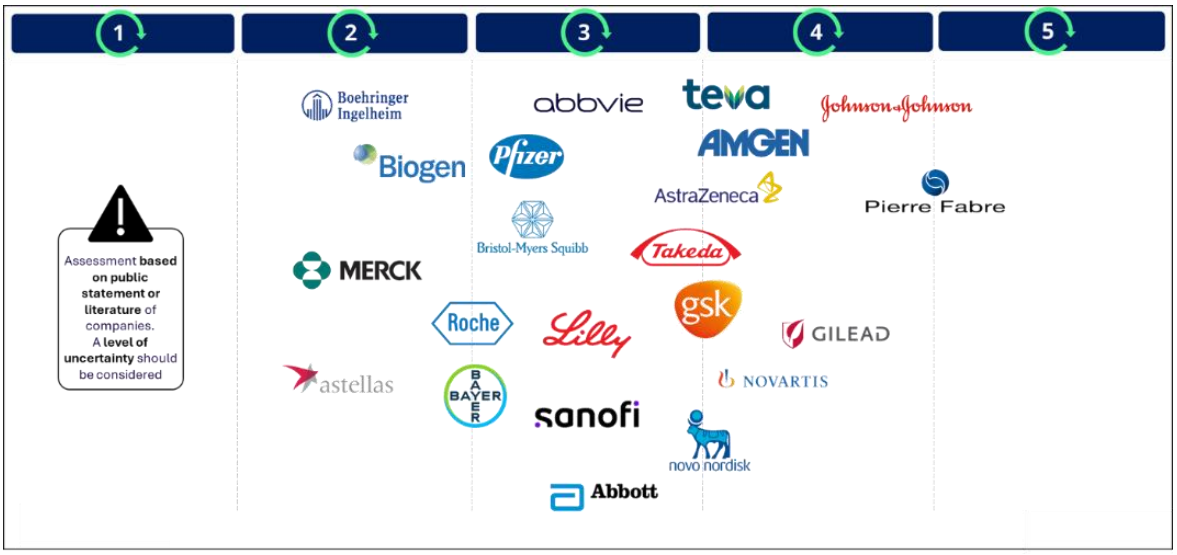

Figure 59. Maturity mapping of key pharmaceutical companies

This categorization did not aim to offer a definitive ranking and might not capture all nuances across different company structures or reporting standards, it served as a useful lens to understand general trends in the sector.

Circular commitments analysis

To complement the qualitative insights, an extended analysis was performed to assess the publicly disclosed CE targets set by the same group of pharmaceutical companies. Across the sector, most companies had defined environmental objectives that implicitly support circularity, even if not explicitly labeled as "circular economy" goals. The most prevalent targets were related to reducing waste, increasing recycling rates, and achieving zero waste to landfill. However, the scope, specificity, and ambition of these targets varied considerably.

Waste generation targets were generally the least developed, with many companies presenting relatively modest or vague ambitions, often in the range of 10–20% reductions from historical baselines, and with limited indication of intermediate milestones or implementation pathways.
In contrast, recycling and reuse targets, particularly for packaging, were more mature. Several firms have committed to 100% recyclable or compostable packaging by 2025, including Biogen, Johnson & Johnson, and Pierre Fabre. Lilly reported that by 2021, 98% of its plastic waste was already reused or recycled, showing advanced performance in this area. Others, such as Gilead, have adopted targets to eliminate single-use plastics and integrate post-consumer recycled content in packaging streams.
Landfill avoidance goals also appeared more commonly and with a higher degree of ambition. Companies such as Lilly and Gilead aimed for zero waste to landfill by 2025 or 2030, while Novo Nordisk had already achieved over 95% waste recovery, reflecting strong internalization of waste diversion practices.
Notably, many circular actions such as solvent reuse, green chemistry, modular packaging, or take-back programs were implemented but not explicitly linked to a CE narrative. This reinforced the broader observation that CE-related goals are often fragmented or embedded within broader sustainability strategies.

Overall, the data showed that while the pharmaceutical industry is increasingly adopting circularity-linked targets, the level of integration remained uneven. Packaging continued to serve as the main entry point, while deeper CE strategies, such as circular product development, secondary materials integration, and closed-loop recovery, were still in early stages for most companies.

Synthesis of CE goals across pharmaceutical companies

The analysis of CE-related targets was conducted using the same maturity framework previously introduced. Each company was assessed based on the nature and depth of its commitments in three key areas: recycling, waste generation, and landfill avoidance. A weighted scoring system was applied to reflect the relative importance of these areas, with recycling, for example, given more weight than landfill targets, due to its stronger alignment with high-value circular principles.

This evaluation allowed for the aggregation of individual scores into a composite CE maturity index for each company, focused on circular economy goals. The results offered a comparative view of ambition levels across the sector (Figure 60).

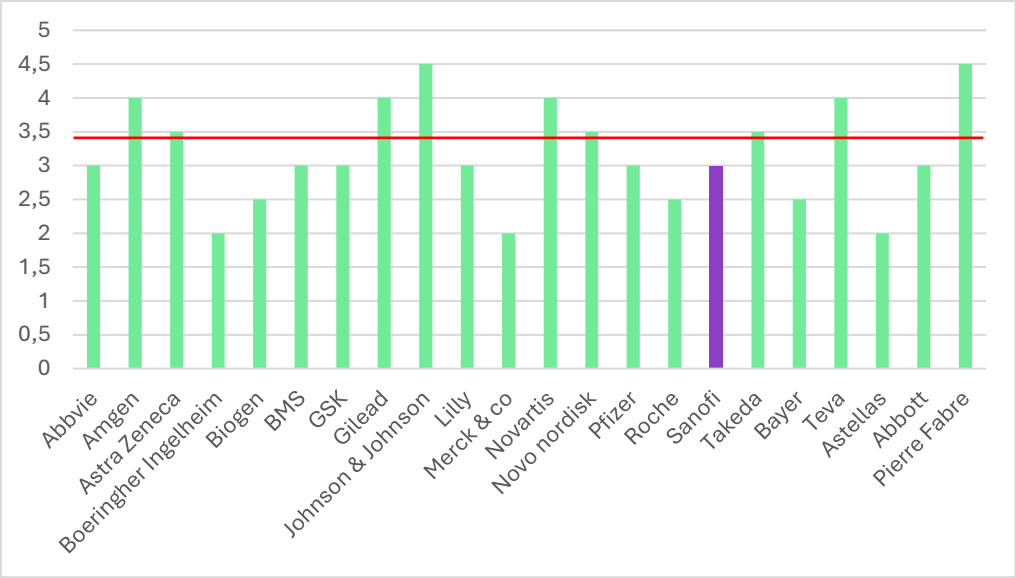

Figure 60. Maturity of key pharmaceutical companies based on their CE goals

In summary, while this benchmarking confirmed a growing interest in CE practices, it also underscored a persistent gap between strategic ambition and operational implementation. Some frontrunners demonstrated a high level of integration and alignment between their circular goals and practices. However, for the majority, CE commitments remained emergent, fragmented, or limited to entry-point domains like packaging reuse or landfill diversion. The final mapping revealed that most pharmaceutical companies fall below the average maturity level in terms of CE goal setting.

Overall synthesis of the benchmarking

The benchmarking reveals a growing awareness and engagement with CE across the pharmaceutical sector. Although a few frontrunners demonstrated advanced integration of CE throughout their operations, most companies were still in early or intermediate stages of maturity.

Common CE-related practices included:

- Packaging improvements and redesign, with a strong focus on recyclability, use of bio-based or post-consumer recycled materials, and reduction of plastic.
- Solvent recovery and reuse, often supported by green chemistry principles and process optimization.
- Take-back programs and waste segregation initiatives, particularly for medical or hazardous materials.
- Waste recycling and water reuse systems, especially in manufacturing and cooling operations.
- Internal tools and guidelines beginning to emerge, though often applied selectively.

Despite these initiatives reflecting increasing operational engagement, strategic coherence and goal setting remained inconsistent. Most companies have defined CE targets, particularly around waste reduction, recycling, and landfill diversion, but these are often limited in scope and ambition. Few firms extend circularity beyond packaging into areas like product design, supply chain, or business models.

4.3.2.3. Survey and semi-structured interviews

The primary data collected through surveys and semi-structured interviews revealed diverse levels of engagement with CE principles across sites and business units. While all GBUs have implemented actions aligned with CE principles, the nature and maturity of these initiatives vary depending on local and operational context, product types, and site-specific challenges.

Across all units, there is evidence of initiatives spanning waste reduction, reuse, recycling, and valorization. However, the implementation depth and innovation varied, with some units focusing more heavily on solvent reuse and others emphasizing organic waste treatment t. Notably, each GBU faces unique barriers and opportunities, reinforcing the need for tailored approaches to CE strategy deployment.

Table 61 synthesizes the key insights from the data collection, summarizing the main waste categories, practices in place, barriers encountered, and future opportunities across the three major GBUs. Additionally, key insights were derived from the analysis:

- **Common CE practices**: all GBUs showed activity in plastic recycling and reuse/recycling of tertiary packaging materials (e.g., trays, pallets, cardboard).
- **Solvent management**: General Medicine, due to the nature of its manufacturing processes, was heavily reliant on solvents and has therefore advanced initiatives in redistillation and reuse, both internally and through external partnerships.
- **Waste valorization innovation**: Vaccines demonstrated advanced methanization and organic waste repurposing strategies, especially for egg waste, reflecting circularity integration in biological manufacturing contexts.
- **Operational and infrastructure constraints**: across all units, equipment constraints, waste contamination, limited space storage, and quality and regulatory hurdles emerged as consistent barriers.
- **Common opportunities**: the potential for cross-site collaboration, data-driven waste tracking, and the standardization of circular economy practices, such as reuse, surfaced as key enablers across units. Leveraging shared learnings could significantly accelerate CE maturity.

The consolidation of these insights revealed several overarching patterns in Sanofi's current circularity practices. One notable finding was that across nearly all sites, the top three waste streams accounted for over 75% of total waste generated. However, these waste types varied significantly depending on production processes, highlighting the need for localized interventions. Also, waste volumes being closely tied to production scale, as production increases, so does waste generation, making absolute waste reductions challenging.

In terms of CE implementation, the analysis highlighted a clear hierarchy within the commonly used 3R framework: Reduce, Reuse, Recycle. Recycling emerged as the most frequently implemented principle, accounting for over half of all identified practices across waste streams. Reduction initiatives followed, representing around 40% of reported actions, often focusing on process optimization or packaging downsizing. Reuse remained the least adopted, with approximately 30% of implementation, largely due to regulatory, quality, or technical constraints such as cleaning requirements or contamination risks. On top of this hierarchy lay the fact that the majority of sites remained engaged in longer-loop strategies, such as incineration with energy recovery. The shorter loops were less common and still in early stages for some of them, reflecting both technological limitations and the highly regulated nature of pharmaceutical production

Category	Specialty Care	General Medicine	Vaccine
Main waste categories	• Plastic waste • Hazardous waste • Single Use Technologies (SUT) waste • Liquid waste • Packaging waste	• Solvent waste • Packaging (plastic/cardboard) • Animal by-products • Ordinary waste	• Hazardous waste • Egg waste • Plastic waste • Metal waste • Autoclaved waste • Paper/cardboard waste • SUT waste
Circular practices	• Process optimization for waste reduction • Recycling plastics and SUT materials • Limited reuse (trays, pallets, PPE)	• Solvent reuse and redistillation • Reuse of PS trays • Methanization of animal by-products • Energy recovery and recycling • Innovative material repurposing	• Methanization of egg waste • Anaerobic digestion planning • Reuse and recycling of trays, packaging, and glass • Composting of kitchen waste
Main barriers	• Quality constraints for reuse and recycling • Space constraints for segregation	• Aging infrastructure • High cost of redistillation • Operational mode constraints • Waste volume forecasting challenges due to product mix variability.	• Regulatory constraints (e.g. egg waste classification) • High treatment costs • Infrastructure and transport limitations • Complex waste streams
Opportunities	• Supplier collaborations • PPE reuse potential • Take-back schemes for key components/materials • Cross-site collaboration • Data-driven waste management	• Solvent compatibility studies • Cross-site scalability • Site-wide MFA and waste mapping	• Egg waste valorization • Glass recycling • SUT reuse projects • Mixed plastic segregation pilots • Awareness campaigns on food waste and water

Figure 61. Synthesis of key findings from internal data collection

4.3.3. Main barriers and gaps: insights from literature and empirical study

The results of the literature review, industry benchmarking, and empirical research at Sanofi converged to highlight a complex landscape of structural, operational, and contextual barriers limiting CE implementation in the pharmaceutical sector. This section synthesizes those findings, organizing the barriers by domain and signaling the most critical gaps for strategic intervention.

Strategic and conceptual gaps

Across both academic and sectoral sources, one of the most persistent gaps was the lack of a systemic view of CE in pharmaceuticals. Most existing efforts, whether in academic publications or corporate disclosures, focused on technical improvements in processes or product-level optimizations (e.g., greener solvents, packaging redesign). In contrast, organizational-level adoption, including integration into strategy, procurement, governance, and cross-functional coordination, remained underdeveloped.

Furthermore, CE in pharma was often not explicitly labeled as such. As observed in the benchmarking, many initiatives aligned with CE principles but were framed within broader sustainability or waste reduction goals, indicating a fragmentation of terminology, objectives, and ownership.

Regulatory and quality constraints

A defining feature of pharmaceutical CE challenges lay in the sector's risk-averse and quality-driven culture. High-purity requirements and Good Manufacturing Practices (GMP) severely restricted the use of secondary or recycled materials. Reuse was often blocked due to concerns over contamination, validation burdens, or regulatory uncertainty.

Design simplification and alternative materials, typically important levers in CE, were also difficult to apply because of strict regulatory frameworks (e.g., for patient leaflets, drug delivery safety, or packaging traceability). These were consistently cited both in literature (EFPIA, 2020; Macneill et al., 2020) and internal interviews as pharma-specific, high-difficulty barriers.

Operational and Infrastructure Barriers

From internal interviews and site-level assessments, several operational challenges were consistently cited:

- **Space limitations and infrastructure** restrict the ability to segregate, store, or treat waste efficiently on-site.
- **The batch or campaign nature of production** in many facilities leads to variability in waste types and quantities, complicating standardization or pooling for recovery.
- **Waste heterogeneity**, particularly for complex or hazardous streams (e.g., infectious waste), poses logistical and treatment challenges.
- **Geographical disparities** mean that sites located in regions with limited recycling or valorization infrastructure face reduced circular options.

These factors often led to reliance on longer-loop strategies like energy recovery, even when shorter loops (e.g., reuse, remanufacturing) would offer more opportunities.

Vendor and ecosystem constraints

Circularity in pharma often depends on external actors (e.g., suppliers, waste vendors), yet:

- Vendors may lack the capacity, motivation, or technology to enable circular options.
- Pharma's relatively small waste volume compared to other industries limits its bargaining power.
- The absence of industry-wide standards for reuse, recovery, or recycling in pharma hindered scale-up.

The limited influence with vendors, combined with the misunderstanding of pharmaceutical waste streams were significant end-of-life barriers identified.

Monitoring, metrics, and governance gaps

The lack of standardized CE metrics, indicators, and data systems was consistently identified as a barrier. Circularity remains difficult to measure, track, and benchmark, particularly in complex, global supply chains.

Internally, many initiatives remained project-based, lacking integration with site-wide or corporate-level targets. This impeded visibility, cross-site learning, and the ability to scale up successful practices.

Cultural and incentive-related gaps

The empirical study also revealed that reuse and other "short loop" strategies remained underexplored. This was not only due to technical barriers, but also cultural preferences for disposability and perceived risks associated with deviation from standard procedures.

Incentive structures are often misaligned. CE initiatives must compete with cost, time-to-market, and compliance priorities, and lack dedicated funding, business cases, or strategic incentives.

4.3.3.1. Synthesis of barriers and gaps

The Table 9 below aims to synthesize the main barriers and gaps limiting CE implementation in pharmaceutical industries.

Table 9. Barriers to CE implementation in pharmaceuticals and their relative difficulty to overcome

Barrier	Description	Pharma-specific	Difficulty
Regulatory & Quality	GMP, High-purity standards, risk of contamination, complex approval processes limit design flexibility and material reuse.	Yes	High
Operational infrastructure	Limited space, aging systems, variable waste profiles, heterogeneous waste streams, site-level variability constrains circular solutions.	Mixed	Medium-High
Waste vendor ecosystem	Low influence in waste markets, lack of circular vendors, inconsistent acceptance criteria	No	Medium
Metrics & data	Fragmented data systems, unclear CE indicators, and poor traceability across the value chain hinder performance monitoring and research translation.	No	Medium
Strategy & governance	CE strategies remain fragmented, often technical and project-based; research and practice lack integration, and system-level implementation models are rare, lack of accountability	Yes	Medium-High
Cultural & incentives	Preference for disposables, perception of higher safety, and absence of business case or internal mandates slow adoption of CE innovations.	Yes	Medium

The convergence of findings revealed a misalignment between ambition and readiness. CE in the pharmaceutical sector is gaining attention, but remains unevenly applied, limited by technical, cultural, and regulatory constraints that require targeted, context-sensitive strategies to overcome.

4.3.4. Synthesis: a CE strategy for the pharmaceutical industry

The results linked to the data collected and analyzed throughout this study allowed the development of different sort of supports representing key elements of a CE strategy in the pharmaceutical sector. These elements are presented in the following sub-sections. First, the CE Integration Model (CEIM) is presented allowing to set the foundations for a good CE strategy, then the Key Performance Indicators (KPI) developed are introduced, along with the roadmap, and finally, CE qualitative and quantitative tools are presented.

4.3.4.1. A CE Integration Model for the pharmaceutical industry

The transition toward a CE in the pharmaceutical sector was marked by significant fragmentation, constrained primarily by several barriers. As identified across the state-of-the-art review, benchmarking study, and primary data collection, CE initiatives often lacked systemic coordination and remained siloed across functions and scales.

To address this fragmentation, we proposed an evidence-based CE Integration Model (CEIM) that offers a systemic lens for embedding circularity within pharmaceutical companies. This model synthesizes insights from the literature, aligning with Design for Sustainability (DfS) approaches and Circular Economy principles, and responds to the multilevel barriers and implementation gaps identified throughout this research.

The model is structured around three interconnected dimensions (Figure 62):



Figure 62. The three dimensions of the CEIM

Each level corresponds to distinct circular action domains, but all must be aligned for CE implementation to become scalable, coherent, and sustainable. The model thus supports both diagnostic analysis (locating barriers) and strategic planning (identifying levers for action).

Model structure and logic

The integration model is visualized as three concentric layers (Figure 63), moving from mainly technical interventions at the product/process level to broader organizational systems and finally to external governance and socio-technical dynamics. Each layer plays a specific role in CE implementation, and misalignment across them constitutes a barrier to transition.

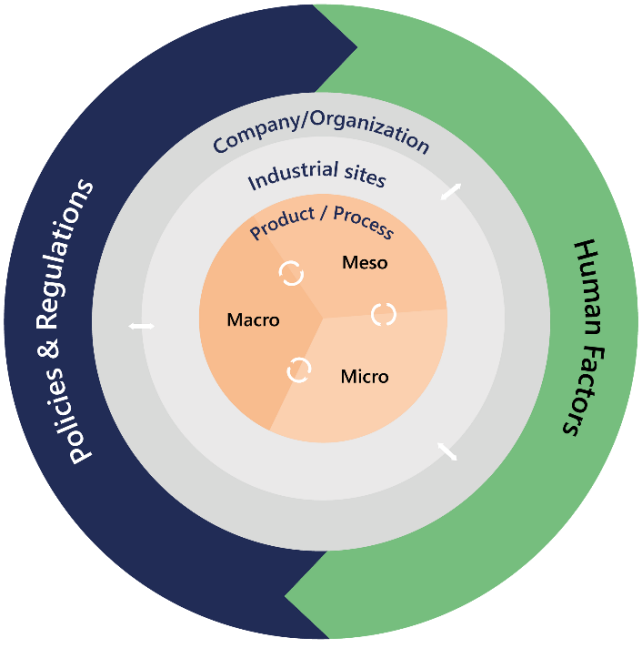

Figure 63. CE Integration Model for the Pharmaceutical Industry

Product & Process dimension
This innermost layer focuses on the integration of CE principles at the product design and manufacturing process level. It corresponds to the operational reality of key functions involved in pharmaceuticals development (e.g., R&D, Manufacturing, Packaging).

At this level, CE efforts are typically driven by eco-design, LCA tools, and material/product/ process optimization. However, both the literature and internal benchmarking revealed that CE actions here are limited to short-loop strategies (e.g., refuse, reduce), with minimal engagement in reuse or remanufacturing. The barriers at this level include elements such as, quality and safety standards, technological constraints, lack of harmonization in terms of DfS integration into PDP and business units.

Despite these challenges, this level remains central to any CE transition, as it is where value creation and product decisions originate. Efforts such as Sanofi's eco-design commitment illustrate its potential as a strategic leverage point when embedded systematically.

Spatio-social & Geographical dimension
Surrounding the core is the organizational and spatial level, encompassing pharmaceutical production sites, logistics networks, internal coordination mechanisms, and corporate strategy. This is the level at which CE strategies face infrastructure, resource, and management constraints, with barriers such as the fragmentation across sites and inconsistent CE maturity, or the lack of integrated site-level CE indicators or tools.

Empirical data revealed that CE implementation was highly site-dependent, with variation in practices driven by local constraints and production modes. Geographical disparities further complicate scaling, especially in regions sites where treatment infrastructure or vendor partnerships are lacking. This layer requires cross-site collaboration, infrastructure investment, and CE-oriented management systems to overcome diffusion bottlenecks.

Socio-Technical dimension
The outermost layer accounts for the external ecosystem in which pharmaceutical companies operate, including regulators, policymakers, suppliers, patients, and broader socio-cultural factors.

Barriers here are direct and indirect but foundational, shaping the enabling environment for CE. Key challenges include the regulatory misalignment, the lack of incentives, the fragmented policy implementation, and the insufficient stakeholder collaboration and knowledge-sharing platforms

Survey data confirmed that CE lacks strategic incentives or executive buy-in across many business units. Meanwhile, despite increasing recognition of CE by entities like the European Commission and EFPIA, translation into operational guidance or incentives remained limited.

This level also includes employee engagement, training, and cultural alignment, essential for sustaining CE initiatives. Without these, technical tools and strategies cannot gain traction.

Strategic use of the model
This CE integration model is both diagnostic and prescriptive. It can be used by practitioners to:

- Identify all relevant elements (dimensions and levels) to be faced when implementing CE and associated practices in the pharmaceutical sector.
- Map current initiatives to specific levels and identify misalignments (e.g., take-back program without procurement strategy)
- Prioritize interventions: e.g., investing in site infrastructure (meso level) vs. building policy alliances (macro level)
- Visualize and compare CE projects across GBUs
- Facilitate stakeholder discussions, using the model to identify where each actor (designer, policy officer, plant manager) can act

Ultimately, the model serves as a strategic framework for pharmaceutical companies to navigate complexity and phase CE into mainstream operations. It acknowledges that CE is not a purely technical challenge, it is an organizational transformation, requiring integration across levels and the active resolution of multiscale barriers.

4.3.4.2. Goals and indicators for a pharmaceutical circular economy

The literature review and empirical study together highlighted a key structural need: the definition of clear Key Performance Indicators (KPIs) to track progress in transitioning from waste management to a company-wide circular economy. Current operational maturity is largely site-based and focuses on waste disposal, with limited alignment across the organization. This reinforces the need to shift from landfill and incineration toward reuse and recycling, while keeping waste reduction as a primary goal.

Building on the CEIM and the related challenges identified, it was evident that eco-design objectives were already well covered. Given the complementarity between eco-design and circular economy, the focus here was placed on defining corporate-level CE goals, while specific product- and process-level objectives remained under the eco-design umbrella, addressing the inner dimension of the proposed CE Integration Model. Combining both dimensions is essential to achieve effective and comprehensive CE integration.

Strategic goals for circularity

To effectively operationalize the CEIM, clear and aligned goals must be established. Insights from the literature and empirical investigation consistently highlighted that transitioning from traditional waste management to circularity requires a redefinition of objectives, from fragmented, site-level compliance to structured, company-wide CE ambition.

Rethinking the focus: Post-Industrial vs. Post-Consumer Waste

It is important to understand the difference between post-industrial and post-consumer waste (Figure 64). Although post-consumer waste, such as packaging and devices, being highly visible, and often, the focus of CE communication and public-facing goals, it represents only a small portion of the total environmental burden in pharmaceuticals. By contrast, post-industrial waste, generated during manufacturing and R&D activities, accounts for the vast majority of waste volumes and associated impacts.



Figure 64. Illustrative view of post-industrial vs post-consumer waste quantities

However, because it is less visible to patients, regulators, and the public, post-industrial waste received proportionally less strategic attention, even though it offers the greatest opportunity for circular transformation. This misalignment underscores the need to rebalance CE goals, shifting attention upstream, toward operations, rather than overly focusing on end-of-life, consumer-facing waste streams.

Post-industrial waste

Post-industrial waste comprises a wide range of streams including solvents, packaging materials, aqueous effluents, single-use components, and others. Three key CE goals have been identified to improve circular performance in this area:

- By 2025, reduce landfill rate of total waste to below 1%.
- By 2025, ensure at least 90% of waste is Reused, Recycled, or Recovered as part of a 3R approach.
- By 2030, achieve a 30% reduction in the Waste Impact Index (vs. 2019 baseline), driving progress up the waste hierarchy.

These goals reflect both ambition and realism: they account for the technical, regulatory, and quality constraints associated with certain waste streams (e.g., contaminated aqueous waste, hazardous materials), while encouraging progressive improvement across the value chain.

Post-consumer waste

Although post-consumer waste not representing the majority of the pharmaceutical sector's environmental impact, it remains a strategic entry point for CE initiatives. Its high visibility, both to regulators and the general public, lends it symbolic importance, and targeted actions in this area can yield both environmental and reputational benefits.

The most common post-consumer waste streams include packaging and injectable devices, which are often difficult to recycle due to their complex materials and safety requirements. Despite this, some specific goals can be developed, such as: By 2027, 100% of vaccine syringe packaging will be blister-free, improving downstream recyclability and reducing unnecessary material use.

These types of actions, while not addressing the most material sources of impact, help build organizational momentum toward circularity and prepare the ground for future product take-back or extended producer responsibility (EPR) schemes.

Key Performance Indicators (KPIs)

To operationalize and track progress against these goals, robust KPIs were needed. These indicators must address both absolute waste performance and relative circularity maturity, allowing for meaningful comparison across sites and over time.

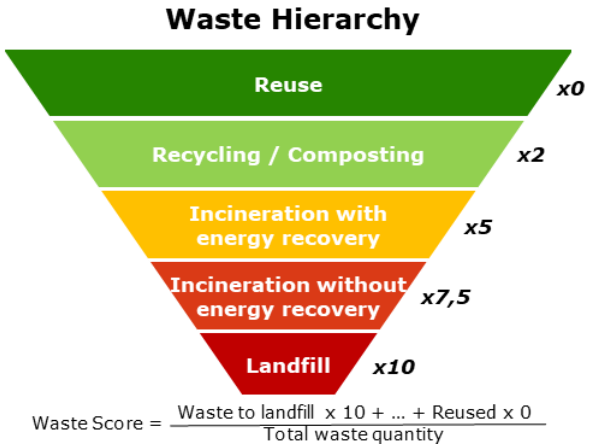

Figure 65. Illustrative view of the waste score following the waste hierarchy

Table 10. CE KPIs proposed

Indicators	Waste impact index	Waste Score
Objective	The objective of this KPI is to assess the overall progress in aligning waste management with circular economy principles at the site, GBU, and company level. This indicator captures the aggregate benefits of circular loops implemented.	To enable the comparison across sites or GBUs with different waste volumes and operational scope, a normalized version of the waste impact index is proposed. The waste score measures the relative circularity maturity of a site.
Methodology	Each type of waste treatment is assigned a weight based on its environmental desirability within the waste hierarchy. The sum gives the Waste Impact Index.	Same as the waste impact index, but the overall score is divided by the total quantity of waste generated, allowing for normalization.
Formula	Waste Impact Index = (Waste Reused × 0) + (Waste Recycled × 2) + (Waste Incinerated with energy recovery × 5) + (Waste Disposed without energy recovery × 7.5) + (Waste Landfilled × 10)	Waste Score = Waste Impact Index / Total Waste Generated

Explanation	A lower score implies better alignment with circularity principles.	A lower score implies better alignment with circularity principles (i.e., a score of 2 indicates that everything is recycled, whereas a score of 10 indicates that only landfill is being used). This relative score removes bias from activity level differences and offers a clear signal of circular performance efficiency.
Main benefits	• Creates a single, trackable metric for reporting across time • Incentivizes a shift away from landfill and low-value disposal methods • Embeds CO_2 and waste hierarchy logic in decision-making	• Enables fair benchmarking between sites of different sizes • Drives internal competition and best practice sharing • Supports localized improvement planning without penalizing high-output sites

Reuse: Waste avoidance (qualitative KPI)
Given the complexity of tracking reuse in pharmaceutical contexts, a structured eligibility framework was introduced to qualify valid reuse practices. These include:

- Same-function reuse (e.g., trays, pallets, containers)
- Managed and traceable loops
- Economic value retained through reuse
- Reuse that displaces otherwise disposable practices

By formalizing the scope of what counts as "reuse," the company avoids over-reporting and maintains credibility in its CE claims.

From KPIs to roadmap development
The establishment of structured KPIs, particularly the Waste Impact Index and Waste Score, not only enables measurement of circularity performance but also serves as a foundation for developing a company-wide CE roadmap. These indicators provide a clear and quantifiable view of current practices, their impact, and the direction required to meet strategic objectives.

Given the well-established correlation between waste management practices and greenhouse gas (GHG) emissions, this KPI framework can be integrated with broader environmental targets, including for example Science-Based Targets (SBTs) based on a 2019 baseline. Each waste treatment option, recycling, incineration, landfill, carries specific environmental impacts, allowing for the Waste Impact Index to be linked directly to carbon performance. This parallel between CE progress and carbon emissions makes it possible to define a glidepath: a clear transition plan from the current state to the 2030 ambition. By comparing today's Waste Impact Index against a 2030 target value, a quantitative performance gap can be identified and addressed through tailored CE actions across sites.

Importantly, the empirical findings from surveys and interviews across the industrial sites highlighted localized opportunities for action. These findings confirm that while the overall CE trajectory must emphasize reduce, reuse, and recycle, the exact contributions will vary by site depending on production profiles, infrastructure, and local constraints. Thus, the KPI system is not only a measurement tool, but it also aims to be a strategic enabler, supporting the prioritization of actions by environmental return, the combination with additional environmental sustainability ambitions, and the tracking of continuous performance.

To support this transition seven key levers for action have been identified across the value chain as an integral part of the roadmap:

- Promote sober and sustainable procurement: reducing input volumes and prioritizing low-impact materials.

- Eco-design products and processes: embedding sustainable design and circularity at the development stage.
- Encourage industrial symbiosis: leveraging external partnerships to valorize co-products and waste.
- Develop health-as-a-service models: shifting from volume to value creation, aligned with functional economy principles.
- Promote responsible consumption: enabling end-users to minimize waste and environmental impacts.
- Extend product lifespans: through modularity, reparability, or reuse.
- Reduce waste and improve reuse/recycling: ensuring material loops are closed as much as possible.

Together, this roadmap and the underlying KPI framework provide a structured, quantifiable, and adaptive approach to advancing circular economy within the pharmaceutical industry. Aiming to create the foundation for coordinated actions at all levels, from strategic decision-making to local operational practices.

4.3.4.3. Tools and supporting documentation

To operationalize the CE strategy and enable its integration across pharmaceutical activities, a range of tools, frameworks, and reference materials were developed. These resources support implementation at different levels of the CE integration model, and form the operational backbone of the CE strategy, ensuring consistency in tracking, decision-making, and performance evaluation.

Measurement tools for circularity

- **CE KPIs (Waste impact index & score):** as presented earlier, CE performance at site, GBU, and corporate levels is tracked using standardized KPIs that quantify progress along the waste hierarchy. These indicators support benchmarking, roadmap alignment, and harmonized reporting across diverse operations.
- **Life Cycle Assessment (LCA):** at the product and process level, LCA serves as the main tool for quantifying the environmental impact of circular strategies (e.g., rethink, reuse, recycling,). By integrating CE principles into LCA, product designers can assess trade-offs, compare end-of-life options, and ensure that circular actions yield net environmental benefits. This is especially valuable where the best strategy among recycling, reuse, or recovery remains uncertain.
- **Material Flow Analysis (MFA) / Value Stream Mapping (VSM)**: MFA can be initiated at several key sites to map material inputs, outputs, and losses across operations. This approach helps to visualize and quantify circularity potentials, identify hotspots for material recovery or reuse, and compare current process efficiency and evaluate opportunities. MFA is particularly useful at the site level, serving as a diagnostic and planning tool for waste minimization and loop closure.

Standardization & operational guidance

- **CE Glossary:** a company-wide glossary of CE and waste management terminology was developed to ensure consistent understanding among stakeholders. Defining terms like “reuse,” “recycling,” or “post-consumer waste” helps reduce ambiguity and align interpretation across teams, functions, and geographies.
- **CE & Waste Management standard**: a practical document was developed to explain the CE strategy, clarify guiding principles, and standardize the implementation process. It outlines expectations, definitions, indicators, and reporting guidelines to guide both strategic planning and day-to-day operations.
- **Best practices handbook**: to support the deployment of circular economy initiatives across Sanofi’s network. The handbook consolidates the CE practices identified through the empirical study, categorized by: GBU, site, type of waste, CE principle applied, ease of implementation, replicability potential across sites. This handbook serves multiple purposes:
    - *Knowledge transfer*: enables sites to learn from each other and avoid reinventing the wheel.
    - *Implementation support*: provides operational teams with concrete examples of successful CE strategies.
    - *Prioritization aid*: helps identify which practices are most feasible or impactful for a given site or waste type.

- *Strategy alignment*: reinforces consistent interpretation and deployment of CE principles across the organization.

Reporting framework

- **Reporting improvements**: as global reporting occurs quarterly; it lacks granularity for detailed site-level follow-up. To close this gap, a dedicated follow-up mechanism was proposed for key sites, enabling more responsive tracking and targeted improvement actions.
- **Waste categorization (operational vs one-time waste):** to improve data accuracy and opportunity detection, a distinction was formalized between regular business waste (from routine operations), and one-time activity waste (from exceptional events) (Figure 66). This clarification improved comparability, helped identify overlooked reuse opportunities, and strengthens the consistency of performance evaluations over time.

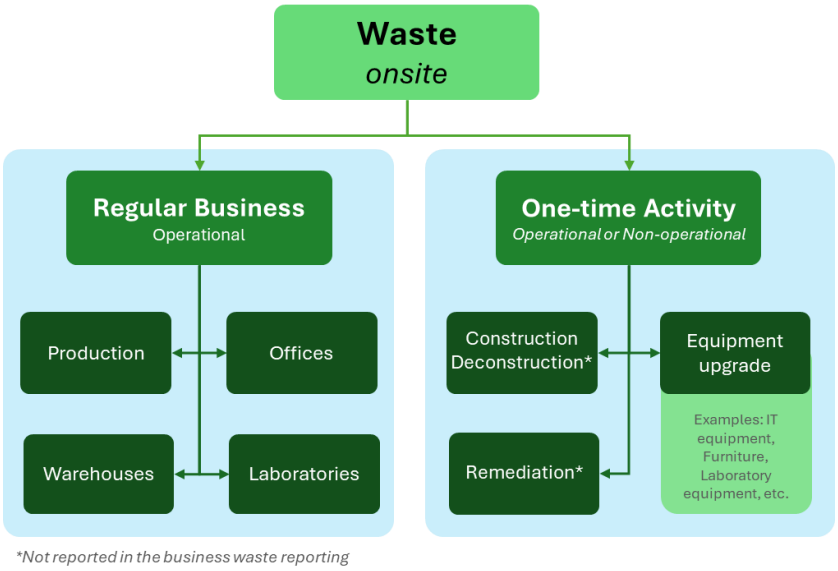

Figure 66. Illustrative view of the internal reporting flow for waste

4.4. DISCUSSION

This chapter discusses the key findings from the research, combining insights from both the SLR and the empirical study. It explores how these findings contribute to the development of a CE strategy for the pharmaceutical sector, and reflects on the tools, frameworks, and models proposed. The discussion is structured into four parts: first, the need for a sector-specific CE strategy is examined; second, the CE integration model developed is compared with existing models; third, the indicators and measurement tools are discussed in light of current CE metrics; and finally, the chapter outlines the study's limitations and areas for future research.

4.4.1. Need for a CE strategy in the pharmaceutical industry

The need for a CE strategy in the pharmaceutical sector emerged from the convergence of two core components of this research: the systematic literature review (SLR) and the empirical data collected through surveys and interviews. Together, these analyses revealed not only a growing interest in circularity but also a series of recurring gaps, barriers, and misalignments that hindered meaningful CE implementation.

Literature analysis

The literature analysis, combined with the SLR from Saha et al., highlighted several converging patterns (K. Saha et al., 2025). First, CE in healthcare remains heavily downstream-focused, with most efforts centered on waste treatment and disposal rather than prevention and design. This echoes the dominance of the "post-waste" logic in pharmaceutical CE practices. Second, sustainable product design is a major and recurring theme but often lacked

structured integration into company-wide systems or regulatory pathways, especially in pharmaceutical industries, where safety constraints complicate circular design. Third, systemic enablers like stakeholder education, governance, and incentives are critically underdeveloped, representing less than 2% of published CE work in the sector (K. Saha et al., 2025). Finally, few robust, quantitative, or scalable studies exist, making benchmarking, comparative analysis, and strategic planning difficult across organizations.
The analysis revealed a mismatch between conceptual frameworks and operational reality: despite CE framed as a system-wide transformation in literature, most empirical studies focus on isolated improvements.

Empirical study

The empirical study validated several of these findings with a focus on downstream loops, most efforts focused on landfill or energy recovery. Reuse remained limited, and design-for-circularity was not systematically embedded in product or process practices. The barriers such as regulatory, vendor dependencies, infrastructure gaps, and campaign-mode production complicate broader CE adoption, reflecting the systemic constraints highlighted in the literature. CE maturity was uneven, some streams benefit of advanced management practices while others do not, and there was only little cross-site coordination or shared governance.

Eco-design as a foundational bridge

A key internal insight was that eco-design is already well established within Sanofi and other pharmaceutical companies and was often viewed as a vehicle for CE. However, the literature positions ED as a foundational layer within the broader Design for Sustainability (DfS) and CE landscape. Rather than debating which concept encompasses the other, the challenge lied in clarifying the overlap and building an explicit bridge between these approaches/models. The proposed CE strategy did precisely that, building on existing ED maturity while expanding scope and ambition.

4.4.2. Need for a CE Integration Model for the pharmaceutical sector

In the words of Bhamra (2004), “models are often understood as simplistic ways of representing and/or understanding the world, usually having the purposes of being descriptive or prescriptive. They have the potential to summarize complex information in a manageable and understandable manner and, for eco-design, represent a range of its characteristics, fields and practices” (Bhamra, 2004; Brones and Carvalho, 2015).

In highly regulated and complex industries such as pharmaceuticals, such models are not just helpful, they are essential. They offer a structured lens through which companies can make sense of complex system, especially when trying to integrate sustainability or CE principles.

According to Sherwin and Bhamra (2001), the concept of integration refers to the principles of concurrent engineering, the promotion of communication and coordination early in the design and development process (Brones and Carvalho, 2015; Sherwin and Bhamra, 2001). Originally intended to improve quality, reduce costs, and shorten development timelines, this idea has more recently expanded to include environmental considerations, especially through eco-design (Brones and Carvalho, 2015). When extended to CE, this integration mindset emphasizes the importance of embedding circular thinking not only at the product level but across entire organizational systems from the outset.

Why a CE integration model for pharma?

Although several CE models exist in the literature, they often fall into one of three categories, each with limitations when applied to the pharmaceutical sector:

- **Generic and conceptual frameworks:** these position CE as part of a systemic societal transition and include high-level CE models that provide flexibility but lack sector-specific tailoring. For example, the CTF from Evans (2023) integrates CE within the wider frame of sustainable development, demonstrating how circularity can drive not only environmental improvements but also social wellbeing and institutional change. If such perspectives are valuable in broadening CE’s scope, their level of abstraction makes them difficult to operationalize in the day-to-day reality of pharmaceutical companies (Evans, 2023).
- **Loop-centric models**: these primarily describe potential material or product-level circular loops (e.g., reuse, recycling, recovery), which are useful for identifying opportunities, but offer limited insight into

how such loops can be structurally integrated within an organization, considering its strategy, operations, and obligations. For example, Ang et al. (2021) propose a CE framework specific to pharmaceutical manufacturing, emphasizing circular loops within production environments (K.L. Ang et al., 2021). However, such models primarily focus on describing "what" circular strategies are possible, rather than "how" CE integration should be structured and governed within the complexities of a pharmaceutical company.

- **Business-model oriented frameworks:**. These models emphasize the role of business model innovation in enabling CE transitions. They highlight how products, services, infrastructures, and regulatory incentives interact to support new forms of value creation. The Circular Transition Framework (Scheepens et al., 2016) is a prominent example, mapping system levels (product, infrastructure, regulation, and society) and the stakeholder dynamics required for circular business systems. If useful for visualizing these interactions, such approaches remain oriented toward business innovation and do not fully address how organizations can integrate CE internally and across functions.

In contrast, the Circular Economy Integration Model (CEIM) developed in this work aimed to address these limitations and to answer to three key gaps identified through both the literature review and the empirical study:

- **Fragmented maturity across the lifecycle**: findings show a clear disconnect between technical CE maturity (e.g., green chemistry, solvent recovery) and systemic integration. While isolated initiatives exist at the operational level, elements such as cross-site reuse, integrated circular business models, or top-down strategic alignment are underdeveloped. The CEIM responds to this by situating these technical practices within a broader multi-layered framework that also encompasses organizational, geographical, and socio-technical dimensions. This highlights the need to move from project-based improvements to systemic circular transformation.
- **Regulatory and risk constraints**: the pharmaceutical sector operates under stringent regulations, GMP, safety protocols, and product quality standards. These conditions impose legitimate constraints on CE practices, particularly in reuse, reverse logistics, or secondary material integration. Unlike other sectors where experimentation with reuse loops is more feasible, pharmaceutical companies require a sector-specific CE model that explicitly incorporates these constraints into its structure. The CEIM does so by recognizing regulatory compliance as an overarching factor shaping all dimensions of circular implementation.
- **Lack of organizational readiness**: findings revealed limited awareness, low stakeholder engagement, fragmented governance, and inconsistent CE-related training across companies. These gaps reinforced the need for a framework that includes human factors, stakeholder alignment, and organizational change management. The CEIM integrates these as a core dimension of circular readiness, recognizing that systemic transformation requires not only tools and processes, but also cultural and behavioral shifts.

Although these categories highlight why a pharma-specific CE integration model is necessary, it is important to note that existing frameworks can be mobilized in complementary ways within such a model. For instance, the Circular Transition Framework (Scheepens et al., 2016) provides guidance on how circular business models can be designed across multiple system levels, from products and infrastructures to regulations and societal interactions. Within the CEIM, such a perspective is particularly relevant to the spatio-social & organizational dimension, where new business models and inter-site coordination mechanisms need to be aligned with regulatory and infrastructural realities. Similarly, the integrated model of Evans (2023) situates CE within the broader logic of sustainable development, emphasizing social wellbeing, equity, and systemic transformation (Evans, 2023). This framing resonates with the socio-technical dimension of the CEIM, ensuring that pharmaceutical CE strategies are not narrowly environmental or operational, but also connected to broader sustainability ambitions.

Other contributions also inform specific dimensions of the CEIM. Chen (2020) highlights the importance of organizational capabilities and transition processes, which can be embedded into the socio-technical dimension of the CEIM to guide how firms move from isolated initiatives to systemic practices (Chen et al., 2020). Daú et al. (2019) emphasize the role of collaborative networks and open innovation, insights that reinforce the spatio-social & organizational dimension where supplier and stakeholder engagement are central (Daú et al., 2019). Finally, Di Vaio et al. (2022) underline the critical role of accountability and measurement systems in enabling CE and waste transitions, an aspect that aligns with the CEIM's transversal treatment of compliance and governance as enablers across all dimensions (Vaio et al., 2023). In this sense, the CEIM does not replace these frameworks but rather offers a sector-specific integrative lens through which their contributions can be operationalized in practice.

The proposed Circular Economy Integration Model (CEIM) for the pharmaceutical sector responds to these needs. It was developed by adapting the vertical and transversal integration logic proposed by Brones and Monteiro de Carvalho (2015) for eco-design (Brones and Carvalho, 2015). Their model, originally applied to eco-design integration, has been expanded here and combined with CE literature to reflect the pharmaceutical industry's multi-dimensional structure and transition requirements.

The CEIM is composed of three nested and interlinked dimensions and levels:

- **Product & Process dimension**: at the center, where product design, development, and process optimization occur (aligned with eco-design strategies).
- **Spatio-social & Organizational dimension**: surrounding the product level, capturing the role of industrial sites, global business units, and inter-organizational collaboration.
- **Socio-Technical dimension**: the outer layer, representing overarching human, cultural, and regulatory influences (change management, policies, regulations, stakeholder engagement).

Importantly, regulatory frameworks and human factors are treated not merely as peripheral elements but as transversal enablers that cut across all dimensions and levels. This acknowledges that CE transformation requires both top-down policy alignment and bottom-up stakeholder engagement, particularly in a compliance-driven industry like the pharma industry.

Clarifying the terminology

It is important to note that the definitions of "micro," "meso," and "macro" vary widely in the CE literature. In some frameworks, the micro level refers to companies, the meso level to group of organizations or industrial parks, and the macro level to nations or industries (Guzzo et al., 2022; Saidani et al., 2022a). In the CEIM, these levels are adapted to fit the pharmaceutical structure. For the product & process dimension, the levels correspond to the definition of Brones and Monteiro de Carvalho (2015): Macro level: strategy and corporate objectives for sustainable product design; Meso level: aimed at PDP and portfolio management; Micro level includes ecodesign tools and project management. For the spatio-social & organizational dimension: Micro level: product and process (the inner dimension); Meso level: site, department, GBU, or value chain segment; Macro level: global company or network of companies.

Mapping barriers identified within the CEIM

Table 11 below presents a synthesis of findings from both the literature review and the empirical study, mapping the key challenges and gaps onto the dimensions of the CEIM. This alignment helps demonstrate how each category of barrier corresponds to a specific part of the system. The barriers listed are not exhaustive but aim to illustrate typical constraints encountered in the pharmaceutical context, serving as concrete example.

Table 11. Synthesis of barriers across CEIM dimensions, from both the literature review and the empirical study

Barriers / Gaps	Product & Process	Spatio-social & Organizational	Socio-technical
Regulatory complexity	Limits to use secondary materials; GMP practices, contamination	Implementation constrained by region-specific laws	Lack of regulatory incentives; unclear guidelines
Technical constraints	Contamination, segregation, mix of substances	Infrastructure gaps (int. and ext.)	Low vendor readiness
Operational misalignment	No eco-design in PDPs; conflicting KPIs	Fragmented practices across sites; production modes	CE not embedded in strategic plans
Infrastructure & logistics	Limited reuse options, no design feedback loops	No space for segregation; outdated systems	Missing investment in regional CE partnerships
Data and monitoring	LCA limited to few products; no process information	No system for tracking CE performance site-wide	Fragmented or missing value chain transparency

Cultural & organizational	Environmental actions isolated from business logic	Local innovation not scaled or shared; no community of practice	No governance structure; weak cross-stakeholder collaboration
Economic disincentives	CE seen as cost/ additional burden, not value driver	No funding for CE infrastructure	No financial incentive structures or subsidies
End-of-life limitations	Limited design for circularity options	Mixed hazardous waste hard to sort	No national take-back programs or disposal standards
Research & pilots	Lack of scaling studies or reuse trials	Little techno-economic evaluation	Policy disconnected from pharma-specific data

4.4.3. Relevance and positioning of the proposed indicators

The Waste Impact Index developed in this study aligned closely with key research themes in the field of CE metrics (C-metrics). This relevance was underscored by the recent comprehensive review by Shevchenko et al. (2024), which synthesizes two decades of literature and identifies six dominant research themes (Shevchenko et al., 2024). Similar hierarchy-weighted waste indicators have already been developed in industry, notably at Merck, where a waste-scoring system based on treatment pathways and the waste hierarchy is used to support circularity-oriented waste management (Merck, 2022). The proposed indicators build on the same underlying logic while tailoring it to Sanofi's operational and reporting context.

(1) First, it contributes to the domain of micro-level C-metrics (theme 1), as it operates at the site, business unit, or company level and focuses on a specific circular strategy, namely, waste management. Like the indicators proposed by Franklin-Johnson et al. (2016) or Mesa et al. (2018), the waste impact index narrows in on a key dimension of circularity rather than attempting a fully integrated product-level assessment (Franklin-Johnson et al., 2016; Mesa et al., 2024). It also shares methodological similarities with Linder et al. (2017), by prioritizing performance-oriented tracking over direct environmental assessment, while still embedding implicit environmental logic through its weighting system based on the waste hierarchy (Linder et al., 2017).
(2) In relation to sustainable circularity metrics (theme 2), the waste impact index is not a fully integrated sustainability tool as it does not incorporate LCA or social dimensions. However, it does partially reflect environmental considerations through its weighting structure, which penalizes low-value or high-impact treatments such as landfill and favors short-loop strategies like reduce or reuse. Compared to holistic frameworks such as those developed by Kravchenko et al. (2020) or Corona et al. (2019), the waste impact index offers a simpler and more operational metric, trading scope for usability and deployability across sites (Corona et al., 2019; Kravchenko et al., 2020b, 2020a).
(3) Most significantly, the waste impact index finds its strongest relevance within the theme of C-metrics for waste management (theme 5). It builds upon the logic of previous indicators like the Waste Hierarchy Index (Pires and Martinho, 2019) or the Waste Cycle Index (Colasante et al., 2022), which also structure performance evaluation around treatment pathways. Like the "Expanded Zero Waste" model by Veleva et al. (2017), the indicator is designed to support internal standardization and monitoring, offering a harmonized KPI that can be applied across industrial sites (Veleva et al., 2017). In that sense, it can be seen as a modern, weighted evolution of the traditional recycling rate, retaining simplicity, while embedding greater environmental relevance.

The added value of the waste impact index is its normalization into a waste score. Indeed, a shared challenge across sources is that absolute waste reduction is constrained by growing production volumes. This emphasizes the need for relative performance indicators (e.g., waste score) and dynamic tracking of circularity outcomes.

In summary, the Waste Impact Index and Waste Score offered a practical way to assess circularity by focusing on waste management outcomes. Their simplicity and alignment with the waste hierarchy made them useful tools for tracking and guiding improvements across sites. However, unlike broader indicators such as MCI, CTI, or Circulytics, they focused only on end-of-life strategies ("closing the loop") and did not address upstream circularity actions like product design or resource efficiency. Even though they embedded environmental logic through

treatment weights, they did not directly measure environmental impacts, highlighting the value of combining them with LCA-based tools. Ultimately, these indicators covered a critical but partial view of circular performance and should be used alongside complementary metrics to capture the full CE picture.

4.4.4. Limitations and future work

This section reflects on the limitations encountered during the research and outlines directions for future improvement and exploration. It is divided into four parts: (1) limitations of the data collected and analyzed; (2) limitations of the CE Integration Model (CEIM); (3) methodological constraints related to indicators and tools; and (4) the evaluation of the CE strategy applicability.

4.4.4.1. Limitations related to data collection and analysis

Literature review

Although the CE is a growing research field, the literature on circularity in the pharmaceutical industry remained limited and fragmented. A core challenge lay in distinguishing between literature on pharmaceutical manufacturing and broader healthcare systems, which often include hospitals, and other services. For example, Ang et al. (2021) specifically analyzed circular loops in pharmaceutical manufacturing (K.L. Ang et al., 2021), while Saha et al. (2025) take a more systemic approach to CE across the healthcare sector, including but not limited to pharma, resulting both with quite different outcomes (K. Saha et al., 2025).
Additionally, CE is a multi-dimensional concept, and the identified literature was highly sensitive to the keywords and scope used in literature searches. The terminology selected in the systematic review (e.g., "loops," "circularity," "waste") shaped the set of papers retrieved. Consequently, some relevant studies, such as those focused on material recovery, industrial symbiosis, or product design, might not have been captured. This limitation underscores the importance of refining classification systems and expanding future reviews to include all the relevant dimensions of a circular economy.

Empirical study

The benchmark analysis relied solely on publicly available data from corporate sustainability reports mainly. As a result, the level of detail and disclosure varied widely across companies. The availability of information did not necessarily reflect the maturity of CE implementation, which introduced potential bias. Nonetheless, the intent of the benchmark was to identify general sectoral trends rather than perform a detailed company-by-company comparison. Future studies could benefit from direct industry engagement to enrich the quality and granularity of data.

The survey and semi-structured interviews also exhibited some thematic limitations. While the interviews and surveys provided valuable insights into CE practices, their emphasis on waste management stems from the researchers' position within the Eco-Design and Circular Economy team, which already had a clear internal overview of eco-design actions and projects. As a result, the empirical study focused more on exploring the less documented and more variable area of waste management across sites. However, a more comprehensive study involving stakeholders from production, procurement, quality, and supply chain functions could help map additional circular practices, especially at the operational and cross-functional levels.

4.4.4.2. Limitations and opportunities of the CEIM

The CEIM provides a multi-level framework for understanding how CE principles can be integrated within the pharmaceutical industry. It clarified the interplay between product/process innovation, organizational infrastructure, and socio-technical conditions. However, the model is mainly descriptive and diagnostic, it does not prescribe specific actions or pathways for overcoming identified barriers. Its value lies in contextualizing challenges, but it must be complemented by operational tools to guide implementation.

For instance, coupling the CEIM with frameworks such as the Circular Business Model Canvas (Geissdoerfer et al., 2020) or with loop-based taxonomies (K.L. Ang et al., 2021) can support actionable planning. In this sense, the CEIM functions as a strategic map, which becomes more powerful when paired with instruments that answer the “how” of circular transformation. Future work could focus on formalizing these linkages or developing CEIM-based playbooks for industry practitioners.

4.4.4.3. Indicators and measurement tools

The performance indicators developed in this study, particularly the Waste Impact Index and Waste Score, prioritize waste management due to its relative maturity and traceability in pharmaceutical operations. However, a robust CE strategy must ultimately go beyond end-of-pipe solutions. Linking waste performance to other dimensions, such as carbon emissions, material sourcing, and eco-design, would allow a more holistic evaluation.

Life Cycle Assessment (LCA) has been highlighted as a valuable tool for evaluating the environmental impacts of circular strategies (Pigosso and McAloone, 2017b; Saidani et al., 2022a; Walzberg et al., 2021). However, LCA presents several limitations when applied to circularity. It tends to prioritize quantifiable, short-term metrics (e.g., carbon emissions), potentially overlooking long-term, systemic benefits or qualitative impacts such as toxicity, ecosystem disruption, or material leakage. Moreover, LCA requires detailed data and is often ill-suited for early-stage innovation (EMF, 2022).

To address this, complementary metrics such as the Material Circularity Indicator (MCI), developed by the Ellen MacArthur Foundation (EMF), could be introduced (EMF, 2015b). MCI focuses on restorative flows, reuse, and material utility. Applied to pharmaceutical products, MCI could provide product-level circularity insights that are not currently captured by site-based indicators. Future research could explore the development of an aggregated MCI that captures circular performance across distinct stages of the pharmaceutical product life cycle. This would involve identifying the key lifecycle steps (e.g., manufacturing, distribution, end-of-life), and defining relevant material categories within each (e.g., water, solvents, and raw materials for manufacturing; packaging and device components for end-of-life). For each category, data would need to be collected, so that circularity indicators could be calculated, such as virgin material content, reuse/recovery rates, recycling rates, and unrecoverable waste. From this, an MCI score per category could be calculated based on restorative and linear flows, following the formula: *MCI = 1 – (linear flow × utility factor)*. The final product-level MCI could then be generated by aggregating and weighing these category scores. This would allow for a more nuanced and actionable view of how specific CE strategies impact product circularity over time. Such an approach could provide a valuable complement to existing site- or corporate-level metrics and should be prioritized in future research.

4.4.4.4. Strategic evaluation and implementation

Finally, one of the most important limitations is that the CE strategy proposed remained conceptual and has not yet been tested through implementation. Despite the strategy and CEIM being built on a synthesis of internal and external insights, their practical applicability across functions and geographies has not been validated.

Pilot projects, ideally at site level, are necessary to test the relevance of the framework in real-world conditions. These pilots could focus on applying the strategy in different contexts (e.g., R&D, manufacturing, distribution) and measuring the environmental and operational outcomes. They would also serve as testing grounds for refining KPIs, validating assumptions embedded in the CEIM, and exploring trade-offs between circularity, compliance, and cost.

4.5. CONCLUSION

This first part of Chapter 4 aimed to address **Hypothesis 1**, which states that a structured Circular Economy strategy, built upon both internal and external collaboration, can support the emergence and scaling of circular initiatives in the pharmaceutical sector. Specifically, this section has focused on answering **Sub-Research Question 1.1**: "*What are the key elements of a Circular Economy strategy in the pharmaceutical sector, and how can they be effectively implemented?"*

To this end, a detailed literature analysis was combined with an empirical study of industry practices to examine both the conceptual foundations and practical gaps in current CE adoption. The findings emphasized that while technical innovations exist in silos, such as green chemistry or solvent recovery, systemic integration across the pharmaceutical value chain remains limited and fragmented.

This research identified five core components to structure an effective CE strategy in the pharmaceutical sector:

(1) **Integration with existing environmental frameworks**: aligning CE principles with established eco-design and Design for Sustainability (DfS) practices ensures coherence and builds on existing maturity.
(2) **Dedicated Circular Economy Integration Model (CEIM)**: A novel model for pharmaceutical industries, centered on the product/process dimension and surrounded by organizational, human, and regulatory factors. This structure reflects sector-specific constraints (e.g., GMP, safety) and supports systemic transformation across scales and functions.
(3) **Company-wide circularity indicators**: Tools like the Waste Impact Index enable tracking of progress, support decision-making, and drive alignment with strategic CE goals.
(4) **Supporting CE tools**: Instruments such as Life Cycle Assessment (LCA) and Value Stream Mapping (VSM) guide operational implementation and performance evaluation.
(5) **Implementation roadmap**: A structured roadmap supported by governance, shared terminology (glossary), standardized reporting, and a handbook of best practices facilitates consistent and scalable action.

Altogether, this framework supports a transition from fragmented efforts to a cohesive, system-wide CE strategy that is both actionable and grounded in the specificities of the pharmaceutical context.

In summary, this section provides a structured answer to SRQ1.1, identifying the essential elements for designing a CE strategy in the pharmaceutical sector. It also underscores the central role of collaboration and stakeholder engagement, both internally and externally, in enabling successful implementation. The next section (Part B) will evaluate the applicability of the proposed CE strategy addressing the Sub-Research Question 1.2, exploring to what extent the designed strategy can be applied and generate value, and how collaboration dynamics influence CE integration in real-world pharmaceutical environments.

PART B: CIRCULAR PROJECTS & CASE STUDIES

The aim of Part B is to apply the CE strategy developed in Part A to a set of real-world initiatives within the pharmaceutical sector, assessing both its operational relevance and its capacity to enable collaboration across internal and external stakeholders. Three detailed case studies: Single-Use Technologies (SUT) circularity, Take-Back Systems (TBS), and solvent recovery, serve as the primary testing ground for the strategy, complemented by additional CE initiatives addressing other loops and operational contexts.

The objectives of this part are twofold: (1) to determine the extent to which the CE strategy is applicable, usable, and useful across different types of circular actions in the pharmaceutical industry, and (2) to analyze how collaboration mechanisms enable or hinder its implementation in practice. This approach provides a direct answer to SRQ1.2 and generates evidence to guide future scaling efforts.

The evaluation combines predefined criteria for assessing strategy effectiveness with a dedicated framework for analyzing collaboration dynamics. The resulting insights not only validate the strategy's strengths and limitations but also highlight the systemic integration gap, setting the stage for Chapter 5, which focuses on the transformation of strategy into organizational capabilities.

4.6. CONTEXT

Building on the CE strategy developed in Part A, Part B situates the work within the intermediate stage of the circular transition pathway. As identified by Zils et al. (2023), organizations progressing toward circularity typically pass through three main phases: (1) identification of opportunities, (2) initiation of pilot projects, and (3) implementation at scale (Zils et al., 2023). Even though many CE building blocks already exist in the pharmaceutical sector, they are often deployed in isolation, without coordinated scaling mechanisms.

Within this framework, Part B focuses on phase 2, the initiation and evaluation of pilot projects as a means to test the applicability, usability, and usefulness of the CE strategy in real-world pharmaceutical contexts. Given the pharmaceutical sector's high regulatory complexity, multi-stakeholder environment, and quality-critical requirements, such pilots are essential to allow innovation and build the evidence base for broader adoption. In the absence of this intermediate step, promising initiatives risk remaining localized, with limited long-term impact.

Therefore, the work in Part B directly addresses **SRQ1.2**: *To what extent can a specific CE strategy for the pharmaceutical sector be applicable, usable, and useful in real contexts, and how do internal–external collaboration mechanisms enable or hinder these outcomes?*

As highlighted in the previous part, the boundaries between circular economy and eco-design are not always clear-cut. Both aim for similar objectives (even though eco-design has a narrower scope focused on the product level) such as reducing environmental impacts, rethinking the processes, and optimizing the product life cycle, and they often overlap in practice. In the CE Integration Model (CEIM) developed in this research, eco-design is positioned as one of the core foundations of a CE approach. It is therefore not surprising that tools traditionally associated with eco-design, such as life cycle assessment (LCA), are included among the initiatives assessed here. For this reason, the set of projects in Part B includes both initiatives explicitly targeting CE loops (e.g., single-use technology circularity, take-back systems, solvent recovery) and broader environmental sustainability practices (e.g., portfolio LCA, manufacturing guidelines). Regardless of their initial framing, these initiatives contribute to the same overarching objective of embedding circular economy, and, more broadly, environmental sustainability, into the pharmaceutical context, and thus fall within the scope of the strategy's evaluation.

By evaluating the strategy through a series of detailed case studies and additional CE-related projects, Part B generates empirical insights into both its operational relevance and the collaboration dynamics influencing its success. These findings provide the foundation for Chapter 5, where the focus shifts to the systemic integration of environmental sustainability within the organization.

4.7. MATERIAL AND METHODS

The purpose of this Part B was to evaluate the effect of the actual support developed, namely, the CE strategy, and to determine the role of collaboration in enabling successful CE implementation within pharmaceutical companies. The evaluation focused on the applicability and effectiveness of the CE strategy developed in Part A, using individual projects as the primary unit of analysis.

This approach followed the steps of a systematic Descriptive Study II (DS-II) as defined in the DRM (Blessing and Chakrabarti, 2009a), which emphasizes grounding evaluation in real applications of the designed support. In DRM terms, the evaluation combines two complementary perspectives: the application evaluation, which examines whether the strategy works in its intended context by assessing both its applicability, its ability to be implemented in diverse settings given constraints, and its usability, meaning its clarity, practicality, and ease of adoption by users. And the success evaluation, which considers whether the strategy achieves its intended purpose, in this case whether its application leads to measurable improvements in CE outcomes and collaboration dynamics. Accordingly, the methods applied here are structured in line with the systematic DS-II evaluation process, which comprises several steps (Figure 67). The final step of the DS-II: drawing conclusions, is addressed in Section 3 (Discussion).

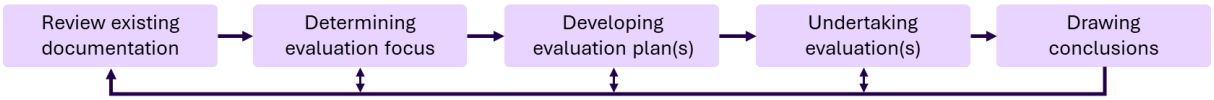

Figure 67. Main stages of a systematic DS-II (adapted from Blessing and Chakrabarti, 2009)

4.7.1. Review of projects and documentation

To ensure a robust and meaningful evaluation of the Circular Economy strategy, the first step was to clearly define the object of evaluation and identify suitable instances in which it could be assessed. In this study, the CE strategy

itself constituted the "support" to be evaluated, with its intended form (as designed in Part A of this chapter) compared to its actual implementation within real projects. This distinction made it possible to account for adaptations, omissions, or contextual changes that occurred during application, and to interpret their influence on outcomes.

In line with DRM guidance, three categories of preparatory information were consolidated prior to the evaluation:

- **Strategy documentation**: including a description of the CE strategy's objectives, underlying principles, and key components (e.g., CE Integration Model, implementation roadmap, indicators, supporting tools).
- **Introduction plan**: covering how the CE strategy was integrated within the organization, including governance structures, stakeholder engagement processes, and alignment with existing environmental initiatives.
- **Reference and impact models**: describing the baseline organizational and sectoral context (e.g., CE maturity, regulatory constraints, existing initiatives) and outlining how the CE strategy was expected to drive change.

Projects were then selected based on their alignment with CE priorities and their potential to provide relevant insights into the strategy's applicability. Both pre-existing initiatives and newly launched projects were considered, provided that they addressed one or more components of the CE strategy. Once selected, projects were managed with a dual aim: first, to deliver their operational objectives, and second, to generate the data and insights required for subsequent evaluation. For each project, data were collected through the review of relevant documentation, direct participation in project activities, and, where appropriate, interviews with key stakeholders.

Baseline performance data were defined for each project according to its scope and intended outcomes. In waste management initiatives, the Waste Impact Index and related KPIs were used to quantify potential improvements. For product-related projects, Life Cycle Assessment (LCA) results provided baseline impact profiles, enabling later comparison of percentage reductions in environmental burdens. In other cases, baselines were established through metrics such as the proportion of components recovered or recycled. This tailored approach ensured that each project's performance could be measured against relevant, context-specific indicators while maintaining overall comparability in the evaluation phase.

This project-based evaluation also drew on principles of Action Research (AR), which, like the DRM, emphasizes the iterative testing of solutions in real-world contexts (Blessing and Chakrabarti, 2009a). In Action Research, change and knowledge creation occur simultaneously through cycles of implementation, observation, and reflection in close collaboration with stakeholders (Coughlan and Coghlan, 2002). Applying this perspective ensured that the evaluation captured both the practical impact of the CE strategy, and the lessons learned from its application, while acknowledging the balance between local relevance and broader applicability across the pharmaceutical sector.

This preparatory work ensured that the subsequent evaluation was grounded in a clear understanding of the strategy's intended purpose, its actual deployment, and the conditions in which it was applied. The next sub-sections define the evaluation focus, and the criteria used to assess the CE strategy and the role of collaboration.

4.7.2. Evaluation focus

The evaluation was designed to address two complementary dimensions. First, it examined the extent to which the CE strategy developed in Part A was applicable, usable, and capable of delivering its intended environmental and operational outcomes in real-world pharmaceutical contexts. This involved assessing the alignment of projects with the strategy's components, the feasibility of their implementation under sector-specific constraints, and the magnitude of environmental benefits achieved.

Second, it investigated the role of collaboration in enabling or hindering the integration of CE practices. The analysis considered the diversity and depth of stakeholder engagement, the quality of knowledge exchange, and the extent to which partnerships fostered during the projects were sustained over time. This dual perspective not only determined whether the strategy worked in practice but also evaluates whether collaboration acted as a critical success factor for its effective application.

Framed by this approach, the evaluation sought to answer the overarching question: *Does the CE strategy developed in Part A enable feasible, scalable, and collaborative circular economy integration in the pharmaceutical sector?* This central question was unpacked into a set of sub-questions aligned with the strategy's five core elements and directly linked to Hypothesis 1, and more specifically to SRQ1.2:

- Is the strategy sector-specific and does it take into account regulatory requirements?
- Does it promote systemic integration across organizational levels?
- Are the tools and KPIs both usable and effective?
- Does it enable meaningful collaboration internally and externally?
- Does it generate measurable environmental improvements?
- Does it stimulate innovation in circular practices?

4.7.3. Evaluation plan

The evaluation was structured to address Sub-Research Question (SRQ) 1.2 and its associated sub-questions through two complementary analytical lenses: (1) strategy effectiveness, and (2) collaboration dynamics. This dual approach reflected the central assumption of Hypothesis 1, that effective CE integration in the pharmaceutical sector depends not only on the technical soundness of the strategy but also on the quality of stakeholder collaboration.

Baseline performance data for each project, as described in Section 2.2, were used as reference points for assessing both environmental outcomes and collaborative processes.

4.7.3.1. Strategy effectiveness

The first evaluation lens assessed how well the CE strategy developed in Part A performed against its intended objectives and core components. The evaluation criteria were directly aligned with the strategy's five core elements and translated into eight measurable dimensions (Table 12). Each dimension was assigned a relative weight reflecting its importance to successful CE integration in the pharmaceutical sector.

Table 12. Criteria for strategy effectiveness evaluation

Criteria	Description	How it is evaluated	Weight (%)
Integration with existing initiatives	Degree to which the project is linked with ongoing projects related to environmental sustainability.	Evidence of synergy with existing frameworks, tools, or policies.	5
Sector-specific relevance	Extent to which pharmaceutical specificities are considered.	Alignment with CEIM dimensions and levels.	15
Alignment with CE goals	Consistency with overall CE and eco-design goals.	Analysis of project objectives and outputs.	15
Operational relevance & roadmap alignment	Practical applicability of the project to operations and consistency with CE KPIs and roadmap (governance, reporting, glossary, best practices).	Comparison with KPIs and roadmap milestones, operational constraints.	15
Collaboration enablement	Ability of the project to foster internal/external partnerships, cross-sector alliances, and shared governance.	Depth of stakeholders engagement, co-created outputs, governance structures	15
Scalability & replicability	Potential for replication across sites, GBUs, or geographies without major redesign.	Feasibility studies, data about similar issues, adaptation guidelines.	15
Environmental impact reduction	Documented reduction in environmental footprint (e.g., LCA).	Quantitative analysis environmental impacts against baseline.	15

Innovation potential	Extent to which the project drives new CE loops, business models, or technical solutions.	Documentation of novel practices, patents, or new process adoption.	5

Among the eight criteria, criteria with lower weightings (Integration with existing initiatives and Innovation potential (each 5%)), were included because they enhance the reach and long-term value of a CE strategy, but they are not considered primary drivers of its operational success in this context. In contrast, the other six dimensions represent the core conditions for strategy effectiveness, such as sector-specific relevance, operational alignment, scalability, and measurable environmental impact.

Scoring approach

Each criterion was rated from 1 to 5 based on documented evidence:

- **5 -Excellent**: fully meets expectations; strong evidence of consistent, replicable success across contexts.
- **4-Good**: meets most expectations, with only minor limitations or occasional gaps.
- **3-Adequate**: partially addresses the criterion; benefits evident but limited in scope, scale, or consistency.
- **2-Weak**: limited or inconsistent evidence of meeting the criterion; significant gaps remain.
- **1-Minimal**: criterion barely addressed; negligible or no measurable contribution.

The overall CE strategy score for each project was calculated as the weighted sum of all criterion ratings. Scores were then interpreted using the following categories (Table 13):

Table 13. Description of CE strategy effectiveness scores

Overall score	Interpretation for CE strategy
> 4,5	**Excellent** – strong sector adaptation, operational integration, and measurable environmental gains; only minor fine-tuning needed**.**
3,5 – 4,5	**Good** – well-implemented with robust results, but at least one key area (e.g., measurement, scalability) needs improvement.
2,5 – 3,4	**Adequate** – some strong areas, but important criteria are only partially met; targeted improvements required.
1,5 – 2,4	**Weak** – substantial gaps in relevance, integration, or impact; significant redesign needed**.**
< 1,5	**Minimal** – major misalignment or lack of evidence of impact**.**

4.7.3.2. Collaboration dynamics

The second evaluation lens examined collaboration dynamics through two complementary components: (1) the quality of collaboration, and (2) the success of CE-related initiatives. This dual approach enabled the assessment of both the robustness of collaborative practices and the tangible outcomes achieved. Together, these components supported the investigation of whether collaboration functions as a driver of CE integration, as proposed in SRQ1.2.

Collaboration quality

Collaboration quality was assessed across five dimensions (Table 14). Each criterion was rated on the same 1–5 scale as above.

Table 14. Criteria for collaboration quality evaluation

Criteria	Description	How it is evaluated
Stakeholder diversity	Range of stakeholder groups engaged (internal functions, external partners, suppliers, regulators, etc.).	Count of stakeholder groups engaged, including both internal and external actors.

Depth of engagement	Extent to which stakeholders are actively involved in decision-making, co-creation, and problem-solving.	Evidence of co-design, shared decision-making, and joint ownership of deliverables.
Knowledge exchange quality	Degree of knowledge transfer and integration between stakeholders.	Documented enablers leveraged and barriers addressed during the project.
Enablers and barriers management	Ability to identify, address, and overcome obstacles to collaboration (e.g., regulatory, logistical, cultural).	Evidence of shared tools, training sessions, workshops, and application of learnings.
Long-term partnership potential	Likelihood that collaboration will continue beyond the project, fostering ongoing CE initiatives.	Post-project commitments, partnership agreements, follow-up projects.

The collaboration quality assessment produced an aggregated score per project, reflecting the breadth, depth, and quality of stakeholder engagement. This score was calculated as the sum of all collaboration-related criteria and provided an integrated measure of the robustness of collaborative practices within the project. Even though it does not directly quantify the impact of collaboration on CE integration, it forms the basis for subsequent analysis exploring potential links between collaboration quality and CE strategy performance. The scores were interpreted according to the categories in Table 15.

Table 15. Description of collaboration quality scores

Overall score	Interpretation for collaboration quality
> 4,5	**Excellent** – diverse stakeholders, deep co-design, strong enablers, frequent knowledge exchange, clear long-term partnership pathways.
3,5 – 4,5	**Good** – broad involvement and good engagement, with minor gaps in diversity, depth, or continuity.
2,5 – 3,4	**Adequate** – some strong aspects (e.g., knowledge sharing), but other elements underdeveloped.
1,5 – 2,4	**Weak** – limited diversity, shallow engagement, few sustained partnerships.
< 1,5	**Minimal** – superficial or absent engagement; no evidence of meaningful joint work.

It is important to note that this score does not directly measure the impact of collaboration on CE integration, it measures the quality of collaborative practices, which was then related to CE projects performances.

Project success

The second part of the collaboration dynamics evaluation examined the actual success of each project in achieving its intended operational and environmental objectives. In spite of the CE strategy evaluation focusing on alignment with the designed framework, this assessment focused on tangible outcomes. It provided the necessary counterpart to collaboration quality, enabling a direct comparison between the degree of collaboration and the level of achieved results.

The criteria used for this evaluation drew on de Wit's (1988) proposals, and distinction between project success and project management success, as well as on subsequent adaptations for multi-stakeholder initiatives (Wit, 1988). Despite traditional measures such as cost, time, and quality being relevant, CE-oriented projects in the pharmaceutical sector required broader criteria that reflect environmental performance, functionality, and stakeholder value. The selected criteria captured both short-term delivery and long-term viability, enabling a nuanced assessment of whether the project's objectives were achieved in a way that supports sustainable adoption (Table 16).

Table 16. Criteria for project success evaluation

Criteria	Description	How it is evaluated
Achievement of project objectives	Extent to which the project met its stated objectives (technical, environmental, operational).	Comparison of actual outcomes against initial CE-related objectives set at project start.
Functionality/ Technical performance	Whether the process, product, or loop delivered the intended functional outcomes.	Assessment of whether the technical solution works as designed.
Stakeholder satisfaction	Degree of satisfaction among key stakeholders.	feedback analysis to gauge perceived value, usability, and alignment with priorities.
Long-term viability	Likelihood that the project's results are maintained, scaled, or replicated beyond the pilot phase.	integration into standard processes, replication in other sites, or follow-on initiatives.
Environmental impacts achievement	Extent to which the project delivered its intended environmental benefits.	Comparison between projected and achieved environmental metrics (e.g., waste reduction %, LCA indicators).

The same 1–5 scoring scale was applied here, with all dimensions considered equally important (Table 17).

Table 17. Description of project success scores

Overall score	Interpretation for project success
> 4,5	**Excellent** – Project is completely successful, achieving or exceeding environmental and operational objectives with clear scalability potential.
3,5 – 4,5	**Good** – Project is highly successful, meeting most objectives and showing strong evidence of replicability, minor gaps remain.
2,5 – 3,4	**Adequate** – Project shows moderate success, with some objectives met but significant limitations in either impact, execution, or scalability.
1,5 – 2,4	**Weak** – Project has limited success, major objectives unmet or impacts minimal; substantial redesign needed.
< 1,5	**Minimal** – Project unsuccessful, little or no evidence of achieved objectives or measurable benefits.

Comparative analysis

To explore the potential link between collaboration and the successful implementation of CE-related initiatives, the project success score was compared with the collaboration score for each case study. This step operationalized SRQ1.2 by asking: *Do higher-quality collaborations systematically coincide with higher success of CE-related projects?*

Results were plotted on a two-axis matrix:

- **X-axis**: Project success score
- **Y-axis**: Collaboration quality score

The resulting matrix was divided into four quadrants:

- **Collaborative success** (top-right): high collaboration & high project success, ideal case, where strong collaboration aligns with the achievement of intended CE-related objectives.
- **Collaboration without impact** (top-left): high collaboration & low project success, collaboration mechanisms are strong but are not yet translating into tangible CE-related outcomes.
- **Isolated wins** (bottom-right): low collaboration & high project success, rare cases where success is achieved despite limited collaboration; may indicate strong technical fit or low stakeholder interdependence.

- **Underdeveloped initiatives** (bottom-left): low collaboration & low project success, weakest case, with both collaboration and results underperforming.

This visual and analytical approach provided evidence on whether the quality of collaboration could be associated with the level of success achieved by CE-related projects, thereby directly informing the answer to SRQ1.2.

4.7.4. Undertaking evaluation

The evaluations were performed following the systematic DS-II process, with adaptations for the context of this study.

Sampling: projects were selected to ensure relevance to the CE strategy and representation of both newly initiated and pre-existing initiatives. Although it was not feasible to control all contextual factors (e.g., site infrastructure, local regulations), potential implications of these differences for the evaluation outcomes were considered during analysis.

Data collection: data were gathered with a clear focus on the evaluation sub-questions (Section 2.3), while maintaining openness to unexpected effects. Sources included project documentation, direct participation in activities, KPI tracking, LCA outputs, and, where relevant, stakeholder interviews.

Analysis and interpretation: data were examined to distinguish effects that could be attributed to the CE strategy from those resulting from other factors (e.g., individual motivation of project stakeholders). Both positive and negative outcomes were considered. Care was taken not to over-attribute successes to the CE strategy where other explanations were plausible, nor to overlook weaker results.

Verification: to strengthen validity, findings were cross-checked across multiple projects, contexts, and data sources. Where possible, results were compared with pre-existing baselines (e.g., CE KPIs, LCA results) to confirm observed changes. This triangulation allowed alternative explanations to be assessed and reduced the risk of misinterpreting results due to isolated contextual effects.

Finally, to conclude the systematic DS-II process, drawing conclusions from the evaluations was performed. However, in this study, that step was addressed in Section 4.9 (Discussion), where the evaluation results were interpreted, alternative explanations considered, and implications for refining and deploying the CE strategy discussed.

4.8. RESULTS

This section presents the main outcomes of the research and evaluations conducted in Part B. It begins by introducing the set of projects selected for assessing the CE strategy. The three case studies are then described in detail, providing insight into their context, outcomes, and challenges. The following sections present the evaluation of the CE strategy and collaboration dynamics through these case studies. Finally, all identified CE initiatives are assessed to provide an overall appraisal of the strategy's performance.

4.8.1. Overview of the projects

To assess the relevance of the CE strategy developed, several initiatives were identified, implemented, and analyzed. These projects served as practical tests to verify how the strategy could be applied across different contexts within the pharmaceutical sector. Some were pre-existing initiatives (e.g., LCA) that were reviewed for alignment with the CE strategy, while others were newly launched in direct response to the circularity priorities identified during strategy development.

A total of six CE-related projects were retained for evaluation, covering diverse areas of application from product design and manufacturing to waste management and recycling. Together, they addressed all five components of

the CE strategy developed in Part A, with varying degrees of maturity and scope. The projects differed in their operational focus, ranging from large-scale collaborative initiatives (e.g., take-back systems) to internal process optimization (e.g., solvent recovery, manufacturability tool).

Table 18 provides an overview of all CE-related projects considered in this assessment, offering a concise view of their scope, objectives, and role in relation to the CE strategy.

Table 18. Overview of CE-related projects

Project name	Short description	Main goal	Start date	Status
SUT Circularity	Development of several initiatives with SUT supplier and waste vendor for specific SUT (e.g., magnets).	Increase recyclability and optimize SUT waste management in compliance with CE strategy.	2023	Ongoing
Take-back systems	Design and pilot of insulin pens take-back programs in collaboration with other pharmaceutical companies and waste vendors.	Close the product loop by enabling large-scale recovery and recycling of post-consumer waste.	2023	Ongoing
Solvent recovery	External regeneration of used solvents from different production campaigns.	Reduce incineration and regenerate solvents to create secondary solvents.	2024	Ongoing
Manufacturing guide	Multi-criteria decision-making tool for the design of pharmaceutical manufacturing processes, for R&D to industrialization or for legacy process changes.	Embed Eco-design and Circular Economy recommendations within the tool.	2024	Ongoing
Portfolio LCA	LCA of a portfolio of products from the same family (e.g., family of insulins)	Increase the efficiency of LCA.	2024	Completed
Value Stream Mapping	Waste streams analysis across specific production sites.	Identify opportunities for improving waste management.	2025	Completed

To provide a deeper understanding of project drivers, execution, and their role in validating the strategy, three projects have been selected for detailed examination: SUT circularity, Take-Back Systems, and Solvent recovery. These are presented as case studies, each initiated specifically to operationalize the CE strategy and therefore directly reflecting its objectives and intended outcomes.

Although no formal Reference Model or Impact Model was created during the development of the CE strategy, the core elements of these models were implicitly embedded in the work conducted in Part A and in the initial project documentation. The reference context, covering baseline CE maturity, existing environmental initiatives, and sector-specific regulatory constraints, was drawn from the literature review, empirical study, and the organizational context analysis. Similarly, the intended impacts of the CE strategy, such as increased material recovery rates, enhanced stakeholder collaboration, and integration of CE tools into operational decision-making, were identified in the strategy's objectives and roadmap.

For the purposes of evaluation, these elements served as a reconstructed baseline and expected impact pathway, allowing project outcomes to be interpreted in light of both the initial context and the strategic goals.

4.8.2. Case study #1 – Single Use Technologies (SUT) circularity

The SUT Circularity project was initiated to explore how CE principles could be applied to one of the fastest-growing manufacturing technologies used in pharmaceutical production. Single Use Technologies, while offering operational flexibility and efficiency gains, generate substantial volumes of complex waste that are rarely recovered. This project targeted both the recovery of high-value components, such as rare-earth magnets, and the improvement of site-level waste management practices for SUT more broadly. By addressing these challenges through pilot trials, procedural tools, and supplier engagement, the project sought to develop actionable pathways for reducing the environmental impact of SUT while maintaining compliance with stringent regulatory requirements.

4.8.2.1. Context and relevance

Single Use Technologies (SUT) have become increasingly prevalent in pharmaceutical manufacturing, particularly within biotechnology processes. Their adoption is driven by operational flexibility, modularity, and reduced infrastructure requirements compared to traditional stainless-steel systems. For example, Sanofi's Modulus production platform is designed to operate almost entirely with SUT, enabling rapid reconfiguration of manufacturing spaces and simultaneous production of different vaccines. This reflects a broader industry trend towards modular facilities and SUT-based manufacturing.

However, as their name suggests, SUT are designed for single use (SU) and are typically discarded after operation. Most components are multi-layer plastic assemblies which can contain metal parts and sensors. For instance, SU mixing bags often contain magnets, made of rare-earth. The majority of these technologies are currently disposed of as contaminated waste, regardless of actual contamination status. This conservative waste classification is driven by strict pharmaceutical and healthcare regulations, as well as a risk-averse culture that prioritizes biosafety. At Modulus, a preliminary estimate suggested that approximately 500 tons of SUT waste could be generated annually, with over 60% being non-contaminated.

Life Cycle Assessment (LCA) studies, most often commissioned by SUT suppliers, indicated that, under certain conditions, SUT present a lower environmental footprint than stainless steel alternatives, largely due to the elimination of cleaning and sterilization cycles (Budzinski et al., 2022b; Flanagan et al., 2011; GE, 2013; Whitford et al., 2019). In pharmaceutical manufacturing, Cleaning-In-Place (CIP) and Sterilization-In-Place (SIP) processes require large quantities of high-purity water (i.e., purified water or water for injection) produced with significant energy inputs, and of chemical agents. Avoiding these steps can offset the impacts of producing and discarding SUT. Nonetheless, comparative LCAs show that this advantage is not universal, at high process volumes (>4,000 L), stainless steel may outperform SUT (Pietrzykowski et al., 2013). Furthermore, the robust multi-material construction of SUT limits disassembly and recycling potential, presenting a significant end-of-life challenge.

Against this backdrop, Sanofi launched several initiatives to explore circular strategies for SUT, including pilot projects with suppliers and waste vendors, with a particular focus on high-value components such as magnets.

4.8.2.2. Objectives

The SUT circularity program was conceived as a strategic component of the broader CE integration effort within pharmaceutical manufacturing. It aimed to address both immediate, high-impact recovery opportunities and the structural barriers preventing systemic end-of-life improvements for SUT. The objectives were threefold:

First, to implement closed-loop recovery for high-value SUT components, with a particular focus on rare-earth magnets embedded in single-use mixers. These magnets represent a scarce and strategically important resource, whose recovery can generate significant economic and environmental benefits. Establishing a viable remanufacturing pathway for such components required not only the technical validation of remanufacturing processes but also the development of safe, compliant, and cost-effective operational and logistics models.

Second, to improve the end-of-life management of SUT more broadly by working closely with suppliers, waste vendors, and internal biosafety experts. This included creating tools and procedures, such as a decision tree for SUT waste classification, that could provide clear, operational guidance to site teams. Such improvements aimed

to overcome the current absence of unified criteria and to ensure that recycling or other recovery options are systematically considered alongside biosafety requirements.

Third, to develop scalable models for combining recovery loops, integrating component remanufacturing, material recycling, and improved waste segregation, so that multiple pathways could operate in parallel. By designing these loops with scalability in mind, the program aimed to facilitate future deployment across sites and potentially across the wider pharmaceutical sector. The ambition was not only to demonstrate technical feasibility through pilot initiatives but also to define organizational, regulatory, and supply chain conditions under which these loops could deliver sustained environmental benefits at scale.

4.8.2.3. Activities

The SUT circularity program was launched with the objective of exploring material recovery loops for high-value components and materials. This program comprised a set of several initiatives summarized in Figure 68.

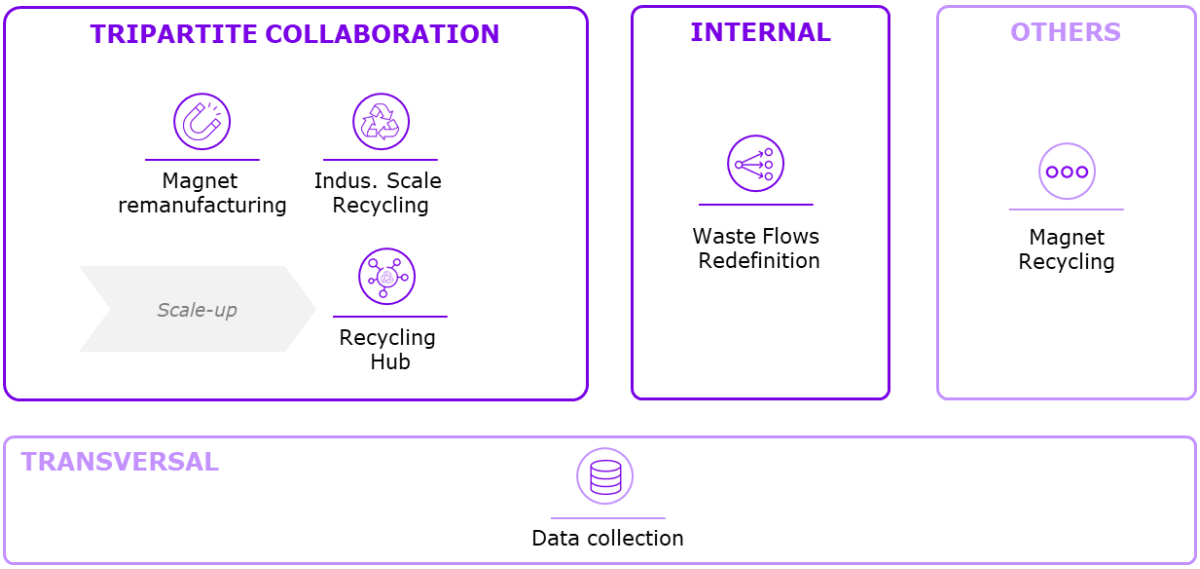

Figure 68. Overview of initiatives on Single-Use Technologies

The first priority was rare-earth magnets embedded in Single-Use (SU) mixing systems, due to their scarcity, high market value, and the relative simplicity of extracting them compared to plastics. The initiative originated from two manufacturing sites that had identified the magnet issue and was co-developed with the supplier producing these magnets.

A Sanofi site was selected for the pilot based on its use of the relevant single-use mixers, its dual R&D and manufacturing function (offering flexibility for testing new approaches), and its interest in reducing the environmental impacts of manufacturing. An operating procedure was developed in collaboration with the site's manufacturing team for recovering magnets from non-contaminated mixers. This involved cutting the bag under controlled conditions, draining any remaining liquid, washing the magnet to remove residual media (e.g., glucose, saccharose), and placing it in a dedicated box.

Early in the pilot, practical issues emerged. Magnets stored together would strongly adhere, making separation difficult. Disassembly of the single-use mixer was also not straightforward, as the design did not facilitate removal of the magnet. Furthermore, uncertainties arose over how magnets should be classified for transport, whether as waste or as a product. Classification as waste would prevent direct return to the supplier, as the supplier was not a qualified waste vendor. Additionally, once sent to the onsite waste management building, the magnets would legally become waste.

An initial face-to-face meeting in June 2023 aligned stakeholders on procedures and constraints. By April 2024, a second site visit was held with the supplier and Sanofi's project team to assess progress. At this stage, 22 magnets

had been collected. The supplier confirmed that reused magnets could match the performance of new ones. At this time, the key challenges identified included:

- Determining how to send magnets to the supplier without attached plastic parts.
- Quantifying potential collection volumes across the site and buildings.
- Addressing storage constraints, as magnets stick together when stored in bulk.
- Safety considerations for handling powerful magnets (e.g., risks to pacemaker wearers, attraction to metal tools).
- The lack of Design-for-Disassembly features in the mixers.
- Adapting packaging and labelling to meet regulatory requirements for transport.
- Cost uncertainty, as reused magnets would be more expensive than new ones.
- The absence of a reverse logistics flow from Sanofi to the supplier, raising questions over ownership and transport costs.

Following this visit, it became evident that the project required stronger coordination. In July 2024, a formal project team was established with bi-monthly meetings, bringing in site representatives, supplier project leads, and technical experts in magnets and packaging. This team addressed three main workstreams:

(1) **Packaging and storage**: prototypes were developed to keep magnets separated during collection and transport, ranging from the use of existing mixer components as separators to dedicated packaging solutions. An intermediary packaging method was implemented on-site to store each magnet individually. The final solutions included: (a) dedicated per-magnet packaging preventing contact, and (b) a larger metal-lined boxes to hold multiple individually packaged magnets.
(2) **Flow and shipping process**: to avoid waste classification, magnets were shipped as products, similar to other equipment returns to suppliers. However, reverse logistics remained complex, and a trial shipment from Sanofi to the supplier was organized to identify bottlenecks.
(3) **Standard Operating Procedures (SOP):** specific SOP were developed, and are under development, for magnet extraction, cleaning, packaging, storage, and shipment.

In parallel, opportunities emerged to complement magnet reuse with recycling pathways. A new magnet recycling plant, planned for 2026 and supported by the French government, sought feedstock from industrial sources. Samples of magnets from various single-use assemblies (beyond the mixers in the pilot) were collected to support process development. The aim was to establish a dual-loop model: reuse for the pilot's specific magnets, and recycling for other type of magnets.

Beyond magnets, the program addressed broader SUT recycling opportunities. Building on a 2022 laboratory study showing the feasibility of mechanically recycling a specific SUT bag with high-quality outputs (Luu et al., 2022a), an industrial-scale study was launched with the supplier and a waste vendor, to determine the industrial feasibility of such project.
Three test campaigns were conducted:

- Recycling a single used SUT bag.
- Recycling 100 kg of production scrap.
- Recycling 1000 kg of production scrap.

Despite the positive outcomes from the recyclability tests, the main challenge remained the on-site segregation of these specific SUTs.

As the various SUT circularity initiatives progressed, it became evident that their impact could be significantly amplified if they were integrated into a coordinated, large-scale system. This led to the development of the recycling hub concept as a scale-up pathway for existing projects (Figure 69). The hub would act as a central facility, consolidating non-contaminated SUT waste from multiple sites and, potentially, from other pharmaceutical companies. Once aggregated, the materials could be sorted and directed into the most suitable recovery route, reuse, remanufacturing, recycling, or other valorization processes. The concept was further explored with the support of Sanofi's innovation lab and a startup studio, focusing on how currently isolated initiatives from pharmaceutical companies, suppliers, and waste management partners could be connected into a unified model. Following the logic of other recycling sectors, the approach recognized that waste management is fundamentally

driven by volume: the greater the aggregated quantity, the more economically viable it becomes to manage materials efficiently and generate secondary raw materials in quantities that are valuable for downstream markets.

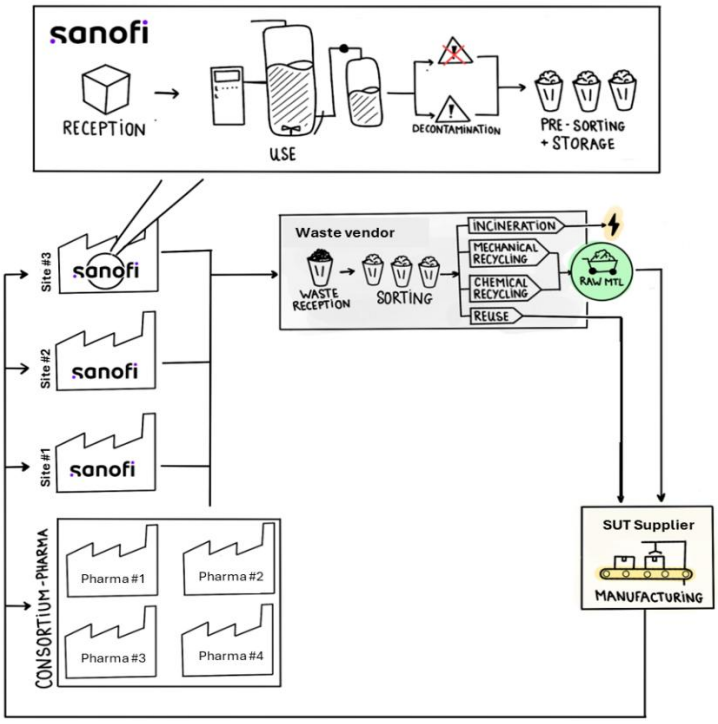

Figure 69. Conceptual illustration of the structure and flows of a potential recycling hub for SUT

To improve end-of-life decision-making for SUT more broadly, it was identified that improving on-site waste management was a key driver. At present, many sites lack clear guidance on handling SUT waste, as no unified criteria had been established. Production teams often faced uncertainty over disposal, and environmental or waste managers, responsible for site-wide waste streams, were not always aware of the specific constraints associated with SUT. Furthermore, the diversity and volume of SUT types made it difficult to identify barriers and potential solutions. To address this, in collaboration with biosafety officers, a decision tree for SUT end-of-life management was developed. This tool classifies SUT streams based on contamination area, hazard level, and other biosafety considerations, identifying which can be recycled and which require inactivation. Validated for France, it can be replicated in other geographies but must be adapted to local regulations. Importantly, the decision tree also facilitates data collection by mapping flows: for example, starting with 100% of SUT entering the process, determining the proportion at each classification stage (biosafety level, contact with pathogen, etc.) to yield a final percentage of potentially recyclable SUT per production line. As such, it provides both a practical decision-making tool and a foundation for data-driven waste management improvement. Its structure could be generalized for other waste types beyond SUT.

Recognizing the role of suppliers in enabling circularity, a final initiative focused on integrating environmental performance into SUT design. While Sanofi has limited influence over the intrinsic environmental impacts of SUT once designed, suppliers can directly influence these through product and packaging design choices. In collaboration with R&D and production experts, a set of key design criteria was developed, covering both functional and environmental aspects of SUT and their packaging. A cross-functional approach involving Manufacturing, Global Environment, Sustainable Procurement, and Procurement teams was created to engage directly with top SUT suppliers. These suppliers were asked to share their current and planned environmental actions, aligned with the identified design criteria and Sanofi's sustainable procurement strategy, which prioritizes carbon emissions reduction. This engagement not only aimed to understand supplier roadmaps but also to signal Sanofi's maturity and expectations on environmental sustainability, positioning environmental performance as a factor that could influence future supplier selection.

4.8.2.4. Key outcomes and challenges of SUT circularity

The SUT circularity program delivered measurable results across multiple recovery pathways, demonstrating both the technical feasibility and operational challenges of implementing CE loops for high-value components and materials in a regulated manufacturing environment (Table 19).

Table 19. Synthesis of the outcomes and challenges related to SUT projects

Pilots	Key outcomes	Key challenges
Magnet reuse	Demonstrated the technical feasibility of reusing rare-earth magnets from SU mixers. A total of 50 units were collected, cleaned, individually packaged to prevent sticking, and returned to the supplier. Performance testing confirmed they were equivalent to new magnets. The process included the creation of SOP for magnet collection and storage, and new ones are planned for shipment, and the development of dedicated packaging solutions to address handling and transport constraints.	Collection volumes remained low and unpredictable due to limited visibility of where relevant mixers were used. Operators faced space and time constraints for recovery activities, and reverse logistic was complicated by the classification of magnets and restrictions on cross-border transport of strong magnetic materials. Cost implications remained uncertain as the pilot stage did not yet yield a mature cost model.
Magnet recycling	Samples from a range of single-use technologies were collected and sent to a new French recycling center, in order to confirm process compatibility and laying the foundation for the recycling of SU magnets.	Although technically feasible, this project was hindered by difficulties in accessing production waste, collecting representative data on magnet usage across multiple sites, and defining optimal processing methods for magnets encapsulated in complex plastic parts.
Industrial-scale recycling	Conducted three trials, 1 bag, 100 kg production scrap, and 1000 kg production scrap, which confirmed the technical feasibility of mechanically recycling certain SUT bags into secondary materials. These results provided industrial proof-of-concept, though their success was contingent on effective on-site segregation of non-contaminated SUT.	Technical success depended heavily on obtaining large, clean, and well-segregated waste streams. Without dedicated on-site sorting processes, the quality and consistency of input materials risk to undermine downstream recycling performance. The availability of suitable local end-markets for recycled outputs was another critical factor for local viability.
Recycling hub concept	Advanced from a conceptual idea to a preliminary feasibility analysis. Data collected across Sanofi sites and from discussions with other pharmaceutical companies, suppliers, and waste vendors supported the identification of potential hub scenarios for consolidating, sorting, and directing SUT waste streams to the most suitable recovery route.	The concept generated strong interest from internal and external stakeholders, but practical deployment would require robust multi-party governance, cost-sharing agreements, and alignment on technical specifications and regulatory compliance.
SUT waste decision tree	Developed, validated for France, and used to classify SUT streams based on biosafety and hazard criteria. The tool not only enables clear, consistent decisions on which SUT could be recycled versus destroyed but also provides a structured framework for mapping material flows and quantifying potentially recyclable volumes along the production process	The tool proved effective for clarifying waste classification and recycling potential but also exposes tensions between biosafety risk avoidance and material recovery. In some cases, non-infectious but hazardous materials (e.g., certain proteins) mandates destruction, reducing recycling potential unless specific risk assessments are justified by high volumes.

Supplier engagement initiative	Implemented a structured dialogue with top SUT suppliers, requesting detailed information on current and planned environmental actions aligned with jointly defined design criteria. The initiative reinforces sustainable procurement goals and positions environmental maturity as a potential differentiator in supplier selection.	The initiative confirmed that supplier environmental maturity can influence procurement decisions but also revealed the need for standardized metrics and evaluation frameworks to enable fair, transparent comparison across suppliers and product lines.

Looking forward, the concept of scaling-up SUT initiatives (e.g., centralized recycling hub), emerged as a promising pathway that could integrate several of the program's initiatives and beyond.

4.8.2.5. Conclusion

The SUT circularity program demonstrated that targeted component recovery and broader end-of-life management improvements can coexist within a coherent circularity framework for pharmaceutical manufacturing. Although the magnet reuse and recycling pilots validating technical feasibility, their scalability will depend on overcoming operational constraints such as waste segregation, reverse logistics, and cost allocation. The decision tree and supplier engagement initiatives provided the procedural and strategic foundations for broader adoption, while the recycling hub concept offers a unifying scale-up pathway capable of integrating multiple recovery loops. Taken together, these initiatives illustrate both the potential and the systemic challenges of embedding circular practices in a regulated, risk-sensitive industrial context.

4.8.3. Case study #2 – Take-Back Systems

The Take-Back Systems project examined how insulin injection pens, a major post-consumer medical waste stream, could be collected and recycled through collaborative, large-scale initiatives. By piloting schemes in Denmark and France, the project aimed to demonstrate technical feasibility, measure environmental benefits, and develop guidelines for future take-back models adapted to different regulatory contexts.

4.8.3.1. Context & Relevance

Insulin injection devices (or pens) represent a major waste stream in diabetes care, with over 84 million units used annually in France alone, requiring around 1,500 tons of plastic for their manufacture. Most are currently disposed of via incineration or landfill due to their classification as sharps waste, despite containing high-quality plastics and metals suitable for recovery. Chronic conditions such as diabetes generate large volumes of such post-consumer medical waste, highlighting the need for safe, compliant, and environmentally responsible disposal solutions.

Take-Back Systems (TBS) offer a structured approach to address this challenge by enabling the collection, decontamination, and recycling of used devices. They require alignment between manufacturers, waste managers, regulators, and healthcare providers, and must be adapted to the local regulatory and infrastructure context. Within this framework, Sanofi has partnered with other pharmaceutical companies to develop collaborative TBS models, aiming to increase material recovery rates, reduce environmental impacts, and prepare for emerging regulatory requirements on recyclability and extended producer responsibility.

4.8.3.2. Objectives

The Take-Back System project was designed to demonstrate the feasibility and value of collaborative, large-scale recycling initiatives for insulin pens, integrating them into existing healthcare and waste management infrastructures. Its first aim was to establish operational pilots that could recover high-quality materials from used devices while maintaining strict compliance with biosafety and regulatory requirements. A second objective was to quantify the environmental performance of these systems through Life Cycle Assessment (LCA), ensuring that their contribution to reducing the overall product footprint was both measurable and credible, supported by third-

party review. Finally, the project aimed to translate the lessons from these pilots into a set of operational, governance, and design guidelines that could serve as a reference for future TBS initiatives, guidelines that would ensure environmental benefit, economic viability, and adaptability to diverse regulatory and infrastructural contexts.

4.8.3.3. Activities

The main activities related to the TBS initiatives are summarized below. Figure 70 presents the overall process, including the inputs and outputs of a TBS. The key activities described hereafter can be directly linked to this diagram.

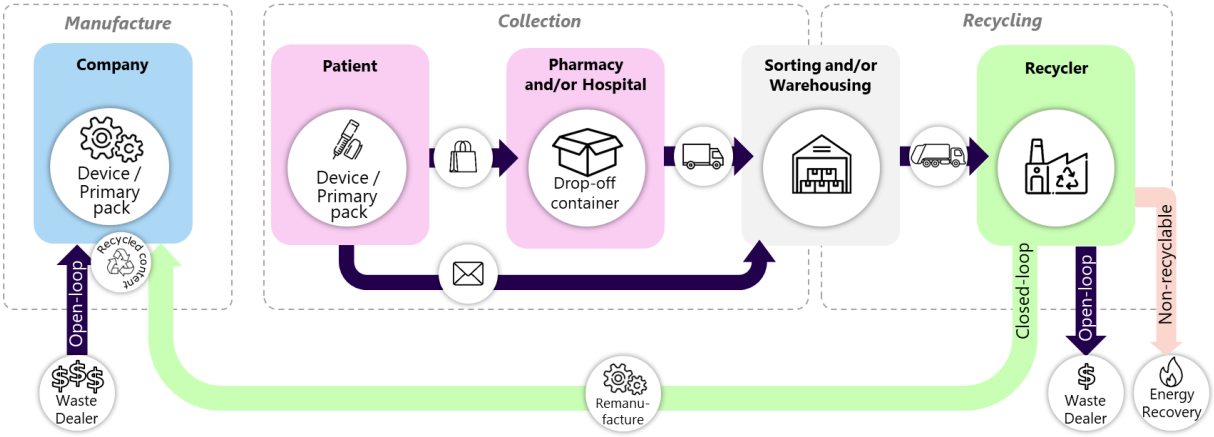

Figure 70. Take-Back Systems essentials: key elements and main environmental considerations

Initiation and partnership setup

The Take-Back System (TBS) project originated in Denmark, where Novo Nordisk had launched the Returpen program to address the end-of-life management of insulin injection pens (Mallick et al., 2022). Sanofi joined the initiative as co-lead, alongside Novo Nordisk, Eli Lilly, and Merck, making it the first cross-industry collaboration of its kind for medical device recycling. The rationale for starting in Denmark was the country's mature recycling infrastructure and strong culture of waste segregation, which provided an enabling environment for piloting a technically complex system. The four companies collectively account for approximately 5.2 million injection pens placed on the Danish market each year, representing a significant stream of high-quality materials, primarily engineering plastics, that would otherwise be incinerated.

Design and implementation of the Danish pilot

The Danish model was designed as a nationwide collection scheme integrated into the existing healthcare supply chain. Pharmacies served as collection points, distributing dedicated collection bags to patients and receiving filled bags for consolidation. These bags were then transported to wholesalers and, via reverse logistics, to the recycling facility. The scheme was designed to minimize additional environmental impacts by leveraging existing transport routes wherever possible. A dedicated recycling partner developed new processing lines to handle the collected pens, which included decontamination, mechanical disassembly, and separation of material fractions. Early tests achieved a more than 70% recycling rate by mass, with the remaining materials directed to incineration with energy recovery.

Environmental assessment and validation

To assess the environmental performance of the pilot, an external consultancy conducted a Life Cycle Assessment (LCA) based on confidential data from all four participating companies. The scope covered both front-end and back-end stages of the TBS. The front-end included the environmental burdens associated with producing and transporting collection bags, pharmacy drop-off containers, and communication materials, as well as the reverse logistics to the recycling facility. The back-end covered the environmental credits associated with recycling, offsetting virgin material production, and the impacts of energy recovery from non-recyclable fractions. Sanofi reviewed the methodology, validated the assumptions, and re-modelled the system internally to confirm results. The Danish pilot was found to deliver a global reduction across several indicators, considering the overall lifecycle of the associated insulin product, with benefits driven primarily by plastic recovery.

Adaptation to the French context: RECYPEN

Building on the Danish experience, Sanofi and Eli Lilly partnered with DASTRI, the national organization managing healthcare sharps waste, to launch RECYPEN, the first injection pen recycling initiative in France (DASTRI, 2024). Following regulatory approvals under the September 2022 decree and November 2022 arrêté, RECYPEN was launched in July 2024 in four pilot regions: Auvergne-Rhône-Alpes, Grand Est, Hauts-de-France, and Occitanie (Figure 71). Although the program aimed to collect 30% of used pens in its first year, early results showed that take-back rates remained very low, with frequent mis-sorting of medical waste by patients and limited engagement at collection points. As a result, the front-end collection process faced operational challenges, and industrial-scale recycling could not yet be achieved; technical issues during disinfection and component separation further constrained processing at the DASTRI Lab. Overall, the pilot confirmed the feasibility of establishing a compliant collection pathway but also highlighted significant room for improvement across both collection and recycling stages.

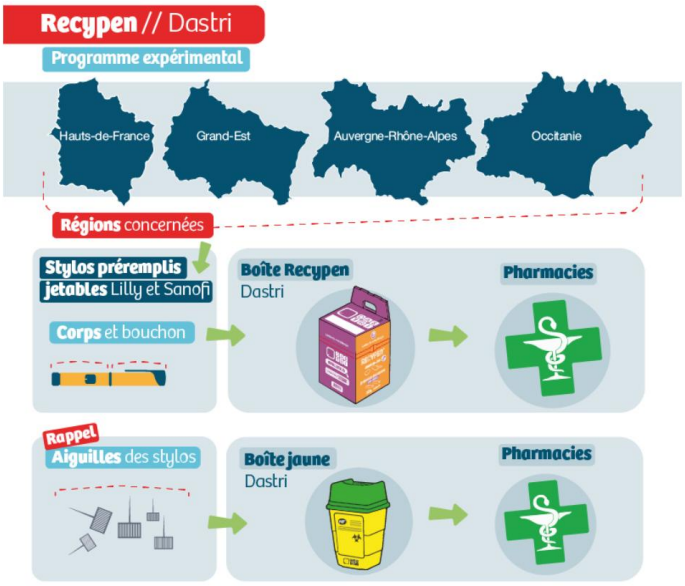

Figure 71. Overview of the Recypen TBS (Source: DASTRI, 2025)

At the DASTRI Lab, collected pens were disinfected and then shredded before being sorted into material fractions. The presence of glass components created operational difficulties during shredding, limiting the efficiency and consistency of downstream separation. Recovered plastics were directed to recycling streams with established market demand, while non-recyclable fractions were sent for energy recovery. The operational model was specifically adapted to the French waste management context, where regulatory classification of sharps waste imposes stricter handling and transport requirements than in Denmark.

Operational learnings and methodology development

The Danish and French pilots highlighted the importance of designing TBS with two distinct elements in mind:

- **Front-end:** all activities and materials required to collect, and transport used devices, where environmental impacts are influenced by design choices (e.g., use of recycled or recyclable collection containers), distance optimization, and integration into existing logistics.
- **Back-end**: Recycling processes and outcomes, where benefits depend heavily on recycling rates (targeted at ≥70–80%), material quality, and market demand for secondary materials.

These insights fed into the development of an internal TBS position paper that synthesized the environmental, operational, and governance aspects of designing effective take-back systems. The document also incorporated recommendations for integrating TBS into product-level LCAs, including third-party critical reviews, to ensure credible environmental performance claims.

Knowledge sharing and extension to other products

In spite of the current TBS focusing on injection pens, the methodology was also evaluated for potential application to other device types and primary packaging, using the same environmental threshold criteria. Opportunities were

identified for alignment with sustainable procurement strategies, regulatory readiness (e.g., future EU Packaging and Packaging Waste Regulation requirements), and broader industry collaboration to achieve economies of scale and harmonized systems.

4.8.3.4. Key outcomes and challenges

The TBS projects yielded positive results, demonstrating both their feasibility and operational challenges of implementing CE loops for post-consumer waste (Table 20).

Table 20. Synthesis of the outcomes and challenges related to TBS

Main elements	Key outcomes	Key challenges
Pilot deployment and geographic coverage	Successful launch of collaborative pilots: the Returpen program in Denmark (nationwide coverage) and RECYPEN in France (four pilot regions). Both programs established proof-of-concept for large-scale, multi-company injection pen recycling.	Collection rates below initial targets in early months, with participation dependent on patient awareness and convenience. Scaling beyond pilot regions requires substantial coordination and resource allocation.
Collection infrastructure and logistics integration	Integration of collection into existing healthcare and waste management infrastructure, minimizing additional environmental burdens. In Denmark, existing pharmacy–wholesaler loops were leveraged; in France, DASTRI's established "purple box" network was used.	Ensuring consistent infrastructure performance across diverse geographies, adapting to different logistics operators and systems; managing space constraints in pharmacies and warehouses.
Material recovery and recycling performance	Achieved >70% recycling rate by mass in the Danish pilot, recovering high-quality plastics and metals with established market demand.	Achieving consistent high recovery rates across device types; variability in material composition; dependence on market demand for secondary materials; technical constraints in processing mixed or difficult fractions.
Environmental performance assessment (LCA)	Conducted LCAs for both pilots using confidential multi-company data, verified through internal re-modelling. Identified overall reduction in product lifecycle footprint, primarily from plastic recovery.	Limited environmental benefit relative to total product footprint; need for rigorous, standardized methodology and third-party review to support external communication; dependency on accurate, site-specific data.
Governance and cross-industry collaboration	Established functional cross-industry partnerships involving multiple pharmaceutical companies, waste management operators, and recyclers. Developed an internal TBS position paper outlining design principles and operational guidelines.	Maintaining long-term commitment from all partners; aligning priorities and resources; navigating competition law constraints in collaborative communications.
Economic and cost-effectiveness considerations	Demonstrated potential to offset some long-term costs through material value recovery and avoidance of disposal fees; identified opportunities for cost sharing across partners.	High initial costs for infrastructure, awareness campaigns, and recycling process adaptation; uncertain economic viability at lower collection volumes; exposure to market fluctuations for recycled material prices.
Regulatory compliance and adaptation	Pilots complied with national biosafety and waste transport regulations; France	Complex and differing national regulations on waste classification and sharps handling; cross-border transport

	adapted the model to meet stricter sharps waste handling requirements.	restrictions; need for site-specific regulatory approvals before implementation.

4.8.3.5. Conclusion

The TBS project demonstrated that large-scale, collaborative take-back programs for insulin pens are both technically and operationally feasible, delivering measurable environmental benefits when high recycling rates and material recovery targets are achieved. Even though the absolute carbon savings per product are modest, these initiatives contribute meaningfully to responsible end-of-life management, regulatory preparedness, and corporate sustainability leadership. The pilot in Denmark has provided not only proof-of-concept but also the practical experience, governance structures, and operational models needed to guide future implementations. Scaling up will require harmonized frameworks adaptable to national regulations, broader industry participation, and continued investment in recycling technologies to improve material purity and yield. Embedding TBS into sustainable procurement criteria and ESG reporting could create further incentives for adoption, while extending the model to other device categories and primary packaging would build a portfolio of take-back solutions capable of delivering measurable environmental gains across product lifecycles.

4.8.4. Case study #3 – Solvent recovery

Solvents represent a substantial share of the materials used in pharmaceutical manufacturing and are often among the most environmentally impactful substances in production processes. They are essential in both synthesis and cleaning operations, yet their high volumes, hazardous nature, and frequent incineration at end-of-life create significant opportunities for environmental impact reduction. This project was initiated to evaluate the technical and operational feasibility of moving from solvent incineration to recovery and regeneration, starting with a detailed analytical phase and progressing through pilot testing to potential industrial implementation.

4.8.4.1. Context & relevance

Pharmaceutical manufacturing frequently operates in campaign mode, meaning that a given site does not produce the same products continuously throughout the year. Instead, production shifts between campaigns, each with its own set of raw materials, processes, and therefore, waste streams. This operational variability complicates the segregation and recovery of solvents, as the composition of solvent waste can change significantly between campaigns.

As highlighted in both the literature review and empirical investigations, solvents account for a considerable portion of the environmental footprint of pharmaceutical manufacturing (K.L. Ang et al., 2021), particularly through their production, use, and disposal, and especially used for small-molecule manufacturing. Current practice in many facilities involves treating waste solvents as hazardous waste and sending them for incineration, leading to both direct CO_2 emissions and the loss of potentially recoverable high-value materials. By establishing a recovery pathway, significant environmental and financial gains could be achieved while also reducing reliance on virgin solvents.

4.8.4.2. Objectives

The solvent regeneration project aimed to establish a clear, scalable process for identifying, segregating, and regenerating waste solvent streams within a pharmaceutical manufacturing site. The first objective (now completed) was to conduct a comprehensive analytical study of solvent waste generation, mapping volumes, compositions, and variability to determine the technical feasibility of recovery. The second objective, currently being initiated, is to validate recovery potential through pilot-scale regeneration trials, using representative samples from production campaigns. The third objective, planned for a later stage, is to define an industrial-scale implementation plan, including collection logistics, regeneration partnerships, and operational integration, with the goal of transitioning from incineration to solvent recovery wherever feasible.

4.8.4.3. Activities

The activities for the solvent recovery initiative were planned in three phases.

Phase 1 – Analytical characterization of solvent waste streams (completed)
The analytical phase focused on building a complete inventory of solvent waste streams generated at the site throughout the year. This involved tracking each solvent waste type and associated volume across different production campaigns. High-volume solvents were prioritized for recovery assessment. This inventory allowed for the identification of a collection planning along the year. For each selected stream, 5-litre samples were collected at key points along the production line. The collected samples resulted from manufacturing, either being used for production, as a raw material, or for cleaning and sterilization operations.

In parallel, the waste vendor engaged with potential solvent regenerators, capable of conducting analyses and trial regenerations. These regenerators received the samples and performed analytical work to identify the precise composition of each waste stream, critical for understanding recovery feasibility, particularly for cleaning solvents containing residues from multiple processes.

The analyses served two purposes: (1) confirming the identity and purity of the main solvent components, and (2) determining the regeneration potential based on impurity profiles and process compatibility. A further objective was to identify opportunities for stream pooling, combining solvent wastes from different campaigns where the main component (e.g., >95% dichloromethane) was common, to increase recovery volumes and improve regeneration economics. The exploration of market considerations for reusing regenerated solvents externally was also considered within this phase as a key component for solvent prioritization and potential of regeneration.

Phase 2 – Pilot-scale regeneration trials (planned)
Based on the findings of Phase 1, the next step will be to send selected solvent waste streams to pilot regeneration trials at the identified regenerators' facilities. To perform these trials, small tanks need to be installed onsite, creating additional burdens and risks. These small-scale trials will assess recovery yield, purity, and manageability of residues with bigger volumes. Pooling opportunities identified in Phase 1 will also be tested to confirm technical and economic viability.

Phase 3 – Industrial implementation planning (not started)
The final phase will design an operational model for solvent recycling at industrial scale. This will include mapping internal collection points, defining storage and transport requirements, integrating regeneration partners into waste management workflows. A key consideration at this stage will be the investment costs associated with implementation. These include mainly the potential installation of new tanks, and dedicated tubing for solvent waste segregation. The cost estimates for such infrastructure are challenging to predict accurately in advance, with preliminary ranges varying from several hundred thousand euros to millions, depending on the site layout, safety requirements, and scale of operations.

4.8.4.4. Key outcomes and challenges

The Solvent recovery project demonstrated key insights for recovery, feasibility and associated challenges. Even though the project is still ongoing, several key outcomes and challenges were identified (Table 21).

Table 21. Synthesis of the outcomes and challenges related to the Solvent recovery project

Main elements	Key outcomes	Key challenges
Project initiation and scope	Defined a clear three-phase project structure (analytical phase, pilot regeneration trials, and industrial implementation planning) to transition from solvent incineration to recovery in campaign mode.	Establishing alignment across internal stakeholders, waste vendor, and regenerators on project scope, priorities, and timelines.
Analytical characterization of solvent waste	Comprehensive mapping of solvent waste streams over multiple production campaigns, including volumes, compositions, and variability.	High variability in solvent composition between campaigns; lack of detailed compositional data at site level before project start. Market acceptance depends

		on meeting strict purity standards; demand for regenerated solvents can fluctuate; commercial viability sensitive to price competition with virgin solvents.
Sample collection and analysis	Samples collection organized monthly; Collected 5L samples of high-volume solvent streams and sent to two potential regenerators for analysis to assess composition and recovery potential.	Logistical complexity of collecting representative samples across multiple campaigns; ensuring safe handling and transport of hazardous samples; Missing the collection of a sample meant waiting another year for collection and analysis.
Pooling opportunities	Identified potential for pooling solvent streams with similar main components (e.g., >95% DCM) to increase regeneration volumes and improve economic viability.	Risk of contamination or reduced purity when pooling streams; need for strict compatibility assessments to maintain quality.
Pilot-scale regeneration trials	N/A	Requires coordination with partners, availability of equipment, specific authorization and sufficient sample volumes; potential variability in results depending on waste stream composition; securing budget for pilot runs.
Industrial implementation planning	N/A	Adapting to site-specific constraints (space, safety procedures, production schedules) is complex; high uncertainty in cost estimation for required infrastructure (new tanks, tubing, segregation systems).

4.8.4.5. Conclusion

The solvent recycling project has established a robust analytical foundation for transitioning from solvent incineration to recovery in a campaign-based manufacturing context. While the regeneration and implementation phases are still ahead, Phase 1 has delivered the necessary technical insights, volume data, and compatibility assessments to guide the next steps. By progressing through pilot testing and industrial design, the project has the potential to significantly reduce the environmental impact of solvent use and align with broader corporate commitments to circular resource management.

4.8.5. Evaluation of the CE strategy

The projects conducted provided a basis to assess both the Circular Economy (CE) strategy implemented and its practical relevance. The evaluation was structured around two complementary dimensions: the fit and applicability of the CE strategy and the dynamics of collaboration, the latter analyzed through both the quality of stakeholder engagement and the actual success of the projects in delivering CE-related outcomes.

This section is organized into two parts. The first presents a detailed evaluation of three selected case studies, examining each in terms of their alignment with the CE strategy, the quality of collaboration, and the level of tangible results achieved. These case studies were selected because they originated directly from CE priorities defined during the strategy design phase, making them particularly suitable for assessing both strategic fit and implementation performance.

The second part provides a cross-case analysis covering all projects described in Section 3.1 (Projects Overview), offering a broader perspective on how the CE strategy has been applied. Together, these analyses aim to determine the degree to which the strategy is relevant and applicable, while also testing whether collaboration functions as a critical driver of effective CE integration in the pharmaceutical context.

4.8.5.1. Evaluation of the strategy through the case studies

The evaluation of the case studies was performed regarding all evaluation plans presented earlier, in Section 4.7.3. Each case study was assessed with the different evaluation frameworks and a comparative analysis was done with all of them. This section provides the detailed results of the evaluation, allowing for a better understanding of what meant each scoring attributed to each criterion.

SUT circularity

This first case study was evaluated through active participation in its planning and execution, complemented by a review of project documentation and outputs. The assessment drew on both firsthand observations and recorded evidence to ensure a comprehensive appraisal against the defined criteria.

Table 22. Evaluation results of strategy effectiveness for the SUT projects

Criteria	Score	Explanation
Integration with existing initiatives	2	No dedicated SUT waste management initiative existed, but general waste practices and environmental awareness were already in place.
Sector-specific relevance	5	Fully considers all CEIM dimensions, especially regulatory requirements (e.g., biosafety contamination) and engagement of relevant stakeholders.
Alignment with CE goals	5	Fully aligned with overall waste management and improvement objectives.
Operational relevance & roadmap alignment	3	Consistent with roadmap and KPIs, but contribution of SUT projects to KPI improvements is unclear due to lack of data.
Collaboration enablement	5	Initiatives identified and advanced through strong collaboration, internally with production teams and externally with suppliers and waste vendors; shared governance established.
Scalability & replicability	4	Most projects could be applied at other sites, though some require significant redesign or changes to work procedures.
Environmental impact reduction	2	Impact reduction potential acknowledged but not quantified; only rough estimates available.
Innovation potential	4	Introduces new loops for specific materials and potential new business models for suppliers (e.g., SU mixer and magnet); could evolve into product–service systems.
Overall score	**3,9**	**Good** – well-implemented with robust results, but at least one key area (e.g., measurement, scalability) needs improvement.

Table 23. Evaluation results of collaboration quality for the SUT projects

Criteria	Score	Explanation
Stakeholder diversity	4	Multiple stakeholder groups engaged, including production, HSE, and procurement, and several external actors.
Depth of engagement	1	Stakeholders showed interest but had limited availability to actively contribute, restricting progress.
Knowledge exchange quality	2	Knowledge transfer was sufficient for some projects but lacking for others due to insufficient data or time to gather it.
Enablers and barriers management	2	Several obstacles were faced; some were overcome, but resolution often took months.
Long-term partnership potential	3	Collaboration with suppliers and waste vendors is likely to continue, but dependent on project outcomes.
Overall score	**2,4**	**Weak** – limited diversity, shallow engagement, few sustained partnerships.

Table 24. Evaluation results of project success for the SUT projects

Criteria	Score	Explanation

Achievement of project objectives	2	Some objectives met, others not; most achieved ones were delayed.
Functionality/ Technical performance	1	Intended outcomes not yet achieved; projects are still ongoing with no final results.
Stakeholder satisfaction	2	While interest was high, frustration emerged over slower-than-expected progress.
Long-term viability	2	Sustainability depends on integration into a broader system; otherwise, viability is low.
Environmental impacts achievement	2	No measurable benefits yet, as initiatives remain in pilot phase.
Overall score	**1,8**	**Weak** – Project has limited success, major objectives unmet or impacts minimal; substantial redesign needed.

Take-Back Systems

This second case study was evaluated mainly through the review of project documentation and outputs. The assessment drew on discussions, observations, and recorded evidence to ensure a comprehensive appraisal against the defined criteria.

Table 25. Evaluation results of strategy effectiveness for Take-Back Systems

Criteria	Score	Explanation
Integration with existing initiatives	3	Linked to eco-design projects and GBU activities.
Sector-specific relevance	5	Fully aligned with all CEIM dimensions and pharmaceutical sector specificities.
Alignment with CE goals	3	Aligned with CE and sustainability objectives by addressing EoL treatment, a relevant Scope 3 impact driver (Category 12) that can be directly influenced by the company. However, long-term post-consumer CE goals remain partially undefined, limiting full alignment.
Operational relevance & roadmap alignment	3	Provided operational learnings for both post-industrial and post-consumer waste handling. Although biohazard management adds constraints after the use phase, the recovery, sorting, and circularity challenges are comparable, offering actionable insights for roadmap development.
Collaboration enablement	5	Initiated by Novo Nordisk; collaboration is essential due to high costs and modest environmental benefits when undertaken alone.
Scalability & replicability	4	Replicable across regions but requires local adaptation to healthcare systems.
Environmental impact reduction	4	Documented reductions across the full product life cycle.
Innovation potential	5	Drives entirely new business models for pharmaceutical companies.
Overall score	**4**	**Good** – well-implemented with robust results, but at least one key area (e.g., measurement, scalability) needs improvement.

Table 26. Evaluation results of collaboration quality for Take-Back Systems

Criteria	Score	Explanation
Stakeholder diversity	5	All key internal and external stakeholders involved, spanning functions and organizations.
Depth of engagement	5	Full participation in decision-making and solution design.
Knowledge exchange quality	4	Comprehensive data sharing, with some confidentiality constraints.
Enablers and barriers management	4	Most barriers overcome, enabling successful pilots and scale-up.

Long-term partnership potential	4	Partnerships are integral to program continuity, barring major shifts in corporate priorities.
Overall score	**4,4**	**Good** – broad involvement and good engagement, with minor gaps in diversity, depth, or continuity.

Table 27. Evaluation results of project success for Take-Back Systems

Criteria	Score	Explanation
Achievement of project objectives	4	Objectives achieved with minor delays; initial recyclability testing gaps noted.
Functionality/ Technical performance	5	Systems delivered intended outcomes, producing and reusing secondary materials from used insulin devices.
Stakeholder satisfaction	4	High satisfaction among all stakeholders, including patients.
Long-term viability	4	Likely to continue as the most complex setup phase is complete and benefits are established.
Environmental impacts achievement	5	Fully achieved intended benefits and documented lifecycle impact reductions.
Overall score	**4,4**	**Good** – Project is highly successful, meeting most objectives and showing strong evidence of replicability, minor gaps remain.

Solvent recovery

This second case study was evaluated through active participation and review of project documentation and outputs. The assessment drew on observations, and recorded evidence to ensure a comprehensive appraisal against the defined criteria.

Table 28. Evaluation results of strategy effectiveness for the Solvent recovery project

Criteria	Score	Explanation
Integration with existing initiatives	2	Aside from on-site waste practice improvements, no strong links to other projects.
Sector-specific relevance	5	Fully aligned with CEIM dimensions, focusing on processes, site, and regulatory requirements.
Alignment with CE goals	5	Fully aligned with defined CE objectives.
Operational relevance & roadmap alignment	5	Shift from solvent incineration to recycling is tracked with CE KPIs.
Collaboration enablement	4	Requires collaboration due to limited internal expertise; involved production, HSE, and external partners for collection, analysis, and regeneration.
Scalability & replicability	3	Replicable where solvents are used, but site and process specifics could make implementation highly variable.
Environmental impact reduction	3	Reduction potential supported by external LCAs but not yet documented for this project.
Innovation potential	3	Creates new loops for solvent management but not a major innovation.
Overall score	**4**	**Good** – well-implemented with robust results, but at least one key area (e.g., measurement, scalability) needs improvement.

Table 29. Evaluation results of collaboration quality for the Solvent recovery project

Criteria	Score	Explanation
Stakeholder diversity	4	Includes multiple functions and external companies.

Depth of engagement	4	Most stakeholders actively contribute to decision-making and problem-solving.
Knowledge exchange quality	3	Knowledge transfer generally effective, though some information took time to circulate.
Enablers and barriers management	4	Most bottlenecks addressed so far; complexity may increase in implementation.
Long-term partnership potential	4	Likely to continue as long as solvents are regenerated under current contracts.
Overall score	**3,8**	**Good** – broad involvement and good engagement, with minor gaps in diversity, depth, or continuity.

Table 30. Evaluation results of project success for the Solvent recovery project

Criteria	Score	Explanation
Achievement of project objectives	4	On track with planned objectives to date.
Functionality/ Technical performance	4	Established processes for sampling, collection, and analysis, enabling informed decisions; pilot regeneration will clarify final outcomes.
Stakeholder satisfaction	4	Most stakeholders satisfied with progress and management.
Long-term viability	4	Expected to continue due to environmental benefits and investment made; minimal additional effort required to sustain.
Environmental impacts achievement	3	Too early for full results but expected to deliver significant benefits if completed as planned.
Overall score	**3,8**	**Good** – Project is highly successful, meeting most objectives and showing strong evidence of replicability, minor gaps remain.

Collaboration dynamics: comparative analysis between case studies

This comparative analysis between the three case studies aimed at addressing one aspect of the SRQ1.2 by examining the relationship between collaboration quality and the success of CE-related initiatives. Using the scores obtained from the collaboration dynamics evaluation (quality and success), each case study was positioned on a two-axis matrix (Figure 72), enabling a visual comparison of how variations in stakeholder engagement align with the achievement of intended CE objectives.



Figure 72. Relation between collaboration and project success (SUT: Single Use Technologies; TBS: Take-Back Systems; Solvent: Solvent Recovery)

4.8.5.2. Cross-project evaluation of the CE strategy performance

This last section of results explored the results across all CE-related projects and their outcomes in terms of CE strategy evaluation (Table 31). This allowed for a broader understanding of the relevance of the CE strategy developed and its potential.

Table 31. Comparison of CE-related projects based on strategy effectiveness scores across evaluation criteria

Projects / Criteria	SUT Circularity	Take-back Systems	Solvent recovery	Manufacturing guide	Portfolio LCA	Value Stream Mapping
Integration with existing initiatives	2	3	2	5	4	3
Sector-specific relevance	5	5	5	5	4	4
Alignment with CE goals	5	3	5	4	4	5
Op. relevance & roadmap alignment	3	3	5	3	3	5
Collaboration enablement	4	5	4	4	4	4
Scalability & replicability	4	4	3	5	4	5
Environmental impact reduction	2	4	3	4	4	3
Innovation potential	4	5	3	3	3	4
Overall score	**3,9**	**4**	**4**	**4,15**	**3,8**	**4,25**

All projects were evaluated with a score between 3,7 and 4,25, placing them in the category: ***Good*** *– well-implemented with robust results, but at least one key area (e.g., measurement, scalability) needs improvement.*

4.9. DISCUSSION

This section interprets and contextualizes the main results obtained. It is organized into four parts. First, the case studies are compared and discussed, both in relation to each other and against the literature reviewed in Part A. Second, the CE strategy is evaluated based on insights from these case studies. Third, the role of collaboration in enabling successful CE-related projects is examined in detail. Finally, the section outlines the study's main limitations and proposes directions for future work.

4.9.1. Key learnings from the case studies

The case studies performed allowed for the identification of key learnings. These learnings are presented and compared between the case studies themselves, and then the challenges identified are linked to prior literature review and empirical study performed in Part A.

4.9.1.1. Cross-case commonalities and differences

The projects linked to CE were not all originally conceived as CE initiatives, yet their contribution to circularity justified their inclusion in the analysis. Together, the case studies addressed three major areas of relevance for CE in the pharmaceutical sector. **SUT circularity** targeted one of today's most pressing challenges in pharmaceutical manufacturing, particularly in large-molecule production, by addressing both sustainable design of SUT and their end-of-life management through remanufacturing, reuse, and recycling. **Solvent recovery** tackled another critical issue: the large-scale use of solvents, especially in small-molecule manufacturing. Even though onsite redistillation

and reuse already exist in many facilities, the selected project focused on a site with specific technical and operational constraints (i.e., campaign mode, number of different solvent types), requiring tailored solutions. **Take-Back Systems (TBS)** represented a higher-level, cross-regional approach, pushing producers to adopt new business models that close product loops, reduce environmental impacts, and extend circular principles into the post-consumer phase. Such programs also stimulated upstream design changes, such as improving recyclability of devices and developing products in line with Design for Circular Economy principles, including Design for Recycling, Design for Disassembly, reducing the number of different materials, and selecting materials with higher recyclability rates.

Taken together, the three case studies covered diverse circular actions and potential loops for the pharmaceutical sector, addressing most of the key components of a comprehensive CE strategy. Their scope and scale, however, varied significantly. Solvent recovery concentrated on a single loop within a single site, adapted to local constraints. SUT circularity encompassed multiple sub-projects and sites, spanning procurement engagement, supplier collaboration, and waste valorization. TBS operated at the strategic level of the company, and for a specific Global Business Unit (GBU), requiring alignment with top management, but also with other pharmaceutical companies and the integration with broader healthcare systems.

This diversity illustrated both the range of opportunities for CE in the sector and the differing levels of complexity involved. While each project delivered key outcomes enabling evaluation against the predefined frameworks, they also faced substantial challenges. Each case study highlighted distinct key challenges tied to particular dimensions of a CE in the pharmaceutical sector. For instance, SUT circularity raised issues around reconciling biosafety requirements with material recovery ambitions, as well as the need for supplier engagement on sustainable design. The take-back systems case exposed the complexity of building patient-facing loops, harmonizing infrastructure across national contexts, and aligning cross-industry actors under common governance. Solvent recovery, in turn, revealed the sensitivity of circular processes to stringent purity requirements, volatile market demand, and site-specific infrastructure constraints.

Beyond these project-specific hurdles, the case studies also pointed to a set of common systemic challenges cutting across all initiatives, including:

- **Logistical and operational constraints**: difficulties related to the collection, segregation, and handling of materials or products (e.g., clean waste streams for SUT, patient return logistics for TBS, representative sample collection for solvents).
- **Regulatory and compliance hurdles**: biosafety classification, cross-border transport restrictions, and site-specific regulatory approvals created delays or required project adaptations in all cases.
- **Economic viability uncertainty**: each project had cost-related uncertainties, whether from immature cost models (SUT), dependency on market prices for secondary materials (TBS, solvents), or high initial infrastructure investment.
- **Stakeholder coordination complexity**: multi-party governance, alignment on priorities, and sustaining engagement over time proved challenging, especially when involving external partners. Confidentiality and non-disclosure agreements were consistently required.
- **Data and measurement limitations**: all projects struggled with limited or variable data (e.g., solvent composition variability, lack of quantification of environmental gains).

Together, these challenges illustrate that while technical feasibility was often attainable, the real barrier to scaling CE in pharma lay in overcoming these organizational, regulatory, and systemic obstacles.

4.9.1.2. Linking case study challenges to identified barriers and gaps

The challenges observed across the three case studies closely reflected the barriers and gaps previously identified through the literature review, industry benchmarking, and empirical assessment at Sanofi. For instance, the SUT circularity initiatives faced biosafety-related restrictions and hazardous waste classifications that limited recycling potential, echoing the regulatory and quality constraints described earlier. Both SUT and solvent recovery projects were also hampered by limited space for waste segregation, variability in waste composition, and the need for site-specific handling procedures, directly linking to operational and infrastructure barriers.

In the case of the Take-Back Systems, the dependence on coordinated action between multiple pharmaceutical companies, waste operators, and recyclers reflected the vendor ecosystem and governance challenges previously highlighted, while the complexity of aligning priorities across organizations reinforced the multi-party coordination difficulties noted in the empirical study. Across all three cases, incomplete or delayed environmental impact quantification underlined the metrics and data gaps, and the fact that each initiative progressed largely as a stand-alone pilot confirmed the fragmentation and project-based nature of CE efforts within the sector.

This alignment between the practical challenges encountered and the systemic barriers identified earlier strengthens the validity of the barrier analysis, while also positioning the case studies as concrete illustrations of how these constraints materialize in real-world CE initiatives. It also raises a critical question: given these persistent barriers, is the CE strategy developed in Part A suited to overcome them, and under what conditions can it be effective? The following section therefore evaluates the CE strategy through the lens of these case studies, assessing both its relevance in practice and the pathways needed to enable its successful implementation.

4.9.2. Implications of the CE strategy evaluation

The evaluation of the CE strategy using the case studies and projects provided a practical test of its applicability, robustness, and potential for broader deployment. Despite the strategy being designed in Part A to address key circular economy opportunities and barriers specific to the pharmaceutical sector, its real-world application inevitably revealed both strengths and limitations.

4.9.2.1. Insights from the strategy evaluation through the case studies

The three case studies: site-specific process loops (solvent recovery), multi-project platforms (SUT circularity), and cross-industry system-level initiatives (take-back systems), confirmed that the strategy's principles and actions areas were relevant across diverse contexts. In all cases, there was clear alignment with the strategy's CE dimensions, levels, loops, and stakeholder engagement principles, demonstrating its conceptual soundness and flexibility across scales.

A comparative synthesis of the strategy effectiveness evaluations showed several consistent strengths:

- **High sector-specific relevance** (score of 5 for all three cases), indicating that the strategy's design, particularly the CEIM, accounted for successfully mapping CE integration levels along pharmaceutical specificities, including regulatory constraints, technical requirements, and stakeholder complexity.
- **Strong collaboration enablement** (score of 4–5), showing that the strategy provided a suitable framework for mobilizing diverse internal and external actors.
- **Innovation potential** strong in most cases, from new circular loops (SUT) to novel business models (TBS), though more limited for improved waste valorization processes (solvent recovery).

At the same time, several recurring limitations reduced the strategy's systemic impact:

- **Measurement gaps**: environmental impact reduction was unquantified (SUT), partially documented (Solvent), or misaligned with corporate KPIs (TBS).
- **Integration gaps**: integration with existing initiatives scored low (2–3) in two cases, showing that projects often remained disconnected from broader organizational programs.
- **Scalability challenges**: replicability was always considered feasible but required significant adaptation to local site processes (Solvent), healthcare systems (TBS), or redesign of procedures (SUT).

Overall, the evaluation confirmed that the CE strategy is fit-for-purpose in principle, capable of guiding diverse CE initiatives in pharmaceuticals. However, its translation into consistent, systemic results depended on enabling conditions, such as early integration into governance, robust data for measurement, and mechanisms for scaling, that were not always in place. These findings directly echo the barriers identified in Part A, particularly regarding metrics, integration, and ecosystem coordination.

4.9.2.2. Insights from cross-project evaluation of the CE strategy performance

Looking across the full set of CE-related projects, including the three case studies and other initiatives such as the manufacturing guide, portfolio LCA, and value stream mapping, the evaluation revealed consistent trends that reinforce the earlier findings from the case studies.

First, sector-specific relevance emerged as a consistent strength, with all projects scoring high in this dimension. This reflects the fact that the CE strategy, and in particular the CEIM, was explicitly designed to account for pharmaceutical sector constraints such as regulatory compliance, technical requirements, and stakeholder complexity. Similarly, collaboration enablement remained strong across the portfolio, confirming that the strategy provided a robust framework for mobilizing diverse actors internally and externally.

At the same time, the same recurring limitations identified in the case studies were also present in the wider portfolio: persistent measurement gaps, uneven integration with existing initiatives, and remaining scalability challenges.

This consistency across both the case studies and the broader set of projects suggests that the CE strategy was fundamentally relevant and adaptable, but that its systemic impact was constrained by structural barriers that cut across project types and scopes. Addressing these cross-cutting issues would be essential to unlocking the full potential of the strategy.

4.9.2.3. Need for systemic integration

The combined evaluation of the case studies and the broader set of CE-related projects confirmed the overall relevance of the designed CE strategy. Across initiatives, sector-specific relevance and collaboration enablement consistently scored high, while recurring limitations, particularly in integration with existing programs, measurement of environmental impact, and scalability, restricted their systemic reach.

A key finding emerging from this cross-project analysis was that most initiatives operated as isolated, project-based actions, often developed in response to specific opportunities, regulatory drivers, or local site needs, rather than as components of a fully integrated organizational system. In spite of these projects demonstrating technical feasibility and, in some cases, innovation potential, they remained largely disconnected from one another and from holistic company integration.

This fragmentation limited the strategy's transformative potential. Without mechanisms to transform the strategy into key organizational capabilities, and to embed circular and sustainable practices into standard processes, cross-functional governance, and management systems, successful pilots risk remaining confined to their original context rather than being replicated, scaled, and sustained.

In Table 32, the systemic integration level of each project is assessed to illustrate the current limitations.

Table 32. Qualitative evaluation of systemic integration levels across identified projects

Project	Systemic integration	Rationale
SUT Circularity	Low	Multiple promising pilots, but limited integration into standard operating procedures or corporate programs; remains site- and supplier-specific.
Take-Back Systems	High	High visibility and cross-industry collaboration with existing standardization across the company.
Solvent Recovery	Medium	Focused on a single site and specific waste streams, though generic solvent recovery is more widely practiced across chemistry sites; not yet integrated into biopharma operations or broader manufacturing policies.
Manufacturing guide	Low	Designed as a standardized tool, but identified environmental actions are limited to its specific application context.
Portfolio LCA	Low	Expansion from product-level to portfolio-level LCA increases potential integration, but the project covered only one product family with no organization-wide practice change.

Value Stream Mapping	Medium	Outcomes integrated into a best practices handbook for organization-wide use, building on existing VSM applications.

Addressing this gap is essential to turn the strategy from a relevant framework into a driver of long-term transformation for environmental sustainability in the pharmaceutical sector.

4.9.3. Implications from the collaboration dynamics evaluation

The dynamics of the collaboration in a CE were assessed through the quality of the collaboration itself and through the outcomes of the project in its capacity of being a successful project. In this section, the patterns across case studies are discussed, then the comparison of both the success of the project and the quality of collaboration combined in the plot are discussed.

4.9.3.1. Collaboration–success patterns across case studies

The evaluation of collaboration quality and project success across the three detailed case studies revealed distinct patterns in how collaborative dynamics translated into outcomes.

(1) **SUT Circularity**: This case combined relatively broad stakeholder diversity with weak overall performance, primarily due to low depth of engagement and slow resolution of barriers. Despite multiple internal functions and external partners involved, their contributions were often sporadic, limiting the pace of progress. The low project success score reflected unmet objectives, delays, and the absence of measurable environmental benefits at this stage. This outcome illustrated how limited engagement depth and weak enabler/barrier management can offset the advantages of stakeholder diversity.

(2) **Take-Back Systems (TBS):** This initiative demonstrated both high collaboration quality and strong project success. Stakeholder diversity was maximized, spanning multiple companies, functions, and patient groups, and engagement was deep throughout decision-making and solution design. The project delivered on most objectives, achieved documented environmental benefits, and established a high likelihood of long-term viability. The main remaining gaps concerned early recyclability testing and confidentiality constraints on certain data flows. TBS illustrated the potential of high-collaboration contexts to deliver strong, scalable outcomes, provided operational execution is well aligned with shared objectives.

(3) **Solvent Recovery**: Collaboration quality was strong, with active involvement from multiple functions and external partners, effective knowledge exchange, and proactive barrier resolution. Project success was similarly rated as good, with objectives on track, technical processes established, and high stakeholder satisfaction. Despite the final environmental impact data not being available yet, early indications suggested significant potential benefits. Solvent Recovery showed how technical, process-oriented projects can perform well in both collaboration and outcome terms, even without the large-scale multi-industry alliances seen in TBS.

Overall, the comparison highlighted that high collaboration does not automatically guarantee high success, as seen in the gap between SUT and TBS, yet sustained, deep engagement combined with strong operational alignment appears to be a common factor in the most successful cases.

4.9.3.2. The role of collaboration in successful CE project delivery

The positioning of the three case studies on the collaboration–success matrix revealed a clear differentiation in how collaboration quality related to outcomes. Two cases, TBS and Solvent Recovery, were positioned in the "collaborative success" quadrant, indicating both strong multi-stakeholder engagement and high achievement of intended CE-related objectives. Even though TBS benefitted from broad, cross-industry partnerships and deep engagement at every stage, Solvent Recovery demonstrated that focused, functionally diverse internal–external collaboration can also deliver strong results when combined with clear technical pathways and process alignment.

In contrast, the SUT Circularity initiative fell in the "underdeveloped initiatives" quadrant, reflecting both limited collaboration depth and modest project success to date. Despite the involvement multiple stakeholder groups, engagement was sporadic, barriers took months to address, and measurable impacts were not yet achieved. This case highlighted that diversity of stakeholders alone is insufficient; depth of participation, timely problem resolution, and shared commitment to outcomes are critical to converting collaborative potential into results.

No cases were observed in the "collaboration without impact" or "isolated wins" quadrants, suggesting that in this context, high collaboration was consistently associated with stronger outcomes, and low collaboration coincided with lower success. While the sample size limits statistical inference, the pattern reinforces the notion that high-quality collaboration, characterized by active involvement, effective information exchange, and proactive barrier management, is a key enabler for the successful implementation of CE-related initiatives and, more broadly, for the effective deployment of a CE strategy in the pharmaceutical sector.

These findings provided empirical support for SRQ1.2, indicating that collaboration quality was not merely a supporting factor but a determinant of CE project performance. They also suggested that collaboration should be addressed as a strategic capability to be built and maintained if circular initiatives are to be scaled beyond pilot contexts.

4.9.4. Limitations and future work

This section outlines the main limitations of the study and associated opportunities for future research. First, methodological limitations related to the study design are presented. Second, limitations resulting from measurements and data are addressed. Finally, the limited systemic integration of the case studies and projects is discussed as a critical constraint, highlighting the need for further work. For each limitation, potential improvement pathways for future work are proposed.

4.9.4.1. Methodological limitations

The research methodology used in this study to evaluate the CE strategy and the level of collaboration through case studies and projects was subject to four main limitations.

The first limitation concerned the small sample size for assessing the CE strategy and collaboration in depth. Only three case studies were used to evaluate the role of collaboration itself, and only six projects in total were used to assess the CE strategy. For the collaboration dynamics evaluation in particular, the results were useful for exploratory insights, but the ability to generalize findings across the pharmaceutical sector remained limited.
The second limitation, closely related to the first, was linked to the projects selected for the evaluations. Although the projects spanned different dimensions and levels of CE integration, the selection of different projects could have produced different results.
The third limitation was also connected to the previous ones and related to the qualitative/semi-quantitative nature of the evaluation. Even though scoring matrices and consistent evaluation frameworks were applied across projects, most assessments were based on qualitative judgements and expert opinions, which introduced potential bias.
The fourth limitation was the lack of long-term data, as most of the initiatives evaluated were in their pilot or early implementation stages. This meant that long-term impacts and associated performance could not be measured. However, this was also a natural consequence of the fact that the case studies resulted from the CE strategy and could therefore not have been identified before 2023.

To address these limitations, future evaluation work should be extended to a broader set of CE projects, including cross-industry comparisons, to strengthen generalizability. Regarding evaluation outcomes and the semi-quantitative approach, reliability could be improved through multi-stakeholder assessments to ensure consistency across results. In addition, specific metrics, rather than generic scores, could be applied to systematically assess and track environmental, operational, and strategic outcomes. Finally, reassessing these projects after several years would make it possible to evaluate their potential evolution and long-term impact.

4.9.4.2. Measurement and data gaps

Several measurements-and data-related limitations affected the evaluation of the CE strategy and associated projects.

First, environmental impact quantification was often limited. For several projects, such as SUT circularity, environmental benefits were either unquantified or only partially estimated, which restricted the ability to compare initiatives based on actual impact reduction.
Second, inconsistencies between corporate KPIs and project-level metrics made it difficult to assess the degree of integration and the contribution of individual initiatives to broader strategic goals. In many cases, existing KPIs were not designed to capture CE-specific outcomes.
Third, while monitoring systems existed, their effectiveness was constrained by these gaps. Without CE-relevant KPIs consistently in place, the systems could not fully track or reflect the environmental and circular performance of the initiatives across sites and organizational levels.

To address these limitations, future work should focus on the development and/or integration of dedicated tools and KPIs that can systematically track both environmental performance and CE implementation at multiple levels: product, site, corporate. This would increase the ability to assess progress, support decision-making, and guide the scaling of successful practices.

4.9.4.3. Limitations of the CE strategy: need for systemic transition

The discussion across case studies and the broader set of CE-related projects highlighted that, while the designed CE strategy demonstrated strong sector-specific relevance, collaboration enablement, and innovation potential, most initiatives still operated as isolated pilots. They were rarely embedded into corporate governance, standard operating procedures, or capability-building structures. The absence of formal mechanisms to replicate and adapt successful pilots across the organization, their impact remained local, temporary, and dependent on the individuals or sites driving them.

This fragmentation confirmed one of the main findings from Section 4.2.3, the absence of systemic integration significantly restricts the strategy's ability to deliver organization-wide transformation. In other words, technical feasibility alone was not sufficient; without deliberate integration into processes, governance, and decision-making systems, and without alignment with existing approaches like eco-design, the CE strategy risked becoming a collection of disconnected wins rather than a sustained organizational capability.

These limitations are not unexpected. Pilot projects are, by definition, limited in scope, duration, and impact. The key challenge for future work is therefore to convert these isolated efforts into systemic initiatives, embedding CE practices into core processes and governance structures, and ultimately transforming the CE strategy into institutionalized organizational capabilities.

4.10. CONCLUSION

In conclusion, Part B provided a practical evaluation of the CE strategy developed in Part A, applying it to three detailed case studies and a broader set of CE-related projects within the pharmaceutical context. This directly addressed H1 and more specifically the Sub Research Question 1.2: *"To what extent can the designed circular economy strategy be effectively applied and generate value in pharmaceutical contexts, and how do internal-external collaboration mechanisms influence its successful implementation and outcomes?"*

The assessment confirmed that the strategy was both relevant and adaptable to different circular actions and loops, from product redesign and material recovery to cross-industry take-back systems, while consistently demonstrating high sector-specific relevance, and adaptation, and enabling strong collaboration. However, several limitations were identified across projects, notably gaps in environmental performance measurement, or challenges in scaling successful initiatives. The comparative analysis of collaboration dynamics further reinforced that high-quality collaboration was a key enabler of project success, aligning with findings from the literature and the empirical study.

A central insight emerging from this evaluation is the need for systemic integration. Most initiatives operated as isolated projects, disconnected from corporate governance, capability-building processes, or standardized operating models. In line with previous observations, pilot projects represent an essential intermediate step in CE implementation, enabling feasibility testing and learning before scale-up (Zils et al., 2023). However, the absence of deliberate mechanisms for transitioning from isolated practices to the organization's strategic and operational core, the transformative potential of the strategy remains underexploited.

These findings lay the foundation for Chapter 5, which addresses this critical gap. Building on the strategy developed in Part B, and its evaluation in Part B, the next chapter introduces a transition framework and capability model designed to connect isolated initiatives, institutionalize environmental practices, and enable long-term, organization-wide integration of environmental sustainability.

SYNTHESIS OF CHAPTER 4

This chapter addressed Hypothesis 1: *A structured Circular Economy (CE) strategy, enabling internal and external collaboration and alignment, can foster the emergence and reinforcement of circular initiatives in the pharmaceutical sector, ultimately contributing to the reduction of environmental impacts across the organization.* To conduct this investigation, Chapter 4 was structured into two complementary parts, each designed to answer one of the sub-research questions supporting H1.

Part A addressed the Sub-Research Question 1.1: *What are the key elements of a Circular Economy strategy in the pharmaceutical sector, and how can they be effectively implemented?*

Through a combination of a systematic literature review and an empirical study of industry practices, Part A identified the structural components needed for an effective CE strategy in pharmaceutical sector. The analysis showed that while many technical solutions (e.g., green chemistry, solvent recovery, eco-design) already exist, they remain fragmented and lack systemic integration. In response, a specific CE strategy for pharmaceutical companies was developed, embedding sector-specific requirements such as regulatory compliance, product safety, and multi-stakeholder complexity. The strategy's key elements include:

- Strategic alignment with existing environmental practices and corporate goals
- An integration model for CE in pharmaceutical organizations
- Performance indicators (e.g., Waste Impact Index) to track progress
- Operational tools (e.g., LCA, Value Stream Mapping) to guide implementation
- Governance mechanisms and best-practice documentation to support scaling

In doing so, Part A answered SRQ1.1 by demonstrating that an effective CE strategy in the pharmaceutical industry requires both vertical integration (from site-level action to corporate governance, and vice versa) and horizontal integration (across internal and external stakeholders, while ensuring regulatory compliance), operationalized through a structured, adaptable framework.

Part B addressed the Sub-Research Question 1.2: *To what extent can the designed circular economy strategy be effectively applied and generate value in pharmaceutical contexts, and how do internal–external collaboration mechanisms influence its successful implementation and outcomes?*

The strategy was tested through three detailed case studies and a broader set of CE-related projects covering both CE loops (e.g., single-use technology circularity, take-back systems, solvent recovery) and broader environmental sustainability initiatives (e.g., portfolio LCA, manufacturing guidelines). The results showed that:

- The strategy is applicable across diverse contexts, from product redesign to cross-industry material recovery through take-back systems.
- It is usable as a guiding framework for project planning and execution, even in complex regulatory environments.
- It is useful in fostering collaboration, enabling information sharing, and aligning stakeholders toward CE objectives.

A comparative analysis revealed that strong collaboration, characterized by stakeholder diversity, deep engagement, and effective barrier management, was a decisive enabler of project success. However, limitations

persisted, including insufficient environmental performance measurement, weak integration into existing systems, and limited scalability. Most initiatives remained isolated pilots rather than components of a systemic transformation.

Overall synthesis

In conclusion, the findings from Parts A and B validate H1. The CE strategy enabled the design and successful implementation of relevant circular initiatives in the pharmaceutical sector, while collaboration mechanisms were shown to be decisive enablers of success. The strategy demonstrated applicability across diverse CE loops, usability in guiding projects within complex sector constraints, and usefulness in fostering collaboration across internal and external stakeholders, leading to measurable or potential environmental impact reductions.

At the same time, the evaluation revealed boundaries to the strategy's transformative potential: in the absence of mechanisms for the systemic transition of current practices into new ways of working, coupled with integration into governance and standardized operations, and without capability-building processes on environmental sustainability, its organizational embedding remains limited. These findings confirm H1 while underscoring that the full realization of its potential depends on systemic integration, an aspect addressed in the next chapter.

These conclusions directly inform the following chapter, which proposes a transition framework aimed at transforming isolated initiatives into standard practices, and a capability framework aimed at transforming strategy into institutionalized organizational capabilities.

Résumé en français - Chapitre 4 : Stratégie d'économie circulaire et projets collaboratifs

Ce chapitre présente la conception et l'évaluation d'une stratégie d'économie circulaire (EC) adaptée au secteur pharmaceutique, répondant directement à l'Hypothèse 1 (H1). Il se structure en deux parties : la Partie A conçoit la stratégie (SRQ1.1), la Partie B l'évalue à travers des études de cas (SRQ1.2).

PARTIE A - Conception de la stratégie d'EC
Contexte et méthode : Malgré la maturité croissante de l'EC dans d'autres secteurs, l'industrie pharmaceutique reste peu explorée en raison de ses spécificités (complexité des produits, réglementation stricte, fragmentation de la chaîne de valeur). L'étude combine une revue systématique de littérature et une investigation empirique chez Sanofi : analyse documentaire interne, benchmark des 20 plus grandes entreprises pharmaceutiques, et sondages puis entretiens semi-directifs menés auprès de 30 sites industriels répartis dans les Global Business Units (GBU).

Résultats de la littérature : La recherche confirme une polarisation du cycle de vie : les études pharmaceutiques se concentrent en amont (chimie verte, récupération de solvants), tandis que la littérature santé se concentre en aval (gestion des déchets hospitaliers). Une logique « post-déchet » domine, privilégiant les solutions techniques en bout de chaîne plutôt que les leviers systémiques.

Résultats empiriques : L'éco-conception s'est révélée être un pilier mature chez Sanofi (27 ACV réalisées d'ici 2024, réductions d'impact significatives pour Cerezyme et Dupixent), servant de fondation implicite à l'EC, bien que le terme n'apparaisse explicitement dans la stratégie qu'à partir de 2024. Le benchmark sectoriel révèle un engagement croissant mais inégal : le benchmark réalisé positionne la plupart des entreprises pharmaceutiques en dessous du niveau moyen, le packaging restant le point d'entrée le plus commun. Chez Sanofi, l'enquête confirme une hiérarchie 3R (Recycler > Réduire > Réutiliser), avec une forte dépendance aux boucles longues (incinération avec valorisation énergétique).

Barrières identifiées : Six catégories de freins sont synthétisées : contraintes réglementaires et qualité (GMP, difficulté élevée), infrastructures opérationnelles, écosystème des prestataires de déchets, lacunes en matière de métriques et données, gouvernance stratégique fragmentée, et freins culturels/incitatifs.

Pour répondre à ces constats, une stratégie d'économie circulaire est proposée, basée sur différents éléments. Un Modèle d'Intégration de l'Économie Circulaire (CEIM) est proposé, structuré en trois dimensions concentriques : (1) Produit & Procédé (éco-conception, ACV), (2) Spatio-social & Organisationnel (sites, GBU, coordination), (3) Socio-technique (régulateurs, culture, parties prenantes internes et externes). Ce modèle sert à la fois d'outil diagnostique et prescriptif. Des indicateurs de performance complémentaires sont développés : le Waste Impact Index (pondéré selon la hiérarchie des déchets) et le Waste Score (normalisé pour comparer des sites de tailles différentes). Des objectifs stratégiques distinguent déchets post-industriels (majoritaires en volume, sous-priorisés) et post-consommateurs (plus visibles). Sept leviers d'action structurent la feuille de route (achats responsables, éco-conception, symbiose industrielle, etc.), complétés par des outils opérationnels (ACV, MFA/VSM, glossaire commun, guide des bonnes pratiques).

PARTIE B - Projets collaboratifs et études de cas
Méthode d'évaluation : Trois études de cas sont examinées en détail afin d'évaluer la pertinence de la stratégie circulaire développée : la circularité des Technologies à Usage Unique (SUT), les systèmes de reprise des stylos à insuline (Take-Back Systems, TBS) et la régénération de solvants, complétées par trois autres projets (guide de fabrication, ACV de portefeuille, cartographie des flux). L'évaluation combine deux grilles : l'efficacité de la stratégie (8 critères pondérés) et la dynamique de collaboration (qualité de collaboration & succès du projet).

Étude de cas 1 - Circularité des SUT : Ce projet visait la récupération des aimants dans les mélangeurs à usage unique, ainsi que le recyclage plus large de ces technologies. Malgré une pertinence sectorielle élevée (score 5/5) et une forte capacité de collaboration, le projet obtient un score de succès faible (1,8/5), freiné par

une logistique inverse complexe, des contraintes de classification des déchets, et un engagement des parties prenantes limité.

Étude de cas 2 - Systèmes de reprise des stylos à insuline (TBS) : Initié au Danemark (programme Returpen avec Novo Nordisk, Eli Lilly et Merck) puis adapté en France (RECYPEN, avec DASTRI), ce projet a démontré un taux de recyclage supérieur à 70% en masse au Danemark. Il obtient les meilleurs scores : stratégie (4/5), collaboration (4,4/5) et succès (4,4/5), illustrant la puissance d'une collaboration inter-entreprises approfondie, bien que les résultats français initiaux soient restés modestes (faible taux de collecte).

Étude de cas 3 - Régénération de solvants : Ce projet, mené en trois phases (caractérisation analytique, essais pilotes, déploiement industriel), montre des résultats solides (stratégie et succès à 3,8-4/5) grâce à une collaboration technique ciblée, malgré la variabilité de composition des solvants entre campagnes de production.

La mise en relation collaboration-succès révèle que TBS et Solvent Recovery se situent dans le quadrant « succès collaboratif », tandis que SUT relève des « initiatives sous-développées », confirmant qu'une collaboration de qualité (diversité, profondeur d'engagement, gestion des obstacles) est un facteur déterminant de succès, sans pour autant être une garantie automatique.

Sur l'ensemble des six projets, tous obtiennent un score global « Bon » (3,8 à 4,25/5), avec une pertinence sectorielle et une capacité de collaboration constamment fortes, mais des lacunes récurrentes en mesure d'impact environnemental, intégration aux initiatives existantes, et de mise à l'échelle. Une évaluation qualitative du niveau d'intégration systémique montre que la plupart des projets (SUT, guide de fabrication, ACV portefeuille) restent à un niveau faible d'intégration, tandis que seul TBS atteint un niveau élevé.

Conclusion et limites
La stratégie d'EC est jugée pertinente, adaptable et efficace pour catalyser des initiatives circulaires, validant ainsi H1. Cependant, la plupart des projets demeurent des pilotes isolés, déconnectés de la gouvernance organisationnelle globale et des mécanismes de développement de capacités. Les limites méthodologiques (petit échantillon, évaluation qualitative, absence de données de long terme) et les lacunes de mesure environnementale sont discutées. Ce constat d'intégration systémique insuffisante ouvre directement sur le Chapitre 5, qui développera un cadre de transition et un modèle de capacités pour transformer ces initiatives isolées en pratiques organisationnelles pérennes.

Chapter 5. Systemic Transition & Organizational Change for Sustainability

This chapter investigates how environmental sustainability can be systemically integrated into pharmaceutical product and process development, addressing **Hypothesis 2**: *Systemic integration of environmental sustainability in the pharmaceutical industry can be achieved by consolidating validated projects into standardized practices and institutionalizing the sustainability strategy through enduring organizational capabilities, thereby enhancing the environmental performance of products and processes.*

Building on the findings of Chapter 4, which focused on the design and evaluation of a CE strategy tailored to the pharmaceutical sector, Chapter 5 turns to a critical challenge: embedding environmental sustainability into the organizational system in a durable and scalable way. Despite pilot projects demonstrating the relevance of the CE strategy, their limited scope and lack of integration highlighted the need for deeper organizational transformation. In this thesis, environmental sustainability has been approached through two complementary lenses already introduced in earlier chapters: eco-design, which emphasizes reducing impacts throughout the life cycle of products, and the circular economy, which broadens the scope. Together, these perspectives underpin the environmental sustainability strategy considered within this study.

This chapter operationalizes H2 through two sub-research questions:

- **SRQ2.1**: *How can validated environmental projects be consolidated and standardized into practices that support systemic integration across pharmaceutical product and process development?*
- **SRQ2.2**: *How can the environmental sustainability strategy and its components be institutionalized across organizational functions to develop durable capabilities?*

To address these questions, the chapter is organized into two complementary parts (Figure 73). Part A examines how isolated projects can be transformed into systemic practices through organizational learning. A transition framework is proposed and tested through two experiments, illustrating both the potential and limits of moving from project-based initiatives to standardized practices. Part B shifts the focus from practices to organizational capabilities, presenting a capability model tailored to the pharmaceutical sector. This model provides both a diagnostic tool and a roadmap for institutionalizing environmental sustainability across strategy, people, culture, processes, and skills.

Together, the two parts provide a dual perspective on systemic integration: one focused on translating project-level learning into reusable practices, and the other on building the organizational capabilities required to sustain and institutionalize them. In doing so, Chapter 5 generates evidence to support H2 and sets the stage for the final discussion of the thesis.

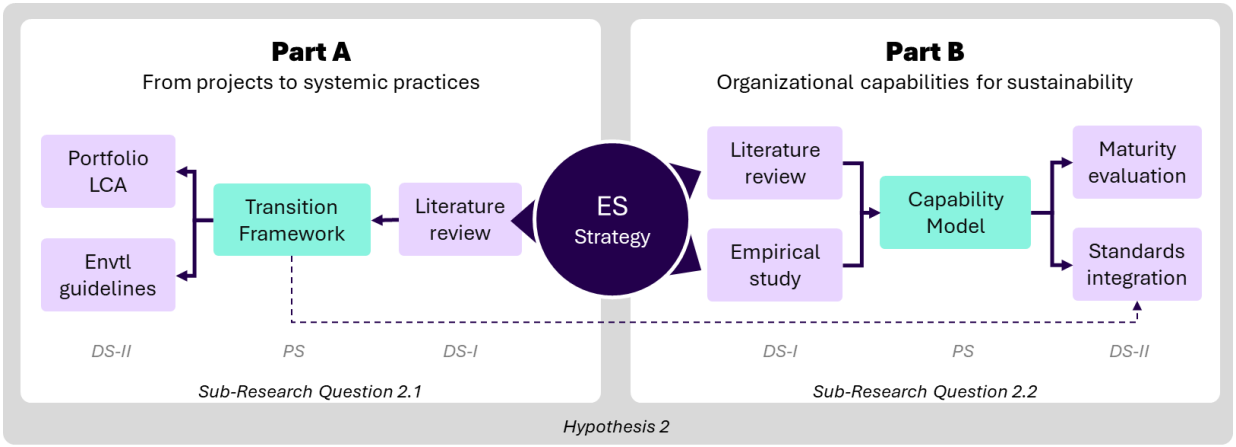

Figure 73. Structure of Chapter 5 and logical flows (ES: Environmental Sustainability)

PART A: OPERATIONALIZING THE STRATEGY THROUGH SYSTEMIC PRACTICES

This first part of Chapter 5 aims to investigate how isolated sustainability initiatives can be transformed into systemic practices that contribute to the operationalization of the environmental sustainability strategy. Building on the CE strategy and related projects developed in Chapter 4, this part focuses on the role of organizational learning in enabling such transformations.

The objectives are twofold: (1) to examine how project-based experiences can be captured, synthesized, and formalized into practices that are reusable and transferable across organizational contexts, and (2) to evaluate the extent to which these practices can support systemic integration of environmental sustainability within the pharmaceutical sector. This approach provides a direct answer to Sub-Research Question 2.1 (SRQ2.1): *How can validated projects be transformed (scaled and standardized) into practices that support the systemic integration of environmental sustainability across pharmaceutical product and process development?*

The analysis combines theoretical insights from the literature with empirical evidence from two experiments. The first experiment applied a portfolio-level LCA to Sanofi's insulin products, while the second developed and tested a methodology for generating environmental guidelines for manufacturing processes design. Together, these experiments illustrate both the potential and the limits of transforming project-based insights into systemic practices, highlighting the central role of organizational learning and knowledge integration in this process.

5.1. CONTEXT

Defining a strategy alone is not sufficient to ensure its implementation. In complex organizations such as pharmaceutical companies, systemic integration requires that strategic intentions be translated into managerial and operational practices embedded across functions, governance layers, and stakeholder groups. One pathway to achieve this is the transformation of pilot projects into standardized and transferable practices. Scaling and formalizing the learnings of individual projects helps bridge the gap between strategic ambitions and day-to-day operations, as emphasized in several models such as the CE implementation approach proposed by Zils et al. (Zils et al., 2023). This perspective aligns with the concept of organizational learning, which stresses a firm's ability to learn from experience and adapt its practices to remain resilient and competitive.

Organizational learning processes are strongly shaped by people. Consequently, stakeholder engagement, cross-functional collaboration, and knowledge-sharing mechanisms are key in enabling the capture of insights from projects and their integration into broader routines. This echoes the dimensions highlighted in Chapter 4, including the transversal role of "change management" (Boks, 2006; Brones and Carvalho, 2015; Brones et al., 2017; Verhulst et al., 2007) and the human factors dimension emphasized in the CE Integration Model (CEIM). Both underline that internal and external stakeholders are central to successful circular and sustainability integration.

From this perspective, project-to-practice transformation emerges as a critical but challenging step. It is necessary to ensure that strategies move beyond isolated pilots and become part of organizational routines, but it remains difficult to achieve in practice. This creates a need for approaches that structure and support the transition from projects to systemic practices, enabling broader and more sustained integration of environmental sustainability.

5.2. MATERIAL AND METHODS

In line with the DRM, the research conducted in Part A followed several stages (Blessing and Chakrabarti, 2009a). First, a Descriptive Study I (DS-I) was carried out to review existing literature and derive requirements for transforming projects into practices. This informed the Prescriptive Study (PS), where a transition framework was developed to support the scaling and standardization of isolated projects into systemic practices. Finally, the

framework was tested through a Descriptive Study II (DS-II), using two experiments: (1) the portfolio Life Cycle Assessment (LCA) and (2) the development of a methodology for sustainable manufacturing.

5.2.1. Literature review

A semi-systematic literature review was conducted (Snyder, 2019) using a thematic approach, with the objective of identifying key concepts, mechanisms, and barriers related to the transformation of projects into organizational practices. The review focused on three complementary bodies of literature: Knowledge Management (KM), Organizational Learning (OL), and pilot-to-practice transitions. The process followed a structured protocol to ensure methodological rigor.

First, a set of guiding questions was formulated to frame the review:

- What is the role of pilots in organizations?
- How do organizations capture and reuse knowledge from projects?
- What mechanisms support the dissemination of new practices?
- What conditions enable or hinder the transition from pilots to broader adoption?

Second, a targeted search strategy was developed, using Boolean combinations of keywords grouped into conceptual clusters aligned with the research focus. The first cluster targeted knowledge capture and reuse, using terms such as "*knowledge capture*," "*lessons learned*," "*project learnings*," and "*knowledge retention*." The second cluster addressed knowledge sharing and dissemination mechanisms, with keywords including "*knowledge sharing*," "*dissemination*", and "*peer learning*." A third cluster focused on integration and institutionalization, using terms like "*embedding practices*", "*standardization*", "*institutionalization*," and "*organizational routines*". Finally, the fourth cluster emphasized scaling and transformation processes, including terms such as "*scaling pilot projects*," "*pilot-to-practice*," "*project transfer*," and "*organizational adoption*." Searches were conducted using Scopus and Google Scholar to ensure coverage of both academic and applied perspectives.

Third, articles were selected based on their relevance to the research objective. Inclusion criteria emphasized peer-reviewed publications, in English, that addressed one or more phases of the transformation from project outcomes to embedded organizational practices. No restrictions were applied regarding the publication date, as the objective was not to assess temporal trends but rather to build a broad thematic understanding of the mechanisms, enablers, and barriers discussed in the literature. Grey literature and practitioner reports were used selectively to complement academic sources, particularly in relation to implementation mechanisms. Backward and forward snowballing was applied to identify frequently cited and foundational references.

Finally, selected literature was reviewed and organized according to recurring themes and stages of transformation, which informed the formulation of design requirements and supported the development of the proposed transition framework.

5.2.2. Conceptualization of a support

The development of the transition framework was guided by the Prescriptive Study (PS) phase of the DRM (Blessing and Chakrabarti, 2009a), which aims to define a desired future state and to propose actionable solutions grounded in prior findings. In this study, the objective was to support the transformation of isolated sustainability initiatives into embedded, systemic practices within pharmaceutical organizations.

The conceptualization drew from two primary inputs: (1) the thematic literature review, which identified key mechanisms, challenges, and enablers in transitioning from project-level outputs to organizational practices; and (2) insights from prior project-based experiences conducted within Sanofi.

These inputs were consolidated into a transition framework composed of four core steps: capture, synthesize, formalize, and disseminate. Each step was associated with specific design requirements derived from the literature and supported by targeted activities and potential organizational outputs. The framework was refined iteratively through reflective application in real projects and informal feedback from internal stakeholders. Generic in

structure, the framework was designed to remain adaptable to the specific needs and constraints of different contexts, facilitating both strategic alignment and operational feasibility.

Therefore, rather than prescribing a rigid sequence of actions, the proposed support aimed to:

- Provide a clear structure to guide the transformation process.
- Help bridge the gap between project outcomes and organizational routines.
- Enable reflection, learning, and reuse of sustainability-related knowledge and tools.
- Promote integration mechanisms that align with existing governance and decision-making processes.

It is important to note that the framework does not aim to introduce novel theoretical constructs in the fields of knowledge management or organizational learning. Instead, it consolidates key mechanisms already well established in the literature and organizes them into a usable structure tailored to industrial sustainability challenges related to this thesis. Its contribution lies in its ability to translate theoretical insights into a structured and operational tool that is well suited to the types of environmental projects conducted in this research. By providing a pragmatic pathway from isolated initiatives to systemic practices, the framework offers actionable guidance for practitioners aiming to embed environmental sustainability more deeply within organizational routines.

5.2.3. Evaluation of the support

The evaluation of the support followed a structured Design Science evaluation process, consistent with the DS-II logic proposed within the DRM (Blessing and Chakrabarti, 2009a). The objective was to assess the support's usefulness and applicability through two experiments, conducted in real-world case studies. The evaluation process comprised four main steps: selection of relevant projects, definition of the evaluation focus, development of the evaluation plan, and the evaluation itself.

5.2.3.1. Projects selection

The projects selected for evaluation were drawn from the broader portfolio of CE and environmental sustainability initiatives analyzed in Chapter 4. Selection was guided by their alignment with the overall research scope and their ability to illustrate the transition from isolated projects to more systemic practices. Projects were retained based on their strategic relevance in advancing environmental sustainability within the organization, their capacity to generate positive outcomes at both the project and organizational levels, their operational maturity with observable results, and their potential to produce learnings that could be generalized beyond a single business unit or product context.

To ensure methodological coherence and relevance to the research scope, two key selection criteria were applied:

1. **Systemic integration level**: drawing on the levels defined in Chapter 4, initiatives were assessed based on their degree of organizational integration. Only isolated projects, those not yet embedded in company-wide practices, were considered eligible. The rationale was that initiatives already institutionalized at the organizational level would not require the type of transformation targeted by the transition framework. By contrast, isolated projects represented suitable candidates for exploring how systemic transition could be achieved.
2. **Demonstrated project validation**: as highlighted in the literature on pilot-to-practice transitions (Boscherini et al., 2010; Hussey et al., 2013; Serrat, 2017), not all initiatives are suitable for scale-up or standardization. Only those that were contextually grounded, strategically aligned, and had delivered validated outcomes were retained. Validation was thus considered a critical prerequisite for selecting initiatives with the potential to inform broader systemic integration.

Although these initiatives were not originally designed as evaluation experiments, they progressively applied the logic of the transition framework and therefore provided a suitable ground for evaluating its relevance and practical utility.

5.2.3.2. Evaluation focus

The objective of the evaluation was to assess whether the transition framework developed in this research effectively supported the transformation of isolated environmental projects into systemic, embedded practices within a large pharmaceutical company.

More specifically, the evaluation focused on the following questions:

- To what extent was the framework applicable and practically useful in guiding pilot-to-practice transitions?
- Did the framework facilitate the transition from project-level outputs (e.g., LCA results, design guidelines) to organizational standards, routines, or tools?
- What barriers and enablers emerged during implementation?
- To what extent could the framework contribute to the systemic integration of environmental sustainability in the pharmaceutical industry?

This evaluation supports Hypothesis 2, and more precisely Sub-Research Question 2.1, which explores how validated projects and outputs can be transformed, scaled, standardized, and integrated, into sustainable practices across pharmaceutical product and process development.

5.2.3.3. Evaluation plan

To address Sub-Research Question 2.1, the evaluation was structured around two complementary perspectives: (1) the assessment of the outcomes generated through the application of the transition framework in real-world projects, and (2) the evaluation of the framework itself as a support tool for transitioning from isolated initiatives to systemic practices.

On the **project level**, each initiative was analyzed, focusing on how the transition framework was applied during the course of the project, either explicitly or implicitly, and what outcomes this process enabled. Particular attention was given to identifying outputs that moved beyond project-specific deliverables, contributing instead to reusable assets such as methods, guidelines, or procedures that could support broader integration within the organization.

On the **framework level**, the analysis focused on how each of the steps of the framework was implemented in practice. For each step, the evaluation aimed to identify the activities and outcomes associated with it, and how these contributed to turning the project into a systemic and repeatable practice. This process was supported by the design requirements (DR1–DR8) previously identified in the literature, which served as analytical lenses for assessing the completeness and coherence of each transition.

To evaluate the framework's utility more broadly, four qualitative criteria were selected: relevance, usability, scalability, quality of outcomes, and degree of integration. These dimensions supported comparative reflection across the projects and informed the broader conclusions of the evaluation. The guiding questions for each criterion are presented below, in Table 33.

Table 33. Criteria and guiding questions for evaluating the transition framework

Criteria	Guiding questions
Relevance	Was the framework useful for structuring the transition? Did it align with project needs and goals?
Usability	Were the steps understandable and adaptable to the project context? Was it clear and easy to apply in the given context?
Scalability	Could the project's outputs be reused, transferred, or scaled? Could outputs be generalized or reused across contexts?
Integration	Were the results actionable, adopted, or institutionalized in any form?

A three-point qualitative scale (high, medium, low) was used to evaluate each criterion, not as a formal scoring system, but as a heuristic approach to support the interpretation of observed patterns and differences. The objective

was not to validate the framework as universally optimal, but rather to assess whether it offered a usable and relevant approach to support the transition from pilot initiatives to systemic environmental practices in the pharmaceutical sector.

5.2.3.4. Undertaking evaluation

The evaluation of the transition framework was conducted a posteriori, once the projects had been completed and the framework had been fully formalized. However, the projects themselves were carried out using the principles and logic that later informed the framework. They thus served as embedded design experiments, allowing for the observation of how initially isolated initiatives could be transformed into systemic practices through the progressive application of the framework's steps.
Although the structure of the framework was not fully defined at the outset, its underlying logic was incrementally applied during project execution. The steps of the framework effectively guided the trajectory of the projects and structured the transformation of isolated project-specific results (e.g., LCA insights) into systemic practices (e.g., organizational routines and tools).

The evaluation followed a dual logic: it retrospectively assessed the applicability, usefulness, and completeness of the formalized framework, while also analyzing the practical outcomes generated during its use. This allowed for a comprehensive understanding not only of what was done, but also of how and why certain steps were implemented or adapted based on contextual needs. A qualitative, practice-based approach was adopted, grounded in the researcher's direct participation in both initiatives. The empirical material used in the evaluation included a broad range of internal documentation, such as project reports, LCA deliverables, decision records, and draft procedures, complemented by insights gathered during informal exchanges, working sessions, and post-project reflection discussions with stakeholders (e.g., project leads, environmental experts, decision-makers).

Each project was analyzed retrospectively and examined in light of the framework's four steps. Rather than applying the framework externally, the evaluation retraced how its components had been instantiated throughout the course of each initiative. This included identifying which steps had been followed explicitly, which had emerged informally, and where formalization or dissemination mechanisms had been put in place.

Finally, to conclude the systematic DS-II process, the synthesis of findings and conclusions drawn from the evaluation are addressed in Section 5.4 (Discussion). In that section, the evaluation results are interpreted, alternative explanations are considered, and implications for refining the transition framework and advancing systemic integration are discussed.

5.3. RESULTS

This section presents the main outcomes of this study. First, it introduces the transition framework developed to support the transformation of isolated projects into systemic practices, drawing on insights from the literature. Second, the selected projects are presented, along with the rationale behind their selection. Each project, acting as an embedded experiment, is then described in detail, with a focus on how the transition framework was applied and what outcomes it enabled. Finally, the framework is evaluated through the lens of these two experiments to assess its applicability, utility, and contribution to the systemic integration of environmental sustainability.

5.3.1. Transitioning from isolated projects to systemic practices

The first parts of this result section focus on the development of a support, derived from the literature, to improve the system-wide positive impact of isolated environmental sustainability initiatives. The outcomes of the literature are presented, directly followed by the framework proposed in response.

5.3.1.1. Insights from the literature review

In the literature, pilot projects are often described as effective mechanisms for implementing new concepts within organizations (Zils et al., 2023). As shown in Chapter 4, were pilot initiatives were used to explore and test the

proposed CE strategy. However, for pilots to act as true enablers of change, they needed to be scaled and transformed into systemic practices.

The literature review focused on two complementary research domains to understand how isolated projects could be embedded as enduring organizational practices: (1) Knowledge Management (KM), especially through lessons learned systems, and (2) Organizational Learning (OL). These were then integrated with insights from the literature on pilot-to-practice transitions.

Across all three domains, a consistent pattern emerged: while organizations often excelled at capturing knowledge, they struggled to interpret, formalize, and embed it into routines that changed how work was actually done.

Knowledge Management and lessons learned: strong in capture, weak in use

The Knowledge Management (KM) literature converged on a common set of processes: capturing, storing, sharing, retrieving, and reusing knowledge. The goal was to leverage both individual and organizational knowledge in support of strategic objectives and project success (Grant, 1996; Nonaka and Takeuchi, 1995). The concept of "lessons learned" evolved from simple checklists of what went right or wrong (Stewart, 1997) to more validated, contextualized, and reusable inputs to future projects (Rowe, 2013; Weber et al., 2001). More recent work emphasized capturing both explicit and tacit insights (Davenport and Prusak, 1998; Heisig, 2009; Nonaka et al., 2006).

However, reviews reported a persistent gap in implementation. Despite many organizations conducting post-project activities, these often stopped at identification, dissemination and especially application remained underdeveloped and under-resourced (Williams, 2008). Practices such as after-action reviews (AARs), debriefs, milestone reviews, and communities of practice (CoPs) were widely used, but often mistaken for a full lessons-learned process. Dissemination tended to rely heavily on codification (using databases or portals) while social transfer methods, more suitable for tacit knowledge (e.g., narratives, mentoring, peer exchanges), received less systematic support (Duffield and Whitty, 2015; Williams, 2008). Barriers were as often cultural and social as technical (Duffield and Whitty, 2015). Unsurprisingly, efforts to translate lessons into changes in behavior or redesigned processes typically failed unless they were explicitly linked to strategic priorities, ownership structures, and routines (Carrillo et al., 2013).

To explain why some efforts succeeded, Duffield and Whitty (2015) proposed the Syllk model, which emphasized that effective dissemination and application required alignment between people-related domains (learning, culture, social systems) and technical domains (technology, process, infrastructure). Using a “Swiss-cheese” metaphor, they argued that facilitators across these dimensions had to align for knowledge transfer to be successful (Duffield and Whitty, 2015, 2016).

In summary, the literature on KM highlighted a frequent overemphasis on capture and storage, and a consistent weakness in interpreting, formalizing, and embedding knowledge into practice.

Organizational Learning: from information to action

The Organizational Learning (OL) literature focused on how information could be transformed into action. Kloot (1997) synthesized OL into four constructs: knowledge acquisition, information distribution, information interpretation, and organizational memory (Kloot, 1997). These aligned closely with the KM categories of capture, interpretation, standardization, and sharing. Skerlavaj et al. (2007) observed that improved acquisition often enhanced interpretation, particularly in terms of recognizing opportunities (Škerlavaj et al., 2007).

Dewey’s (1933) classic learning cycle: discovery, invention, production, and generalization, clarified why synthesis (extracting generalizable mechanisms from cases) needed to precede standardization (Alas, 2007) . Senge (1999) distinguished between adaptive learning (focused on incremental adjustments) and generative learning (aimed at innovation), which set different levels of ambition for organizations (Senge, 1990).

Change models from the literature provided insight into how new practices could be embedded over time. For example, Lewin’s three-stage model: unfreeze, move, refreeze, outlined how organizations created readiness, introduced change, and stabilized new practices (Alas, 2007). Tichy & Devanna proposed a similar sequence:

recognize the need for change, create a compelling vision, institutionalize the new approach (Alas, 2007). Both models emphasized that successful change required preparation, implementation, and consolidation, not just deployment. Hendry et al. (1996) stressed the importance of feedback loops at each stage, while Senge (1990) pointed to the role of language, routines, and collective meaning-making in enabling adoption (Hendry, 1996; Senge, 1990).

Strategy execution research offered an essential complement to these models. Ford and Evans (2001) differentiated strategic change (direction-setting) from process change (operational execution and adaptation through routines) (Ford and Evans, 2001). These were seen as complementary: strategies required deliberate process redesign to materialize. Serrat (2017) reframed this through the lens of "strategy-as-practice," highlighting the importance of roles, routines, metrics, and feedback in making strategy actionable. He also recontextualized tools like AARs within a broader continuous improvement agenda (Serrat, 2017).

In summary, the literature emphasized that a successful transition process depended on structured interpretation, formalization into standards or routines, and alignment between strategic intent and operational processes supported by feedback mechanisms.

From pilots to practice: beyond "scale-up"

Pilot projects were widely used in organizations to test new ideas under controlled conditions. They were often conceptualized as "agencies for change", temporary structures created to support strategic transformation (Williams, 2008). In the context of open innovation, pilots were shown to trigger organizational change, validate key principles, and enable standardization through boundary objects (shared evaluation tools, templates, IT artifacts), internal champions, and external validation to overcome internal resistance (Boscherini et al., 2010). These mechanisms reflected the same unfreeze–move–institutionalize sequence seen in change management models.

However, the literature emphasized that scaling up was not equivalent to institutionalizing. For example, the SC4CCM program stressed that benefits from pilot projects could only persist if they were embedded into organizational routines and continuously improved over time. In healthcare contexts (SC4CCM, 2014). Hussey et al. (2013) further emphasized the need to design pilots with spread in mind, that is, to start quickly, iterate, involve local leaders, and establish learning communities (Hussey et al., 2013).
They also identified a critical gap: decision-makers frequently lacked data on mechanisms and context-specific factors, meaning that not all pilots should necessarily be scaled.

In conclusion, the literature on pilot implementation highlighted the need for intentional design of the transfer process. This included developing standards, appointing champions, using external validation panels, and building governance structures. Spread was understood not as a singular replication, but as an iterative process involving staged rollouts, performance audits, and adaptive learning mechanisms.

Cross-cutting gaps from the literature

The review revealed five persistent gaps across the three literature domains:

- **Capture bias**: organizations over-invested in knowledge capture, while interpretation and application were often underdeveloped (Duffield and Whitty, 2015; Williams, 2008).
- **Tacit–explicit imbalance**: codified repositories dominated, while tacit knowledge transfer mechanisms (e.g., peer learning, mentoring) were underutilized(Duffield and Whitty, 2015; Williams, 2008).
- **Tool–system misalignment**: tools were implemented in isolation, without aligning them to broader systems (people, processes, infrastructure, culture) (Duffield and Whitty, 2015).
- **Strategy–process gap**: strategic goals lacked operational hooks and feedback mechanisms, preventing learning from projects to inform execution (Ford and Evans, 2001; Serrat, 2017).
- **Context blindness**: pilots were often evaluated without attention to mechanisms and contextual factors, limiting transferability (Hussey et al., 2013).

In summary, while organizations were generally capable of generating information from individual projects, the literature highlighted consistent challenges in interpreting this information, translating it into reusable standards, and embedding it through governance mechanisms and social learning processes. These observations, along with

the recurring gaps identified across KM, OL, and pilot implementation literatures, pointed to the need for a structured transition approach, one that moves systematically from knowledge capture to organizational integration. Based on these insights, a set of design requirements was distilled from the literature to guide such a transition. These requirements informed the structure of the proposed framework, which is presented in the next section.

5.3.1.2. Proposed transition framework

Building on the insights and patterns identified in the literature, this section introduces a structured framework to support the transition from isolated initiatives to systemic practices.

As outlined in the previous section, the literature provided clear indications of what must be done for project learnings to be embedded and sustained. From this analysis, a set of Design Requirements (DRs) was synthesized to define the essential features that any viable transition approach should incorporate. These DRs serve both as criteria for evaluating transition efforts and as foundational elements that informed the structure of the proposed framework.

Design requirements derived from literature

The DRs represent principle-level conditions distilled from the literature analyzed. They reflect what the literature has shown to be necessary for effective knowledge capture, learning, standardization, and organizational embedding.

- **DR1 - Structured capture of explicit and tacit evidence**: combine templates and repositories with interviews, narratives, and causal mapping; ground after-action reviews in data and real-world artifacts (Coughlan and Coghlan, 2002; Duffield and Whitty, 2015; Williams, 2008).
- **DR2 - Cross-case interpretation and generalization**: analyze learnings to derive context–mechanism–outcome patterns and formulate generalizable design principles; validate through peer or stakeholder feedback (Hussey et al., 2013).
- **DR3 - Translation into boundary objects and standards**: formalize insights into SOPs, checklists, decision trees, KPI sets, and IT tools to make knowledge actionable.
- **DR4 - Strategy–process coupling and governance anchoring**: connect each standard to strategic objectives, clarify roles and responsibilities (e.g., via RACI), and integrate with stage-gates and feedback loops (Nonaka et al., 2006; Nonaka and Takeuchi, 1995).
- **DR5 - Dual-channel knowledge transfer**: combine codified mechanisms (e.g., databases, toolkits) with social transfer (e.g., champions, coaching, communities of practice) to support both explicit and tacit learning (Duffield and Whitty, 2015; Williams, 2008).
- **DR6 - System alignment across people, process, technology, infrastructure, and culture**: ensure these dimensions reinforce rather than block adoption of new practices (Amui et al., 2017; Duffield and Whitty, 2015).
- **DR7 - Iterative spread and continuous improvement**: implement mechanisms for staged rollout, performance audits, incentives, and improvement tracking; treat spread as an iterative process (Pigosso et al., 2013; SEI, 2006).
- **DR8 - Context-fit and selective scaling**: define rules for determining which pilots should scale, under what conditions, and how to adapt to local constraints or opportunities (Bezerra et al., 2020; Hussey et al., 2013).

A transition framework for transforming projects into practices

To operationalize the design requirements identified in the literature, a structured framework was developed to guide the transition from isolated initiatives to systemic, embedded practices. The framework is organized around four iterative and interdependent steps, each targeting specific activities and outcomes required for organizational learning and integration. Figure 74 presents the proposed transition framework, highlighting the structuring steps and their associated objectives. It should be noted that the framework does not claim to introduce entirely new theoretical constructs; rather, it consolidates and structures existing insights from the literature into a format that is operational and directly applicable within the context of this research.

Framework overview

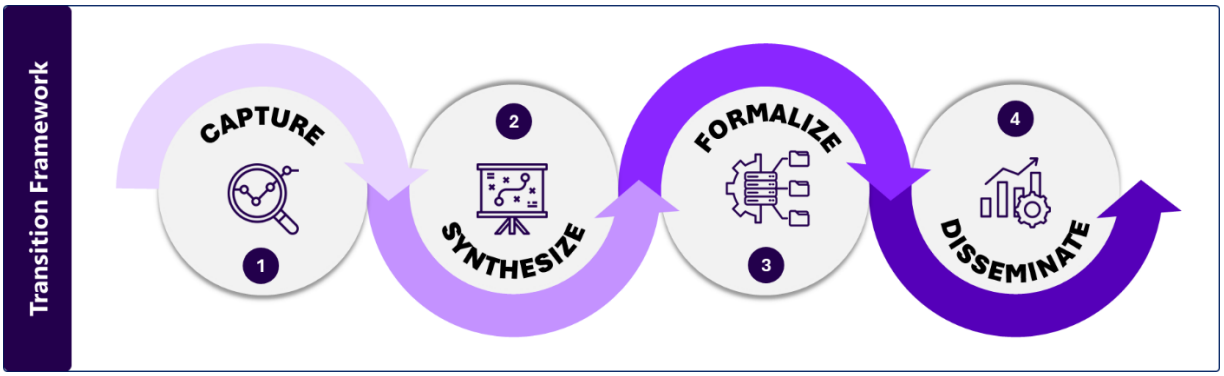

Figure 74. Transition framework: from pilots to practices - Overview

The steps defined in this framework aim to:

- **Step 1 – Capture:** the first step focuses on the systematic capture of both explicit and tacit knowledge from completed initiatives. This includes technical outcomes, process insights, stakeholder experiences, and contextual factors.

- **Step 2 – Synthesize:** this step involves interpreting and abstracting the captured knowledge into generalizable insights (taking a step back). Rather than treating each project in isolation, this stage looks across cases to identify patterns, contextual factors, and mechanisms that explain outcomes.

- **Step 3 – Formalize:** once synthesized, insights are translated into actionable organizational assets such as tools, standards, or processes. This step ensures knowledge becomes executable and aligned with strategic objectives. It is important to acknowledge that before being standardized, the knowledge and associated practices need to be simplified to not complexify organizational processes.

- **Step 4 – Disseminate:** the final step ensures that formalized knowledge is transferred, adopted, and embedded across the organization, enabling continuous improvement and institutionalization. It combines codified and social learning mechanisms to ensure effective transfer.

Finally, Table 34 provides an overview of the four framework steps, illustrative activities for each, and the associated design requirements identified in the literature.

Table 34. Overview of the transition framework steps, activities, and design requirements

Step	Goal	Example of activities	DR addressed
1. Capture	Collect key insights from projects.	• Structured after-action reviews (AARs) • Stakeholder interviews and reflection sessions • Documentation of success/failure factors and enablers/barriers	DR1, DR7
2. Synthesize	Identify patterns and general principles.	• Thematic analysis and clustering of lessons • Identification of context–mechanism–outcome patterns • Validation through peer review or cross-functional feedback	DR2, DR7
3. Formalize	Convert insights into tools and standards.	• Development of SOPs, checklists, decision aids • Creation of boundary objects and IT hooks • Alignment with governance systems and performance metrics	DR3, DR4, DR6

4. Disseminate	Transfer and integrate practices across the organization.	• Deployment of training materials and repositories • Mobilization of champions, peer coaching, and CoPs • Roll-out strategies, audits, feedback loops, and adaptation for local contexts	DR4, DR5, DR6, DR7, DR8

5.3.2. Selected projects

As the purpose of this study was to follow up on the outcomes of the defined CE strategy and associated initiatives, with a focus on their potential for broader organizational integration, it appeared logical to consider the set of pilot projects initially presented in Chapter 4 (Part B, Section 4.8.1). However, not all projects were retained for further analysis. Selection was constrained by time and, more importantly, by the relevance and maturity of each initiative for evaluating the transition framework.

A key insight from the earlier analysis was that while scalability was often identified as a desirable outcome, it was rarely achieved in practice due to the need for adaptation. Challenges included differences in local site processes (as in the case of solvent recovery), variations in healthcare system contexts (as in take-back systems), or the necessity of redesigning procedures (as seen with single-use technologies). Although many initiatives demonstrated technical feasibility and innovation potential, they often remained isolated, opportunistic responses to local needs or regulatory pressures. As a result, they were not embedded in a fully integrated system, which limited the transformative impact of the overall strategy.

To ensure a relevant selection, two criteria were applied: (1) the project's systemic integration level, as defined in Chapter 4, and (2) its demonstrated validation in practice. Only projects still operating in a relatively isolated mode were considered, as those already integrated at the organizational level did not require further transformation. At the same time, validation was essential to ensure that the selected initiatives had produced sufficiently robust and relevant outcomes to justify scale-up or standardization efforts.

The application of these two criteria is detailed below, explaining how each informed the selection of the final projects retained for evaluation:

(1) **Systemic integration level:** two projects were excluded based on their advanced level of integration. The Take-Back Systems initiative had already achieved high visibility and cross-functional implementation, with existing standardization across the company. The Value Stream Mapping (VSM) project had also progressed beyond the isolated project stage, with several VSM performed across the company, and with its outcomes integrated into a best practices handbook. These projects, therefore, no longer required support from the proposed transition framework.

(2) **Validated project selection:** of the remaining four projects, two were further excluded due to insufficient maturity or outcome clarity. The SUT Circularity project, while promising, had not yet produced results that could inform actionable transformation. Similarly, the specific Solvent Recovery pilot evaluated in this study was still ongoing, with key deliverables pending. In addition, generic solvent recovery practices are already established and partially systemic across chemistry sites, meaning that the transition framework would offer limited added value in this case. In both cases, future iterations of these projects may warrant integration into the transition framework once more concrete outcomes are available.

As a consequence, two projects were selected as the most appropriate for this evaluation:

- The **Manufacturing guide**, which had been finalized for one GBU, with actionable eco-design levers identified and embedded into the decision-making tool.
- The **Portfolio LCA** project, which followed earlier product-level LCA efforts and was in the process of synthesizing cross-product insights

These initiatives offered a robust basis for applying and evaluating the transition framework, both because of their validated outcomes and their potential to inform systemic practices.

In both cases, the framework was used to guide the transformation of isolated knowledge outputs (e.g., individual LCAs or eco-design recommendations) into reusable, operational practices. The four-step logic (capture, synthesize, formalize, disseminate) provided a flexible but structured approach for aligning project outputs with organizational integration goals. Despite the steps being not always followed linearly, they served as a useful reference for decision-making and reflection throughout the initiatives.

The following subsections present each selected project in greater detail. For each experiment, the project context, initial needs and gaps, and the key outcomes or practices developed are first described. This is followed by an analysis of how the transition framework was applied and how it contributed to embedding environmental sustainability within the organization.

5.3.3. Experiment #1 – Insulin Portfolio LCA

The following study applies the transition framework described in Section 3.2 to structure a portfolio-level environmental assessment. Despite the study itself focusing on quantifying and improving the environmental performance of insulin products using LCA, it also exemplifies how the framework can be used to consolidate scattered environmental analyses into systemic practices. This experiment contributes to the thesis by demonstrating a move from isolated product LCAs to a reusable, standardized approach for environmental impact assessment of a family of products within the pharmaceutical industry.

5.3.3.1. Experiment overview

As presented previously in this thesis, one of the core challenges in achieving systemic integration of sustainability is the fragmentation of projects and approaches, such as environmental assessments. To address this within the context of pharmaceutical manufacturing, a portfolio-based LCA approach was developed and applied to Sanofi's insulin products, with the aim of transitioning from isolated assessments to a more integrated, systemic understanding of environmental impacts.

The goal was to generate a comprehensive view of environmental performance across the insulin portfolio, while also streamlining data collection and modeling to improve consistency, comparability, and usability for decision-makers. The assessment revealed that the largest contributors to environmental impacts were the manufacturing of the active pharmaceutical ingredient (API), the production of primary packaging, and the manufacture of drug delivery devices. Based on these insights, targeted improvement strategies were identified, including reducing energy consumption, switching to cleaner energy sources, and minimizing the use of harmful substances. Beyond individual findings, the study demonstrates how a portfolio-based LCA can act as a lever for scaling environmental analysis across products in the pharmaceutical industry, laying the groundwork for broader integration into organizational practices and sustainability-driven decision-making.

5.3.3.2. Introduction

Human activities have placed enormous pressure on natural ecosystems and the global environment. These environmental burdens have been highlighted by various scientific frameworks and are now recognized as some of the most pressing challenges of the 21st century (UNEP, 2012). Our current modes of production and consumption are central contributors to environmental degradation, underscoring the urgent need to adopt cleaner production systems and alternative consumption models (e.g., SDG 12) (UN, 2015b).

The pharmaceutical industry, responsible for the development of medicines, vaccines, and medical devices, plays a vital role in improving human health but also contributes significantly to environmental degradation. This duality creates a fundamental paradox: while the sector's core mission is to enhance public health, it must simultaneously reduce its environmental footprint (Mackenzie and Jeggo, 2019). Balancing these objectives presents a complex challenge that is increasingly central to pharmaceutical sustainability agendas.

Among the pharmaceutical products with high public health relevance, insulin is particularly critical. Used to manage both type 1 and type 2 diabetes, insulin regulates glucose levels and has transformed outcomes for millions of patients since its first synthesis in 1922 (Pouwer and Hermanns, 2009). As of 2021, 537 million adults were living with diabetes, leading to an estimated 6.7 million deaths (IDF, 2021). The increasing global demand for

insulin, projected to grow by over 8% by 2030 (GRV, 2024), amplifies the urgency of evaluating and mitigating its environmental impacts, especially given the use of injectables, packaging, and complex supply chains.

Life Cycle Assessment (LCA) is widely recognized as a robust methodology for evaluating environmental impacts across the full life cycle of products. In the pharmaceutical sector, the application of LCA has expanded considerably in recent years. Sabour et al. (2023), in a review of over 200 studies, noted a shift from carbon footprint–only assessments to more comprehensive impact categories such as toxicity and wastewater (Sabour et al., 2023). Other authors have highlighted persistent methodological limitations, such as the exclusion of use and end-of-life phases, the complexity of modeling API emissions, and the frequent reliance on cradle-to-gate boundaries (Emara et al., 2019; Wilkinson et al., 2022). These challenges are compounded by data gaps and the limited integration of LCA results into corporate decision-making (Jiménez-González and Overcash, 2014).
Even though these studies represent important progress, significant gaps remain, particularly regarding comprehensive LCAs covering the full life cycle of pharmaceutical products and enabling strategic comparisons across product lines. In addition, few studies explore how LCA outputs can be reused, scaled, or embedded into broader environmental decision-making processes. Notably, to date, no complete LCA has been published for insulin products, despite their importance and growing demand.

To address these gaps, this experiment provides a comparative, cradle-to-grave LCA of Sanofi's insulin portfolio, quantifying the environmental impacts of multiple insulin products and identifying leverage points for improvement. Beyond individual product assessments, the study adopts a portfolio-level approach to streamline modeling efforts and facilitate broader applicability and integration of results. This experiment thus serves to evaluate the potential of LCA not only as a technical tool, but also as a scalable support mechanism for transitioning from isolated analyses toward systemic practices in environmental sustainability.

5.3.3.3. Background on insulin process development

The life cycle of a pharmaceutical product involves several distinct stages, each critical to its final form and therapeutic efficacy. The process begins with the production of the Active Pharmaceutical Ingredient (API), the primary compound responsible for delivering the intended therapeutic effect. Then, the API undergoes galenic formulation, where it is combined with excipients, substances that enhance stability and optimal absorption within the patient's system. The formulated drug is then placed into its primary packaging; for drug–device combination products, this is inserted into a device, followed by secondary packaging, and finally tertiary transport packaging (Luu et al., 2022b).

Bioprocessing of the API and galenic formulation

Insulin production technologies have evolved over time, reflecting advancements in biotechnology. Initially sourced from animals, modern insulin production now predominantly relies on the recombinant DNA biosynthesis process (Beals et al., 2019; Mayer et al., 2007). This technology enables the pharmaceutical industry to meet the substantial demand for insulin worldwide while also managing the complexity of the insulin molecule. This process begins with the biosynthesis of insulin, where the insulin or proinsulin gene is inserted into host organisms, such as Escherichia coli or yeast (Hwang et al., 2016). Depending on the process and the genetic sequence encoded in the inserted insulin gene, different types of insulin can be developed, including rapid- and long-acting formulations.

For this study, the focus was put on different insulins, which follow approximately the same process. These steps can be categorized into upstream and downstream bioprocessing.

Upstream bioprocessing

The first steps of the process are based on fermentation in microorganisms, with the production of insulin analogs in Escherichia coli or yeast (Hwang et al., 2016). The aim of fermentation is to cultivate sufficient proinsulin-producing Escherichia coli bacteria to obtain an adequate amount of insulin per batch. The cells are fed with culture media containing several nutrients, such as glucose. Fermentation in large scale bioreactors enables the production of a substantial quantity of the desired product.

Downstream bioprocessing
Once the resulting product has been obtained, a complex series of steps begins, including extraction, purification, and filtration (Siew and Zhang, 2021). Initially, the proinsulin containing cells are isolated by filtration or centrifugation. The cells are then disrupted, and the fusion protein is isolated, which is then folded into its correct conformation to achieve its biologically active form. The down-stream process includes enzymatic cleavage to convert proinsulin into native insulin, as well as multiple chromatographic steps for impurity removal. Insulin is then isolated as part of this process.

Galenic formulation
To obtain the galenic form of the product, the insulin is mixed with excipients which will impact the absorption kinetics of the insulin by the patient, and ensure the stability of the medicine, with m-cresol for example (Ohno et al., 2019).

Packaging and device
Packaging for pharmaceuticals typically involves three levels, each serving a distinct purpose in relation to the drug. Primary packaging is in direct contact with the product, while secondary packaging provides protection and identification, and tertiary packaging is used for distribution. For liquid pharmaceuticals, especially those requiring precise dosing like insulins, the integration into medical devices is crucial for effective administration. In the case of insulin, the medication is contained within a cartridge, which constitutes the primary packaging. This cartridge is then placed into a specialized device (disposable or reusable), commonly known as an insulin pen, which facilitates accurate dosing and ease of use for patients. However, other forms of insulin packaging also exist, such as vials, which are primarily used in insulin pumps or, in some cases, in hospital settings.

The daily dosage of insulin varies based on the type of insulin (e.g., long-acting vs. short-acting) and individual patient needs. For instance, the World Health Organization recommends a daily dose of 40 units for insulin glargine (ATC A10AE04). Insulin cartridges come in different sizes, typically ranging from 1.5 ml to 3 ml. In disposable devices, the cartridge and device are discarded together once the cartridge is empty. In reusable systems, only the cartridge is replaced, while the device can be reused over multiple treatment cycles.

5.3.3.4. Material & Methods

Life Cycle Assessment
The Life Cycle Assessment is a science-based tool that allow the quantification of potential environmental impacts throughout the overall life cycle of a system (Finnveden et al., 2009; Hauschild et al., 2017). The ISO14044 defines the main steps of an LCA as the definition of the goal and scope, the life cycle inventory analysis, the life cycle impact assessment, and the interpretation of the results (ISO, 2006a). The following sections describe the stages executed in this study.

Goal and scope
Three objectives were identified for this LCA study:
(1) Calculate the environmental impacts of several insulin products (insulin portfolio).
(2) Identify the environmental hotspots throughout the whole life cycle of the products.
(3) Identify new areas of improvement.

In the treatment of diabetes, the function of insulin is to regulate the glucose level in the body, in other words, to replicate endogenous insulin production with-out compromising peripheral glucose utilization (Clements and Bello, 2016). The Defined Daily Dose (DDD) provided by the WHO offers an effective method for characterizing the Functional Unit (Luu, 2023a). However, the recommended dose and type of insulin can vary by country due to physiological differences among populations. Consequently, the Functional Unit (FU) for this study is defined as the average dose of insulin administered to a typical type I or type II diabetic patient to maintain glycemic control over one day. To meet this functional unit, and based on the global average DDD for insulin, the reference flow is set at an injection of an average of 30 units per day for one group of products, and 27.72 units per day for another group. Rapid-acting insulin is typically administered up to three times per day, while long-acting (basal) insulin is usually given once, or at most twice, per day.

The system boundary selected for this Life Cycle Assessment is a cradle-to-grave approach, covering the whole life cycle of the product, from the production of the API and galenic formulation, to the end-of-life of packaging, through the filling process, packaging production, storage and distribution, and use (Figure 75).

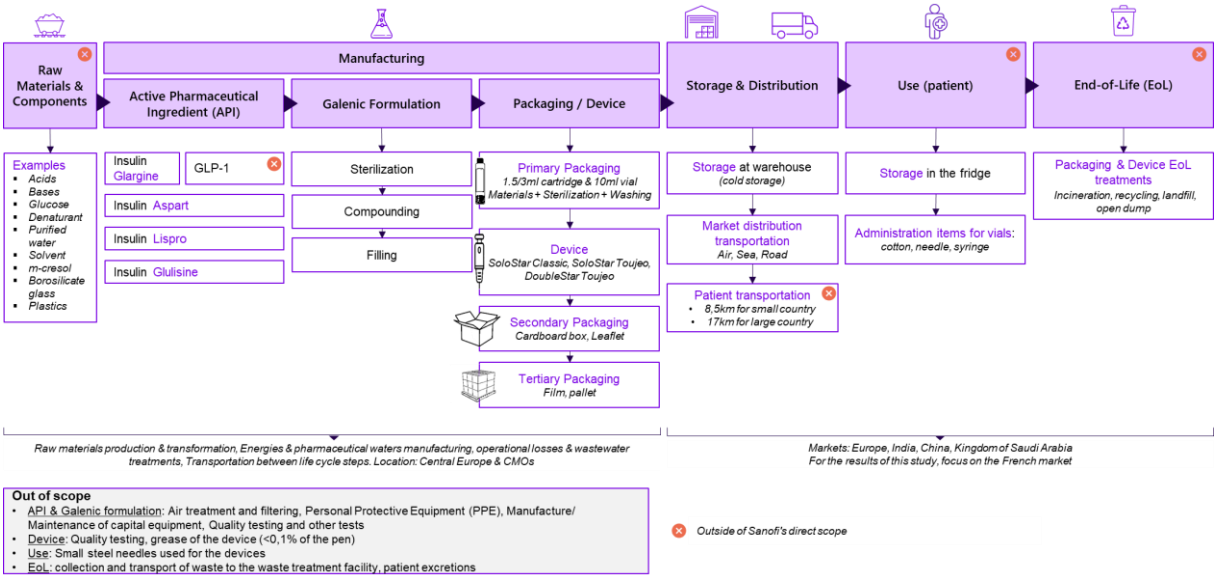

Figure 75. Scope of the Portfolio LCA: Flows and Boundaries

The focus of this study is performed on six insulin products developed by Sanofi, with different duration effects, which represent the overall insulin portfolio of the company, with hundreds of millions of insulin products provided to patients every year. The products considered within this study are based on the following Active Pharmaceutical Ingredients (APIs): Glargine, Glulisine, Lispro, and As-part. Each API is combined with specific excipients to obtain the galenic formulation and then integrated within a cartridge. There is a specific type of device for each insulin product to allow the drug administration by the patient, with each device consisting of multiple components.

This study evaluates various scenarios for six insulin products derived from these four APIs. These APIs are used to produce the following insulin products: Toujeo®, Lantus®, Soliqua®, insulin LISPRO Sanofi®, insulin ASPART Sanofi®, and Apidra®. Toujeo® is available on the market in two different forms: Toujeo SoloStar®, which contains 1.5 ml cartridges, and Toujeo DoubleStar®, with 3 ml cartridges. Soliqua® is available in three different versions to meet varying patient needs, based on the combination of insulin glargine and a GLP-1 receptor agonist. The three versions of Soliqua® available are: Soliqua® 3:1, Soliqua® 2:1, and Soliqua® 1:1. These ratios indicate the proportion of insulin glargine to the GLP-1 component in the drug, with higher ratios signifying a greater amount of the GLP-1 receptor agonist relative to insulin glargine. These products are distributed across diverse markets, including European countries like France, as well as India, China, and the Kingdom of Saudi Arabia. Availability may vary by market. While the study adopts a portfolio approach, the results primarily focus on Toujeo® products (SoloStar® and DoubleStar®) in the French market. Despite the varied distribution, the APIs are manufactured in central Europe.

Life cycle inventory analysis

As a crucial stage in the LCA, the Life Cycle Inventory (LCI) includes primary data collected from industrial production processes which are representative of the production year 2022 and 2023. Background data is sourced from Ecoinvent v3.8 database. The method for the inventory calculation is the process-based approach. The study follows the Product Environmental Footprint (PEF) methodology (Damiani et al., 2022), therefore, in cases where specific data was unavailable, assumptions and information from the PEF were given priority.

The LCA was conducted using the Brightway 2 tool, with Activity Browser (AB) serving as the graphical interface. The model incorporated environmental datasets from three key databases: Ecoinvent cut-off (version 3.8), Biosphere3 (which regroups all elementary flows), and a specialized database developed by Sanofi. In the Sanofi database, datasets extracted from Ecoinvent v3.8 were du-plicated and adapted to serve as proxies and models specifically adapted for pharmaceutical products.

For each product and process, mass balance documents were collected to identify raw materials (chemicals and consumables) and their quantities. As specific energy data per product was not available, the total energy use of each production building was allocated to estimate generic consumption per kilogram of insulin. API manufacturing steps are generally consistent across insulin products. The LCI included raw materials and their transport, cleaning agents, energy consumption, hazardous and liquid waste treatment, and consumables such as filters and chromatography buffers. When supplier-specific data for consumables was unavailable, an economic allocation method was used to estimate their environmental impacts.

For the galenic formulation, energy, raw materials, consumables, waste, and as-sociated transport were included. Sterilization and cartridge filling were also accounted for, as the product is in liquid form.

Packaging formats include pens, cartridges, and vials. Pens integrate cartridges within disposable or reusable devices; cartridges are also sold separately for compatible pens, while vials are standalone containers used with syringes. Pen packaging includes four levels: (1) Primary packaging: a glass cartridge (glass, metal, rubber) inserted into the device; (2) Device: multiple components (e.g., cap, body, clutch), mainly plastic (e.g., polycarbonate, polypropylene) with some metal parts; (3) Secondary packaging: leaflet, label, and cardboard box, typically containing five devices; (4) Tertiary packaging: transport-level materials like pallets, cardboard, and film. Vials do not require a device; they are filled directly and then packaged similarly. Syringes are required for use but are not provided with the vial..

For the device and primary packaging, data covered raw materials, energy, and transport to the production site. For secondary and tertiary packaging, only raw materials and their transport were considered.

Regarding storage and distribution to warehouses, the collected data primarily focused on transport, with additional consideration given to patient transportation from home to pharmacies. The distances for patient transportation were estimated using national statistics for small/medium and large countries. The use phase included injection consumables, their end-of-life, and energy for insulin storage. End-of-life data covered waste treatment for all packaging types, using a mix of landfill and incineration depending on country and material. The phase was modelled using the Circular Footprint Formula (CFF) method (Ardente et al., 2023).

Life cycle impact assessment

The Environmental Footprint 3.0 is a Life Cycle Impact Assessment (LCIA) method, proposed by the European Commission, was chosen as the impact assessment methodology for this study (EU, 2021). Although all 16 indicators of the methodology were evaluated, special emphasis was placed on six indicators: climate change (kg CO2.eq), energy resources: non-renewable (MJ, net calorific value), material resources: metals/minerals (kg Sb.Eq), water use (m3 world eq. deprived), freshwater eutrophication (kg P.Eq), particulate matter formation (dis-ease incidence). These six indicators were identified as being the most relevant, collectively accounting for 76% to 79% of the total environmental impact, de-pending on the product assessed.

Results & Interpretation

The results obtained were normalized with the normalization method of the EF, based on the reference impact of an average European over one year. Subsequently, the results were combined with a weighting factor from the EF 3.0 methodology.

The results of this study are available for nine types of insulin products, de-rived from four insulin APIs, with variations designed to meet specific market and patient needs (e.g., Toujeo® is available in both 1.5 ml cartridges (SoloStar®) and 3 ml cartridges (DoubleStar)). However, due to confidentiality constraints associated with pharmaceutical product data, detailed results for all products are not disclosed. Accordingly, the presentation of results in this study focuses primarily on Toujeo®, consistent with the emphasis on the French market.

Product portfolio LCA

This study adopted a comparative LCA approach across a portfolio of insulin products. The initial assessment, conducted in 2023, served not only to quantify environmental impacts but also to identify hotspots and critical life cycle stages that are common across insulin formulations and devices. By considering multiple products

simultaneously, the portfolio approach allowed for a systemic evaluation of Sanofi's insulin offer, providing a robust baseline for future improvements and internal decision-making.

Primary data were collected for each insulin product, particularly for the API manufacturing and galenic formulation stages, enabling precise process modeling. However, in order to streamline the assessment and facilitate consistency across the portfolio, data from similar or identical process steps (e.g., primary packaging) were aggregated. This approach allowed for the identification of both shared hotspots and product-specific divergences, supporting a more comprehensive environmental understanding across the product line.
Crucially, the portfolio perspective revealed several inconsistencies in the modeling of otherwise similar products. These discrepancies, encountered during both the inventory (LCI) and impact assessment (LCIA) phases, highlighted areas for improvement in data quality and modeling practices. In this way, the LCA not only provided results for environmental performance, but also contributed to improving internal modeling capabilities and reinforcing data governance.
All assumptions, modeling choices, and results were documented in internal technical reports and compiled in an ISO-compliant LCA report to ensure transparency and traceability.

Beyond its analytical value, this portfolio LCA contributed to the broader goals of the thesis by illustrating how individual assessments (i.e., the initial LCA conducted in 2023) can be scaled and structured to support systemic sustainability practices.

5.3.3.5. Results

This section presents the main results obtained from the LCA and their interpretation. The presentation of the results begins with an overview of the environ-mental impacts of the insulin portfolio to contextualize common life cycle pat-terns across products. The focus then shifts to Toujeo®, with a detailed analysis of its overall impacts and key contributing stages. These include API manufacturing, primary packaging, and the injection device.

Environmental impacts of the insulin portfolio

The presentation of the overall results for the global life cycle of insulins enables a comparison of all insulin types. To facilitate the analysis and focus on the steps where pharmaceutical companies have greater influence, patient transportation has been excluded from the results presented here. For example, for Toujeo®, the results indicate that patient transportation accounts for more than 60% of the impact across most indicators, making it the primary contributor. This decision to exclude patient transportation was also driven by the significant uncertainties in the data due to the lack of primary information, the large interindividual guidance, and the limited influence pharmaceutical companies have over this stage.

The analysis allowed the identification of impacts distribution for each insulin across their life cycle steps. The slight variations in daily drug dosage among insulin products contribute to the minor differences in their environmental im-pacts, even when certain life cycle steps, such as primary packaging and device, are similar across the portfolio. This comparative approach highlights the differences in environmental impacts between the insulin products. Despite similarities in primary packaging and device components across products, API manufacturing is the primary driver of these differences. Insulin glargine, being used for most insulin products in the portfolio (Soliqua®, Lantus®, Toujeo®), is the insulin representing the least of the impacts per dosing unit, due to the fact that its production process has been optimized in recent years.

Another crucial finding of the portfolio approach is the identification of the three major contributing life cycle steps across the product portfolio: API manufacturing, primary packaging, and device. In fact, the remaining life cycle stages contribute less than 20% of the total impact across all indicators, with variations by product. Specifically, secondary and tertiary packaging consistently account for approximately 5% of the impact across all indicators. In contrast, storage and distribution contribute between 3% and 8%, while the use phase accounts for less than 1% to 3% and the end-of-life stage 2% to 5%, depending on the indicator. To enhance the clarity and focus of the results, the subsequent section will provide a detailed analysis of Toujeo® and its critical life cycle stages.

Overall environmental impacts of Toujeo®

As introduced previously, the environmental impacts presented in this and the following sections exclude patient transportation, to ensure consistency and facilitate interpretation. The results for Toujeo® are presented based on the functional unit of 31.8 insulin units delivered per day of treatment, for a patient in France.

Across all impact indicators, the three major contributing life cycle stages are API manufacturing, primary packaging, and the injection device. These stages account for approximately 81% to 93% of the total environmental impact, de-pending on the indicator. Figure 76 shows the distribution of impacts across life cycle stages and indicators, supporting the rationale for focusing on these elements in the following subsections.

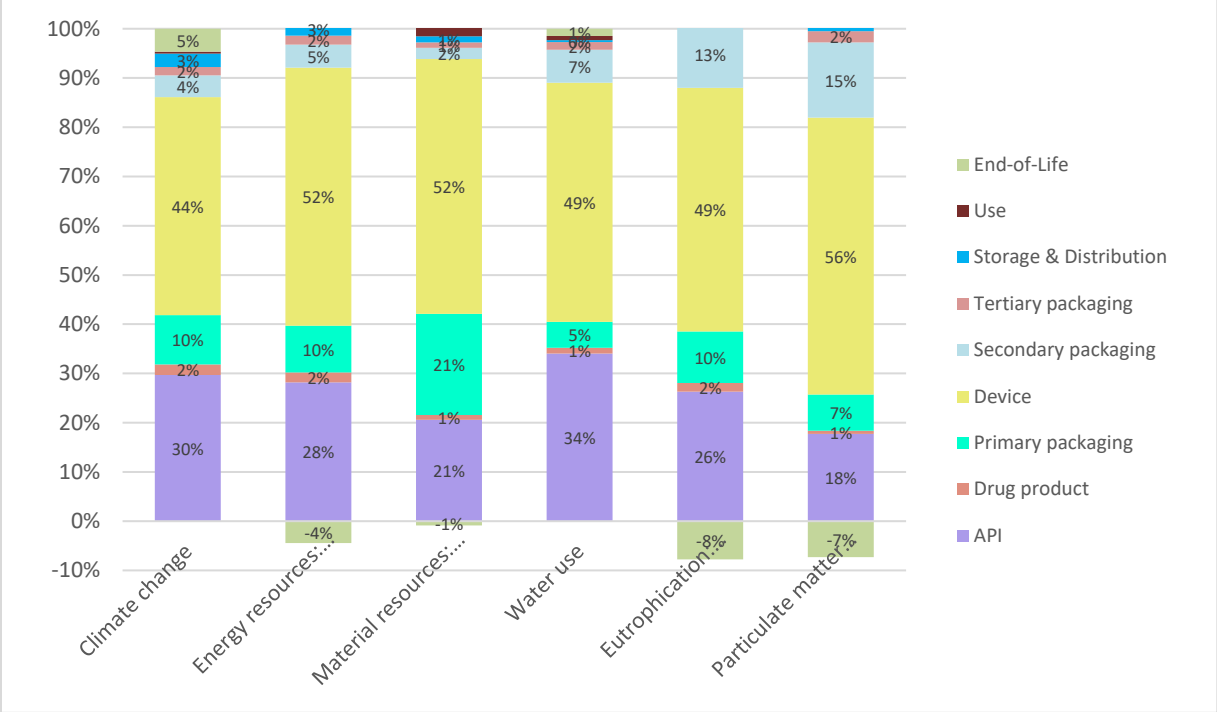

Figure 76. Environmental impact distribution of Toujeo® (SoloStar® 1.5 mL) by life cycle stage, per daily dose, in the French market

Impacts of Toujeo® API manufacturing

To facilitate the analysis of API production, the impacts are grouped into two categories: energy consumption and chemical inputs. This distinction helps clarify the origin of environmental impacts depending on the indicator considered. Figure 77 illustrates this distribution of impacts across several indicators for Toujeo®. Energy consumption accounts for the majority of impacts (approximately 65%) in relation to two indicators: climate change and non-renewable energy resources. This high energy demand is primarily driven by the heat required to generate pressurized steam at the manufacturing site used for both production processes, cleaning and sanitization. This heat is mainly produced through waste incineration, with a smaller share coming from natural gas. For the remaining indicators, the majority of impacts are attributed to the chemicals used in production.

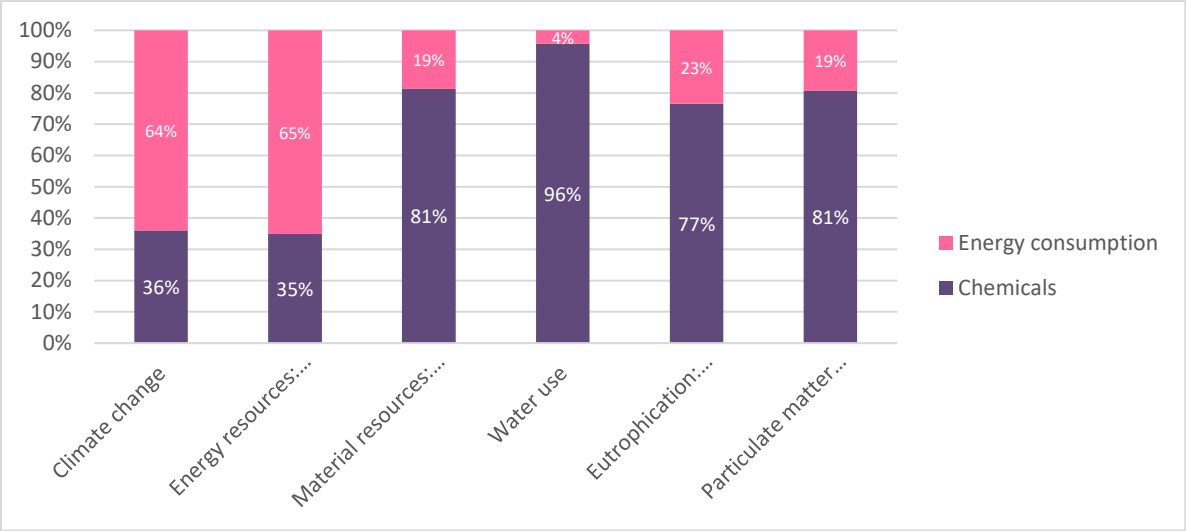

Figure 77. Allocation of the environmental impacts of insulin glargine, across all selected indicators

Due to the substantial contribution of these chemical inputs, a more detailed analysis was conducted to assess their relative contribution across indicators, excluding energy consumption (Figure 78). The detailed analysis of the share of these substances, permits the identification of main contributing chemicals across all indicators. Four major chemicals were identified: Glucose, Denaturing agent, Sodium hydroxide, and Reducing agent. These substances contribute between 64% and 77% of the total chemical-related impacts, depending on the indicator.

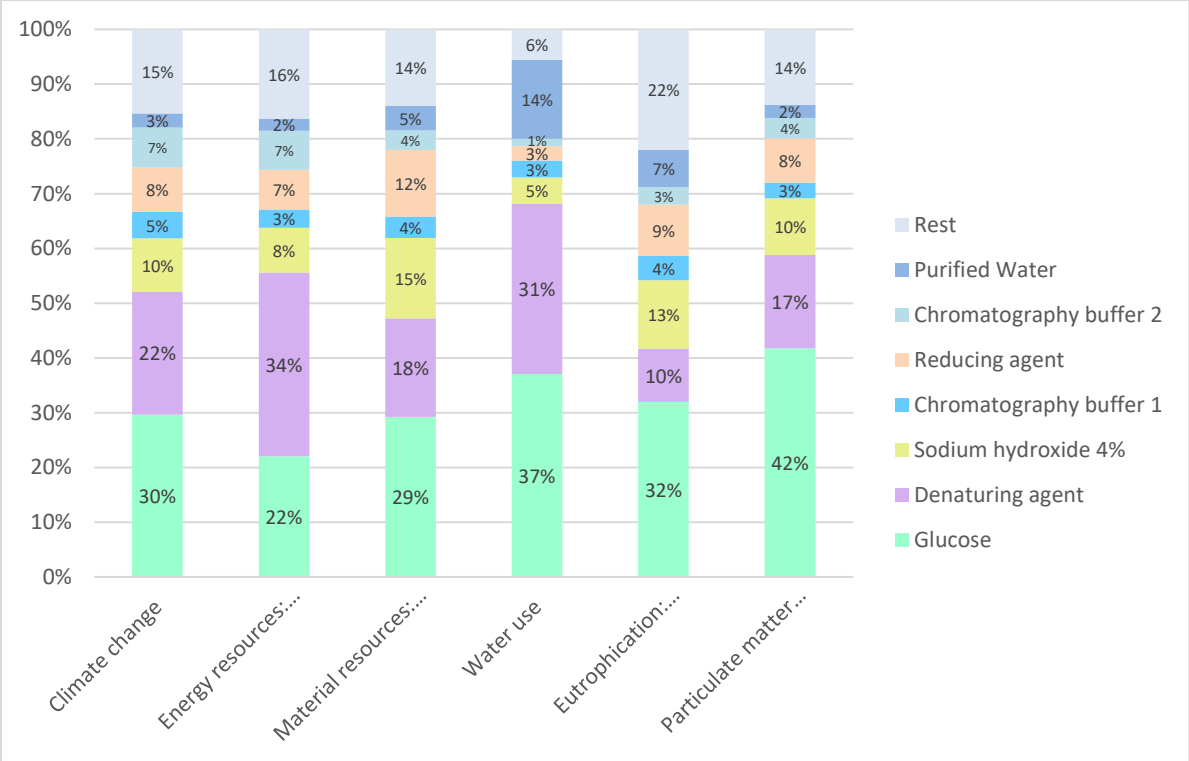

Figure 78. API chemicals contribution across all indicators, for One Daily Dose of Insulin glargine, on the French market

For the non-renewable energy indicator, the denaturing agent is the main contributor, accounting for 34% of the impacts. Glucose also plays a major role (22%), primarily due to electricity consumption and maize starch production. Sodium hydroxide also contributes to non-renewable energy impacts, due to the electricity required for its electrolysis.

For all other indicators, glucose is the primary contributor, accounting for 29% to 42% of the impact, mainly due to maize starch production and electricity use during its production. Glucose is followed by the denaturing agent, which contributes significantly (10% to 31%) due to its synthesis, and by sodium hydroxide (5% to 15%), which impacts climate change through electricity consumption for electrolysis.

In addition to its role in production, sodium hydroxide is also used in "Cleaning in Place" (CIP) processes to clean production equipment after each batch. This cleaning requirement, along with the notable impact of wastewater, highlights the critical role of cleaning processes in the overall environmental performance of API manufacturing.

Impacts of the primary packaging

The primary packaging used for Toujeo® in the French market is a glass cartridge filled with insulin glargine, designed to be inserted into a dedicated injection device. Figure 79 presents the environmental impact distribution of the cartridge across the selected indicators. The main contributors to environmental impacts include energy consumption related to sterilization and filling, the borosilicate glass used in the cartridge body, and the aluminum cap used to seal the cartridge. The cartridge is made with a specialty glass valued in pharmaceutical applications for its chemical resistance, purity, and stability under temperature variations. Borosilicate glass is particularly impactful for the material resource use and particulate matter formation indicators, accounting for 80% and 46% of the total impact, respectively. This contribution is mainly due to the extraction of calcium borates used in its production. Energy consumption is the primary contributor to the climate change, energy resource use, water use, and freshwater eutrophication indicators, largely due to the steam required for cartridge sterilization, which is energy-intensive to generate. For these same indicators, borosilicate glass is the second-largest contributor, primarily due to the substantial heat demand during its production. For all indicators, the aluminum cap is the third-largest contributor due to emissions associated with its extraction and processing.

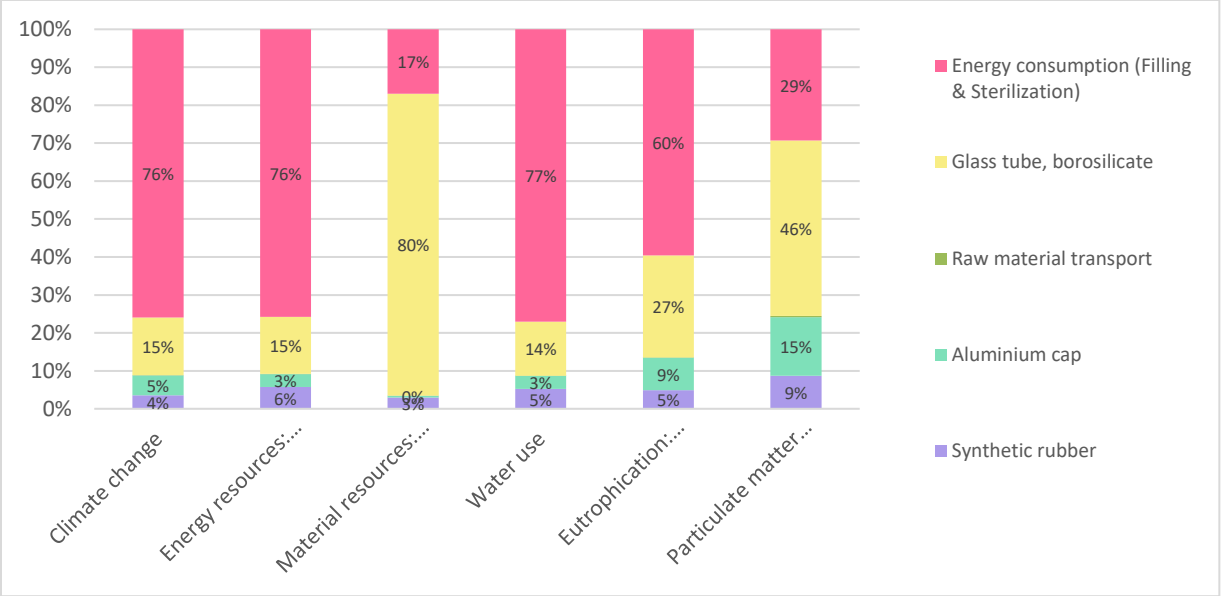

Figure 79. Profile of primary packaging impacts across all indicators

Impacts of the device

Each insulin product uses a specific device into which the glass cartridge (primary packaging) is inserted to ensure accurate dosing and injection. The specific device used may vary depending on the product. The SoloStar Classic® is used for insulin ASPART Sanofi®, insulin LISPRO®, Apidra®, Soliqua®, and Lantus®, while Toujeo® is available in two versions, Toujeo SoloStar® and Toujeo DoubleStar®.

Devices are composed of multiple components, primarily plastics, with material composition varying across models. These components are sourced and pre-assembled by global suppliers before being sent to the insulin production site for final assembly. The device modeling revealed two key impact sub-categories: raw material production and the assembly and transport of materials. Across all devices, raw material production is the dominant contributor to climate change, responsible for 61% to 76% of the total impacts.

This section focuses on the Toujeo SoloStar®, the primary device used for ad-ministering Toujeo®. Figure 80 presents the environmental impact distribution of the device across the six selected indicators. The results are consistent with earlier observations: raw material production is the dominant contributor across all impact

categories. A clear correlation was observed between material weight and environmental impact: heavier components contribute more significantly. However, the analysis also reveals the significant environmental impacts of specific materials, particularly polycarbonate for climate change and polyoxymethylene for water use. Sub-assembly manufacturing is the second-largest contributor for all indicators except energy resource use, accounting for up to 40% of the im-pacts for material resource and water use indicators. The main impacts are linked to the energy-intensive pre-assembly process and the copper required for the electricity distribution network.

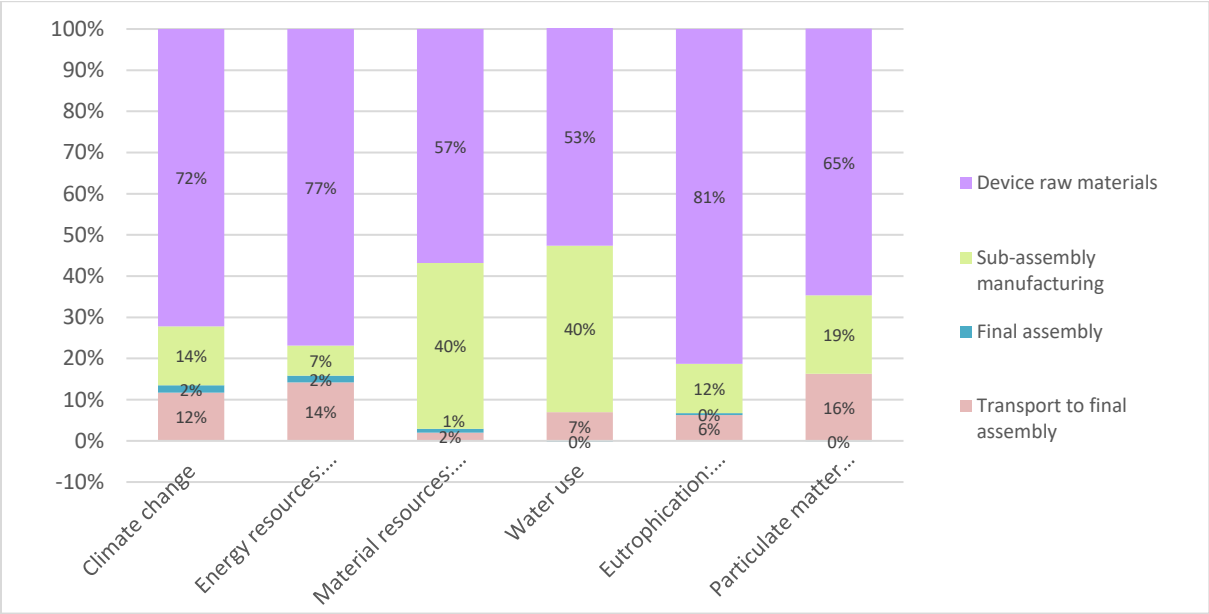

Figure 80. Environmental impact distribution of the Toujeo SoloStar® device across all indicators

As Toujeo® is available in two formats, a comparative analysis was conducted to evaluate the environmental impacts of Toujeo SoloStar® and Toujeo DoubleStar® (Figure 81). For one daily dose in France, Toujeo DoubleStar® shows a 24% to 42% reduction across all impact categories compared to Toujeo SoloStar®. At the device level alone, this reduction ranges from 51% to 59%. These differences are primarily due to the larger cartridge size of the DoubleStar® format (3 mL vs. 1.5 mL), which allows twice the volume to be administered per device.

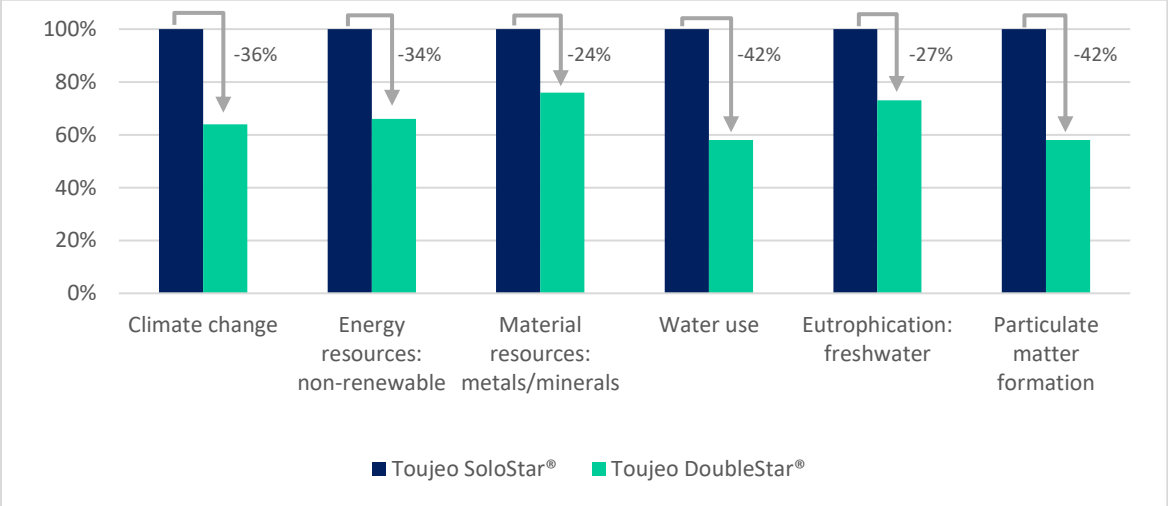

Figure 81. Impacts of Toujeo SoloStar® and Toujeo DoubleStar®, per daily dose, for the full life cycle

5.3.3.6. Discussion

This section reflects on the main results of the insulin portfolio LCA, emphasizing both environmental improvement opportunities and methodological contributions. It discusses how key findings across production,

packaging, and distribution stages can inform cleaner manufacturing practices and guide strategic decision-making. In addition, it evaluates the strengths and limitations of the portfolio LCA approach in the pharmaceutical context and proposes strategies for broader application.

Cleaner production methods

The results of this study provide valuable insights into the environmental impact of insulin products and identify key environmental drivers at each stage of their life cycle. By pinpointing these drivers and linking them to the literature, we can recommend more sustainable production methods for insulin products manufacturing. These methods are crucial for developing an environmental strategy aimed at reducing impacts and improving overall product efficiency.

Our insulin portfolio LCA revealed that the most significant environmental drivers are associated with the API manufacturing, primary packaging, and devices. Among these, the API manufacturing stage showed the most substantial environmental differences between various insulin products. Despite well-established production processes, there is significant potential to reduce environmental impacts, particularly in API production, which faces challenges related to energy use, harmful chemicals, and waste. Process optimization using cleaner energy sources, sustainable chemicals, and more efficient practices is therefore essential (Chen et al., 2024; Sabour et al., 2023). Applying green chemistry principles is also valuable (Sabour et al., 2023); managing solvents, especially those used in chromatographic steps, is crucial. Given the large quantities of solvents used, the implemented short-loop solvent reuse system through distillation significantly reduces environmental impacts (Raymond et al., 2010). Additionally, implementing CE principles, such as rethinking processes, reusing and extending the lifespan of materials (e.g., prolonged use of chromatographic resins) offers further benefits. Replacing hazardous chemicals with less impactful alternatives and focusing on renewable energy sources are critical steps. As energy consumption is a major driver of environmental impact, transitioning to renewable energy and incorporating more efficient technologies can significantly reduce the overall environmental footprint. In general, optimizing manufacturing processes to increase efficiency and product yield can contribute to reduced environmental impacts. Such optimization may include the integration of continuous manufacturing principles, which have shown potential for improving environmental performance without compromising product quality or safety (Chen et al., 2024; Sabour et al., 2023; Soete et al., 2017).

For the primary packaging, the impact can vary significantly depending on the dosage forms (e.g., vial vs. cartridge) (Chen et al., 2024; Wang et al., 2021). In evaluating the environmental impact of insulin packaging and devices, several opportunities for impacts reduction emerged. The choice and number of materials play a crucial role in determining environmental impacts. Emissions from material extraction and recyclability rates vary significantly between materials, complicating end-of-life management. Optimizing both material selection and the size of packaging and devices is therefore essential for reducing environmental impacts.

Device capacity also significantly influences environmental impacts. The comparison between Toujeo SoloStar® and Toujeo DoubleStar® demonstrated that increasing cartridge volume can notably reduce impacts per dose. This highlights how higher-capacity devices, by extending usage duration and reducing material consumption per unit of insulin delivered, can contribute to more resource-efficient and environmentally sustainable product design. However, this approach depends on market acceptance and patient willingness. Reusable devices offer another opportunity for impact reduction, potentially lowering environmental impacts compared to single-use models. The feasibility of implementing reusable devices depends on technical considerations and mainly, on market acceptance. For single-use and reusable devices, take-back programs or end-of-life management initiatives can facilitate component reuse and minimize waste (Mallick et al., 2023, 2022).

Although this study focused on the French market, the environmental impacts of distribution, particularly those resulting from intercontinental transport, should not be overlooked. Exploring alternatives to air transportation could further re-duce these impacts.

A significant area of concern and potential improvement lies in the management and treatment of wastewater (Emara et al., 2019), both at industrial sites and in municipal systems following the manufacturing and use phases. While down-stream treatments, such as advanced oxidation processes, membrane filtration, and biological treatments, can help reduce the presence of APIs and their metabolites in the environment (Sabour et al., 2023;

Wilkinson et al., 2022), upstream measures are equally important. These include reducing wastewater generation through optimized cleaning processes, intelligent design of cleaning circuits, and more efficient process design.

Portfolio LCA methodology

Drivers and Barriers

The portfolio LCA approach applied in this experiment addresses key challenges commonly encountered in pharmaceutical LCA research, including data complexity, comparability issues, and opportunities for streamlining process improvements across multiple products.

Data complexity in the pharmaceutical industry presents significant challenges for LCA. The intricate and global nature of products and processes complicates accurate data collection and analysis (Jiménez-González and Overcash, 2014). The complexity of pharmaceutical supply chains often obscures environmental impacts, and the lack of comprehensive data for many raw materials and precursor chemicals, make it difficult to obtain reliable and detailed information (Emara et al., 2019; Sabour et al., 2023). The portfolio approach helps to simplify data management by standardizing data collection across similar processes. Aggregating data from these shared processes ensures consistency and improves overall data quality, reducing the risk of relying on incomplete or unreliable sources (e.g., primary packaging, similar API process steps). However, it is important to acknowledge that data aggregation can sometimes obscure product-specific nuances, risking an oversimplification of unique impacts associated with certain products (e.g., GLP-1 receptor).

Comparing environmental impacts across pharmaceutical products is inherently complex due to potential data uncertainties, differing allocation methods, and proprietary information (Jiménez-González and Overcash, 2014) , amplified by the additional variability introduced during the conversion of LCI data to LCIA results (Sabour et al., 2023). This complexity is further increased with the absence of standardized methodologies tailored to pharmaceutical products LCAs (Luu, 2023a). By adopting a portfolio approach, these comparability challenges can be mitigated. Standardizing data collection and analysis methods across multiple products allows for more reliable comparisons. The consistent use of methodologies across the product portfolio improves the robustness of these comparisons, providing clearer insights into the environmental performance of each product.

Another key advantage of portfolio LCAs lies in its ability to offer a holistic view of environmental impacts across multiple products, enabling organizations to identify shared sustainability improvement opportunities (Jiménez-González and Overcash, 2014). This broader perspective supports more effective decision-making by highlighting initiatives that can be implemented across several products and processes, thereby maximizing impact. However, it is essential to recognize product-specific discrepancies and account for them during the assessment to avoid overlooking unique product characteristics.

Recommendations for conducting effective portfolio LCAs

Although taking on a portfolio approach in LCA offers significant benefits, the complexities associated with pharmaceutical products require careful consideration to ensure the accuracy and effectiveness of the LCA. Based on the findings of this study, several strategies can be proposed to facilitate the successful implementation of a portfolio LCA (Table 35).

Table 35. Strategies to perform pharmaceutical portfolio-LCA

Strategies	Descriptions
Standardization of data collection methods	Establish standardized protocols for data collection at similar life cycle stages, to ensure consistency.
Identification of common vs unique process steps	Develop process maps that clearly identify shared and unique stages, treating divergent processes separately to prevent oversimplification.
Centralization and aggregation of data	Implement centralized data management tools (e.g., Excel spreadsheet) to facilitate the tracking of complex LCI and ensure easy comparisons.
Iterations for data and modeling validation	Establish validation protocols that generate iterative reviews when inconsistencies arise during LCI or LCIA stages to ensure data reliability.
Prioritization of generic improvement levers	During hotspot analysis, prioritize improvements in shared processes that benefit multiple products simultaneously.
Ensuring continuous improvement	Establish review cycles and feedback loops to update the LCA with new data and ensure continuous improvement.

Cross-functional engagement	Ensure involvement and alignment of all relevant stakeholders from the outset, as portfolio LCAs typically engage a wide range of actors..

Although these strategies were developed in the context of insulins, many of the recommendations are broadly applicable to other pharmaceutical products. However, it is recommended that these strategies be tailored to account for the specific challenges of each unique product portfolio.

Limitations of the study

While the results offer valuable insights, several limitations should be acknowledged, particularly with respect to data quality and generalizability. One limitation lies in the accuracy of the datasets used for modeling certain raw materials and components. In some cases, chemical substances were modeled using generic approximations due to a lack of specific data on their production processes, though these sub-stances were not major contributors. Improving data quality in future studies will require closer collaboration with suppliers to access more specific information. Similarly, consumables used in the processes were modeled using economic equivalents, which could be improved by obtaining direct data from suppliers. Regarding the use phase modeling, certain assumptions were made, such as the use of a syringe for the vial, which may result in deviations from actual conditions. Additionally, not all indicators used in this LCA study possess the same level of robustness. For instance, the climate change indicator was found to be more reliable compared to the water use indicator, which should be considered when interpreting the results. Moreover, energy consumption was modeled using mass allocation, which does not enable a precise comparison between products. Given its significant contribution, improving the data collection for energy use is a priority. The results of this study were specific to the French market, but it is important to extend the analysis to other international markets due to the global access to insulin products. Lastly, the study utilized version 3.8 of the Ecoinvent database, though version 3.10 is now available, and its use should be considered in future studies.

5.3.3.7. Conclusion

LCA represents a key method for evaluating pharmaceutical product impacts associated with pharmaceutical products. This study evaluated the environmental footprint of six insulins developed by Sanofi, highlighting the value of a portfolio approach in LCA. Key findings identified Active Pharmaceutical Ingredient (API) manufacturing, primary packaging, and device production as the primary contributors to the life cycle impacts of all insulin products (excluding the patient transportation phase). Although the same life cycle stages consistently drive the impacts, some variation in environmental performance was observed between products.

The portfolio methodology employed in this research proved effective in ad-dressing challenges specific to pharmaceutical LCAs, such as reducing the complexity of data collection for raw materials and chemicals used in production. By streamlining the data across similar processes, this approach enhanced data consistency and comparability across the insulin portfolio. Several strategies were suggested to facilitate the adoption of the portfolio approach for comparative LCA studies in the industry.

This experiment represents one of the first comparative assessments of multiple insulin products within a single LCA portfolio, setting a foundation for further investigations into insulins and broader pharmaceutical LCAs. Future studies should prioritize accurate data collection and management to capture the full complexity of pharmaceutical production. Moreover, expanding the analysis to other markets and product portfolios could provide valuable insights into the global environmental footprint of pharmaceutical products. Additionally, formalizing clear criteria for defining a consistent portfolio will be essential to ensure comprehensive and comparable assessments.

5.3.3.8. Synthesis of Experiment 1

This experiment provided a comprehensive environmental assessment of Sanofi's insulin portfolio and led to the identification of transferable practices for conducting portfolio-level LCAs more efficiently within pharmaceutical context. By comparing multiple insulin products across shared and distinct processes, the project enabled the extraction of key insights related to data structuring, modeling consistency, and prioritization of impact sources. These findings were consolidated into a streamlined approach that improves comparability across products and reduces redundancies.

The resulting practices were formalized into methodological strategies that consolidate the learnings from this experiment. Despite these outputs not yet being integrated into Sanofi's standard operating procedures (SOPs) for LCA execution, their adoption is foreseen in the near future to support the institutionalization of portfolio-level assessments. In doing so, this experiment demonstrates a shift from isolated assessments to a structured, portfolio-level methodology, aligned with the transition framework introduced in this chapter.

Specifically, the project reflects the first three steps of the framework: capturing learnings from prior LCAs, synthesizing insights across products, and formalizing reusable modeling practices. Dissemination and integration activities are ongoing through internal channels. As such, this study illustrates the operationalization of the framework and confirms its potential to support the standardization, scaling, and systemic integration of sustainability practices in a complex industrial environment.

5.3.4. Experiment #2 – Methodology for sustainable manufacturing

The second experiment builds directly on the proposed transition framework. It originates from industrial work where LCA results were translated into environmental levers and integrated into a multi-criteria decision-making tool, for the development of vaccine manufacturing processes, within one Global Business Unit (GBU). From this experience, key learnings were captured and synthesized and were then reinforced through a targeted literature analysis that provided complementary scientific insights on guideline development and customization. This dual knowledge base strengthened the robustness of the proposal and supported the formalization of a structured methodology for developing environmental guidelines in manufacturing process design.

Although the methodology was derived from this specific trajectory, it was designed to be more general, enabling the creation of environmental guidelines for different purposes beyond decision-making tools. The methodology was subsequently tested in another GBU, representing an initial step in the dissemination of the practice. This replication demonstrated its transferability across organizational contexts and highlighted conditions for broader adoption. In this way, the experiment illustrates how the transition framework can support the evolution of project-based and scientific insights into standardized and reusable practices, progressing through the phases of capture, synthesis, formalization, and early dissemination.

5.3.4.1. Experiment overview

Manufacturing processes are a major contributor to the environmental impacts of industrial products, yet most sustainability methodologies focus on product development or high-level principles. Approaches rarely provide structured ways to translate environmental assessments into actionable, process-specific guidelines, and process engineers are seldom strongly involved in their development. This gap limits the ability of companies to embed sustainability at the manufacturing design stage, where large-scale impacts can be avoided.

To address this limitation, a structured guide was developed to support the design of environmentally sustainable manufacturing processes. The guide follows a three-phase approach (Investigation, Transformation, and Customization) which enables the identification of environmental challenges, the extraction of insights from assessments such as LCA, and their translation into practical guidelines adapted to process constraints. The development process followed the DRM (Blessing and Chakrabarti, 2009a) and combined a literature review, empirical studies, and iterative expert evaluations. The final guide was then applied in an industrial case study, where it supported the generation of tailored environmental guidelines and demonstrated its potential for integration into manufacturing practice.

The study highlights three key features of the guide: its modularity, allowing flexible entry points depending on project maturity; its collaborative structure, embedding both environmental and process experts; and its focus on contextual adaptation, ensuring relevance to specific manufacturing settings. Together, these elements illustrate a pathway for moving from environmental assessment toward systematic, process-level implementation, contributing to the broader integration of sustainability into manufacturing development.

5.3.4.2. Introduction

While manufacturing industries bring economic and societal value, they also contribute significantly to environmental degradation (Sutherland et al., 2020; UNEP, 2012). Six of nine planetary boundaries, critical thresholds for human development, have already been exceeded (Richardson et al., 2023). Ensuring continued production within ecological limits requires more sustainable production and consumption systems (K.L. Ang et al., 2021; Vilochani et al., 2025, 2024).

A wide range of environmental frameworks has emerged to help companies reduce their environmental footprint. At the product development stage, strategies such as Eco-design (Karlsson and Luttropp, 2006), Cradle-to-Cradle (McDonough and Braungart, 2003), or Circular Design (EMF, 2015a) guide early-stage decisions. At the manufacturing level, Cleaner Production, Green Manufacturing, and Sustainable Manufacturing models (Giannetti et al., 2020; Hauschild et al., 2019; Jayal et al., 2010) promote resource efficiency and emissions reduction. Cross-cutting tools like LCA (ISO, 2006a) support impact evaluation. However, many of these frameworks emphasize either product development or high-level principles (Smith and Ball, 2012), leaving a gap at the level of manufacturing process design. Traditional approaches tend to remain abstract, lacking direct operational applicability (Muñoz et al., 2013). As discussed below, this disconnection contributes to persistent difficulties in translating assessments into actionable, process-specific improvements (Subal et al., 2024).

In recent years, the use of LCA in manufacturing has expanded, driven by regulation, corporate goals, and circular economy transitions. This has improved environmental awareness and helped identify life cycle hotspots (Finnveden et al., 2009; Moutik et al., 2023; Sabour et al., 2023). Still, many companies struggle to move from assessment to implementation, particularly at the process level (Karuppiah et al., 2024; Subal et al., 2024). Bridging this gap requires not just evaluation tools but methodologies that enable concrete actions (Smith and Ball, 2012).

This challenge reflects broader trends in sustainable manufacturing research, which has long focused on product development and end-of-life strategies, often overlooking early-stage process design (Smith and Ball, 2012). While product-focused tools are numerous, they rarely support process engineers with practical guidance (Ahmad et al., 2018; Bovea and Pérez-Belis, 2012). Many approaches remain generic and conceptual (Dornfeld, 2014; Kishawy et al., 2018), making them hard to adapt to specific industrial contexts (Knight and Jenkins, 2009; Rosen and Kishawy, 2012). Furthermore, most tools are designed for environmental specialists and are not easily usable by process experts (Pochat et al., 2007). Some require full process specifications before environmental evaluation, limiting their utility during process design phases (Santucci and Esterman, 2015). Others focus on strategic or organizational levels (Muñoz et al., 2013), rather than day-to-day operational needs.

As a result, three persistent gaps hinder the integration of environmental sustainability into manufacturing process design:

i. **Process design is often addressed only indirectly**, limiting the potential for early life cycle impact reduction. Most frameworks prioritize product-level or post-design process optimization (Bovea and Pérez-Belis, 2012; Smith and Ball, 2012). When environmental tools are used, they typically come after process definition, reducing their influence during the critical design phase (Ahmad et al., 2018; Santucci and Esterman, 2015; Vezzoli and Sciama, 2006).
ii. **Process experts are insufficiently involved in developing or applying environmental guidelines**. While stakeholder integration is acknowledged as key to change (Verhulst et al., 2007), limited collaboration between environmental and operational teams remains a barrier (Onu et al., 2023; Righi et al., 2018; Utama and Abirfatin, 2023). Many tools are overly technical or disconnected from industrial practice, limiting adoption (Ahmad et al., 2018; Pochat et al., 2007).
iii. **Environmental initiatives are considered in an ad hoc manner within industrialization processes**. Sustainable manufacturing efforts are often project-based rather than systematically embedded in workflows (Almeida et al., 2010; Smith and Ball, 2012), resulting in fragmented and reactive implementation (Tiuncika and Bormane, 2024). Environmental performance is frequently deprioritized relative to cost, time, or technical constraints (Jayal et al., 2010).

In response to these limitations, this experiment develops and tests a practical methodology for developing environmental guidelines tailored to manufacturing process design. By involving both environmental and process experts and adapting insights to process-specific constraints, the proposed guide enables the translation of LCA and other environmental assessments into actionable, context-specific manufacturing practices. In doing so, it addresses key implementation barriers, promotes cross-functional collaboration, and contributes to the broader transition toward sustainable manufacturing (Karuppiah et al., 2024; Kishawy et al., 2018).

5.3.4.3. Material & Methods

The research presented in this experiment follows the DRM (Blessing and Chakrabarti, 2009a), comprising three stages: Descriptive Study I (DS-I), Prescriptive Study (PS), and Descriptive Study II (DS-II).

Figure 82. illustrates the iterative research process based on DRM. The activities undertaken in each phase are detailed in the following sub-sections.

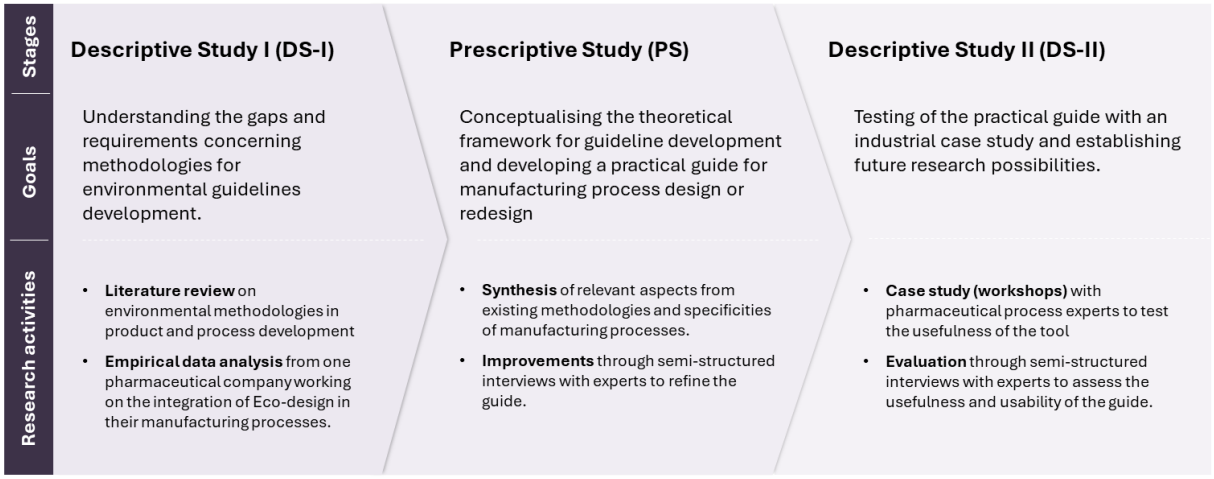

Figure 82. Research goals and activities according to DRM stages

5.3.4.4. Descriptive Study I (DS I)

In the first stage of the theoretical development, a combination of literature review and empirical work in collaboration with the partner company was adopted as the research method. This step facilitated the definition of the research goal and scope, as well as the identification of needs, requirements, and existing gaps for the development of the proposed tool.

The literature review was conducted in two stages using Scopus and Google Scholar, covering 89 peer-reviewed studies:

(1) The first part focused on methodologies for developing environmental guidelines, addressing the question: What existing approaches support guideline development for product and manufacturing process design?
(2) Based on those findings, a second review examined guideline customization, identified as a critical yet often overlooked aspect. This stage aimed to identify tools and methods for adapting guidelines to specific contexts, thereby enhancing their relevance, usability, and practical application.

In parallel with the literature review, empirical data were gathered from internal documentation, strategic reports, and interviews with process experts. This revealed key insights into existing tools and challenges in integrating environmental aspects into process design. These findings, combined with the literature review, helped define the essential elements and steps for effective guideline development.

Prescriptive study (PS)

The tool was developed and refined during the PS phase through three iterative cycles, combining insights from the partner company and experts in Design for Sustainability.

- Cycle 1 established the tool's foundation by analyzing existing methodologies for guideline development and integrating manufacturing process requirements. This resulted in the first version of the guide, structured around its main phases and steps.
- Cycle 2 involved feedback from five academic experts in sustainable design (3–13 years of experience), selected via the DS-I literature review. Their input informed refinements focused on usability, adaptability, and completeness.
- Cycle 3 expanded the panel to eight experts from academia and industry (8–31 years of experience), who evaluated the tool's practical relevance and applicability in manufacturing. Their feedback led to final refinements.

In total, 13 semi-structured interviews were conducted, gathering qualitative feedback and quantitative ratings on the guide's coherence, usability, and industrial relevance (Table 36).

Table 36. List of selected experts for the semi-structured interviews for evaluation and refinement of the guide

Expert n°	Field of expertise	Affiliation	Years of experiences	Cycle
1	Environmental sustainability assessments	Academia, Industry	5 years	1
2	Circular Economy and Sustainability	Academia	6 years	1
3	Sustainable product development	Academia, Industry	13 years	1
4	Sustainability and Product-Service System	Academia	3 years	1
5	Absolute sustainability, Environmental science and business development	Academia	2 years	1
6	Eco-design, Eco-innovation, LCA	Industry	19 years	2
7	Eco-design, Sustainability, Low-tech	Academia	30 years	2
8	Design for sustainability, User centered design	Academia	15 years	2
9	Design for Sustainability, Circular Economy	Academia	31 years	2
10	Circular economy transitions, Design for Sustainability, Rebound effects	Academia	8 years	2
11	Eco-design, Circular economy	Academia	24 years	2
12	Eco-design, Environmental assessments, Sustainable development	Industry	14 years	2
13	Design for sustainability, Product development	Academia	27 years	2

Both interview rounds followed a consistent structure, with sessions lasting about one hour (Table 37). Participants were encouraged to ask questions and engage critically with the tool, especially during the use case presentation. Each session concluded with an evaluation of the tool's usefulness and usability.

Table 37. Organization of the semi-structured interviews conducted with selected Design for Sustainability experts

Steps	Content	Duration
Introduction	• Structure and actors of the project • Key information about the participant	5 min
Context & Methodology	• Context of the project (What? How? Why?) • Presentation of the tool, main phases and steps	10 min
Use case example	Presentation of the use of the tool using a hypothetical scenario: illustrating inputs, outputs and expected results.	30 min
Questions and discussion	Evaluation of key criteria: • Comprehensiveness and alignment • Logical flow and coherence • Practicality and applicability • Environmental impacts reduction	15 min

Descriptive study II (DS II)

To incorporate an additional layer of evaluation, a case study was conducted to evaluate the final version of the tool in an industrial setting. Three workshops with two experienced process experts assessed its feasibility and helped refine the generic guidelines to align with specific manufacturing constraints.

- Workshop #1: Presentation of the generic guidelines, in-depth analysis of the manufacturing process in question, and initial mapping of the guidelines to process stages.

- Workshop #2: Further mapping of guidelines onto the process steps and sub-steps, and customization of guidelines to align with process-specific constraints.
- Workshop #3: Further customization of the guidelines, final review and refinement of the customized guidelines, and evaluation of the applicability of the finalized guidelines.

The tool's utility was assessed based on the outcomes generated, first through the identification of generic environmental guidelines, and subsequently through the development of process-specific guidelines tailored to manufacturing operations.

5.3.4.5. Results

The results are presented following the DRM phases. The first subsection reports the results of DS-I and is followed by the results of PS and DS-II.

Descriptive Study I: Literature review & Empirical data analysis

Findings from the literature review

The literature review examined existing methodologies for developing and customizing environmental guidelines, assessing their relevance to manufacturing process design. In the first phase, 60 papers were reviewed, 26 of which introduced such methodologies. While most offer structured approaches for product design, their applicability to manufacturing remains limited. Three key gaps were identified:

(1) Firstly, most approaches emphasize environmental strategies for product development, with limited attention to manufacturing processes (Bey et al., 2013; Hallstedt et al., 2023; Lofthouse, 2006; McAloone and Pigosso, 2017; Rossi et al., 2019b). This emphasis is largely driven by eco-design perspectives, which prioritize early-stage design. Consequently, the manufacturing phase, where large-scale decisions substantially affect environmental performance, has been underrepresented. While these tools support sustainable product development, they lack structured guidance for reducing the impacts of industrialization. This gap aligns with broader reviews noting that while LCA are increasingly applied, their integration into process-level strategies remains limited (Bendig et al., 2023; Karuppiah et al., 2024).

(2) Secondly, existing methodologies are primarily designed for environmental experts, limiting their accessibility to process engineers, operators, and decision-makers. Although stakeholder involvement is often mentioned (Bey et al., 2013; Dekoninck et al., 2016; Knight and Jenkins, 2009; Telenko et al., 2009), it is not systematically integrated into the development process. Yet, engaging key actors is essential to embed environmental considerations into practical manufacturing decisions and facilitate organizational uptake (Holgado et al., 2020; Ijomah et al., 2007).

(3) Lastly, the transformation of Life Cycle Assessment (LCA) results and other environmental evaluations into actionable process guidelines remains largely unstructured (Chun and Bidanda, 2013; Eslami et al., 2021; Knight and Jenkins, 2009). Despite the value of environmental data, there is no standardized process to translate it into process-specific recommendations that manufacturing teams can implement directly. Some recent contributions have explored this challenge through case-specific approaches (Maes et al., 2021; Utama and Abirfatin, 2023), but broader methodologies remain limited.

The review also synthesized common phases in guideline development, consistently found across studies (Lindahl, 2006; Luttropp and Lagerstedt, 2006; Maccioni et al., 2021; McAloone and Bey, 2009; McAloone and Pigosso, 2017; Ramanujan et al., 2018; Rossi et al., 2019b; Schöggl et al., 2017; Telenko et al., 2009):

- Investigation: understand the current context, impacts, and opportunities.
- Transformation: convert insights into structured guidelines.
- Customization: adapt guidelines to specific contexts and constraints.

Despite the implementation of environmental guidelines being frequently discussed in the literature, findings indicated that implementation strategies are highly context dependent. Therefore, due to the wide range of possible implementation approaches, this study focused on the key phases abovementioned.

Customization, however, emerged as particularly underdeveloped (Holgado et al., 2020; Knight and Jenkins, 2009; Luttropp and Lagerstedt, 2006; O'Hare et al., 2009; Rossi et al., 2019b; Verhulst et al., 2007). To address this, a second review phase explored customization strategies in adjacent fields, identifying 30 additional sources. A

consolidated framework of key steps and sub-steps was derived (Table 38), and tools supporting guideline development were identified.

Table 38. Main phases and steps identified from the literature and their descriptions

Phases	Steps	Description	References
Investigation	Context analysis	Understand the current situation	(Goepp et al., 2013; Keoleian et al., 1995; Knight and Jenkins, 2009; McAloone and Pigosso, 2017; O'Hare et al., 2009; Pochat et al., 2007; Russo et al., 2014; Telenko et al., 2009)
	Mapping of impacts	Understand the existing environmental impacts	(Gungor and Gupta, 1999; Johnson and Gay, 1995; Maccioni et al., 2021; Maltese et al., 2017; Mani et al., 2014; McAloone and Pigosso, 2017; Pochat et al., 2007; Ramanujan et al., 2018; Russo et al., 2014; Telenko et al., 2009; Willskytt and Brambila-Macias, 2020)
	Categorization	Classify the impacts based on relevant criteria	(Harstall et al., 2011; McAloone and Pigosso, 2017)
	Requirements definition	Define the needs for guideline development	(Keoleian et al., 1995; Masui et al., 2001; O'Hare et al., 2009; Russo et al., 2014)
Transformation	Guideline development	Develop guidelines to face the impacts identified	(Knight and Jenkins, 2009; Kreuter et al., 1999; Luttropp and Lagerstedt, 2006; McAloone and Pigosso, 2017; Pochat et al., 2007; Rossi et al., 2019a; Russo et al., 2014; Schöggl et al., 2017; Telenko, 2009; Telenko et al., 2009; Willskytt and Brambila-Macias, 2020)
	Guideline categorization	Classify the guidelines based on relevant criteria	(Telenko, 2009; Willskytt and Brambila-Macias, 2020)
	Guideline validation	Ensure the usefulness of the guidelines	(Hallstedt, 2017; Harstall et al., 2011; Pochat et al., 2007; Rossi et al., 2019b; Telenko et al., 2009)
Customization	In-depth understand of context	Understand the details of the situation: stakeholders, constraints, sub-steps, technologies, etc.	(Dizon et al., 2016; Francisco et al., 2024; Grimshaw et al., 2012; Harrison et al., 2013; Harstall et al., 2011; Holgado et al., 2020; Hu et al., 2023; Jänsch and Birkhofer, 2007; Knight and Jenkins, 2009; Luttropp and Lagerstedt, 2006; McAloone and Pigosso, 2017; O'Hare et al., 2009; Reiman et al., 2021; Straus et al., 2009; Telenko et al., 2009; Vallet et al., 2009)
	Guideline adaptation	Customize the guidelines to match the detailed context analysis	(Byggeth et al., 2007; Fervers et al., 2006; Gagliardi et al., 2011; Harrison et al., 2013; Jänsch and Birkhofer, 2007; Knight and Jenkins, 2009; Luttropp and Lagerstedt, 2006; O'Hare et al., 2009; Thomann, 2015; Vallet et al., 2009)
	Applicability evaluation	Determine the usefulness and usability of the customized guidelines	(Cluzel et al., 2016; Grimshaw et al., 2012; Hallstedt, 2017; Harstall et al., 2011; O'Hare et al., 2009; Rossi et al., 2019a; Vallet et al., 2009)

Findings from the empirical study

Internal reports and expert interviews revealed that environmental sustainability is not well integrated into manufacturing, despite R&D-level efforts. LCA data showed significant impacts during industrialization, especially in the pharmaceutical sector where processes are complex and regulated, though some flexibility remains in concurrent development stages (Luu et al., 2022b).

Experts noted a lack of structured tools to support decision-making. While sustainability is recognized, it is rarely translated into action due to regulatory and efficiency priorities. Customization was seen as key to feasibility and adoption.

Overall, the empirical findings echoed the literature: awareness exists, but structured methodologies are lacking. There is a clear need to link environmental assessments with process-specific, operationally relevant guidelines.

Prescriptive Study: Designing the tool

The tool was developed by integrating insights from the literature review, empirical study, and expert interviews, ensuring alignment with both scientific foundations and industrial needs. This section presents the final version, incorporating refinements identified through expert feedback (Figure 84)].

A methodology for designing environmentally sustainable manufacturing processes

Building on insights from the literature and empirical studies, a structured tool was developed to support the creation of process-specific environmental guidelines. Designed for use by both environmental and process experts, it facilitates the translation of environmental assessments into actionable recommendations applicable throughout manufacturing development.

The tool adopts a modular, three-phase structure (Figure 83), guiding users through Investigation, Transformation, and Customization.



Figure 83. Overview: structured three-phase approach for developing environmental guidelines

Preliminary steps

Before application, two preparatory steps ensure relevance and efficiency:

(1) Scope definition: identifies the targeted process, relevant platforms, and potential sites. It also clarifies involved stakeholders, whose engagement is essential from the outset.

(2) Needs assessment: evaluates the current environmental maturity of the project, guiding where to begin:
   - Investigation: if starting from scratch.
   - Transformation: if impact data is available and synthesized.
   - Customization: if generic guidelines exist and need contextualization.

Modularity allows users to select relevant steps based on project context, ensuring the tool is applied at an appropriate level of detail and supports effective guideline development. For example, in the case study, the process began at Phase 3 since generic guidelines were already available. The guide's modularity is structured around two key dimensions, both linked to the initial needs assessment: the starting point, which depends on existing environmental knowledge, and the level of detail, determined by process complexity and available resources. Some sub-steps, particularly in the Customization phase, are optional.

Phase 1: Investigation

This phase develops a structured understanding of the manufacturing process, its stakeholders, and associated environmental impacts. Conducted by one or more environmental experts, it synthesizes available data to identify key challenges and opportunities.

Key steps:

1. Context analysis: reviews process documents and sustainability strategies.
2. Environmental mapping: aligns environmental assessments with process steps.
3. Categorization: group impacts into thematic areas for focused action.

This phase sets the foundation and ensures the relevance and traceability of all subsequent guideline development activities.

Phase 2: Transformation

Performed by one or more environmental experts, the goal of this phase is to convert environmental insights into generic environmental guidelines. Each insight informs a guideline, supported by existing best practices (Coustillac et al., 2023; Keoleian et al., 1995; Pigosso et al., 2013; Russo et al., 2017; Telenko, 2009). Supporting materials, such as decision trees, examples, visuals, may also be developed to improve usability.

Key steps:

1. Guidelines development: each insight is documented in an "evidence inventory table" to ensure traceability.
2. Supporting materials (optional): tools to facilitate application.
3. Validation & Prioritization: guidelines are reviewed based on environmental relevance, feasibility, and strategic alignment.

At the end of the transformation phase, a validated and prioritized set of structured environmental guidelines are developed. This phase bridges environmental data and structured, implementable knowledge.

Phase 3: Customization

Co-led by environmental and process experts, this phase adapts generic guidelines to specific manufacturing contexts. It requires close collaboration to align with technologies, constraints, and operational needs.
Adaptation may involve simple reformulation or the creation of detailed procedures. Final outputs are reviewed to ensure feasibility, impact, and clarity.

Key steps:

1. Compatibility analysis: maps guidelines onto process steps and constraints.
2. Guideline adaptation: refines content based on context and expert input. Impact reduction potential may be qualitatively or quantitatively assessed
3. Applicability assessment: ensures guidelines are prioritized based on impact potential, feasibility, and resource needs.

The outcome is a set of practical, process-specific guidelines co-developed with implementation in mind, supporting the design and optimization of industrialization processes within the studied manufacturing context.

Remarks for Implementation

Once the guide is applied and guidelines are prioritized, implementation becomes the next step. Although the needs assessment helps define intended use, implementation should be considered from the start. Guidelines may support evaluation, decision-making tools, or continuous improvement. In all cases, a clear strategy is needed to ensure they are used, maintained, and embedded in existing procedures.

Experts interviews

Thirteen experts evaluated the guide's structure, clarity, and industrial applicability. Overall feedback was positive: the methodology was considered comprehensive, systematic, and well-aligned with both scientific literature and operational needs.

The three-phase structure was seen as a major strength, offering a clear and logical path from analysis to implementation. Modularity was especially appreciated for its adaptability across diverse contexts and levels of environmental maturity. Experts suggested further enhancing this flexibility by clarifying transitions between phases and refining prioritization criteria. While the guide was viewed as robust, some experts noted that specific steps, particularly in the Customization phase, could be time- and resource-intensive. Challenges included data availability, interdepartmental coordination, and sustaining engagement over time. To improve usability, recommendations included developing templates, aligning with company workflows, and introducing the tool incrementally.

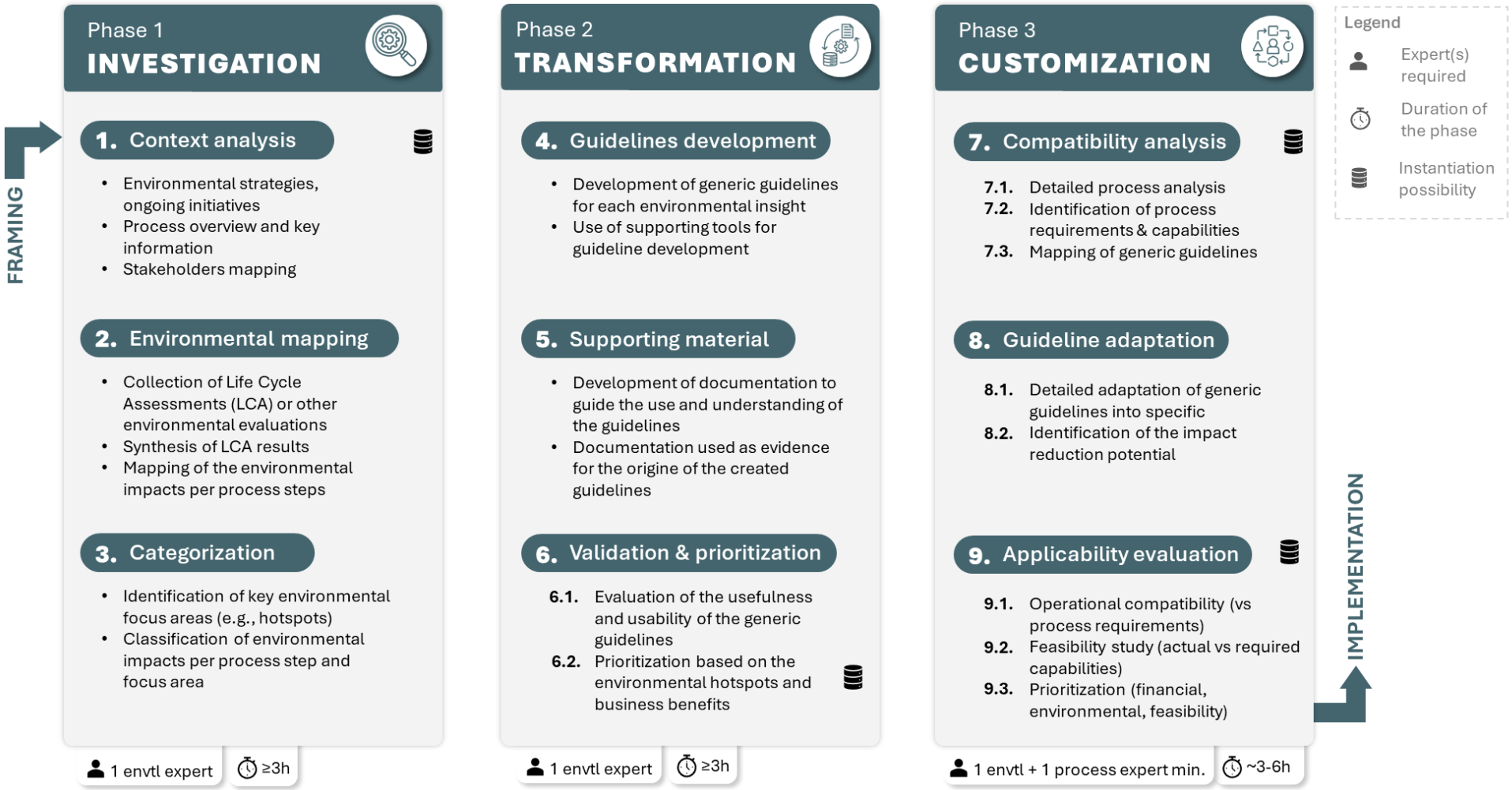

Figure 84. Detailed view of the guide with phases, steps and sub-steps

Despite these concerns, the guide's potential to reduce environmental impacts was consistently recognized. Experts highlighted that success depends largely on two factors: access to reliable environmental data and active stakeholder collaboration. Experts rated the guide's coherence and relevance on a five-point Likert scale. Seven rated it "mostly coherent" and six "very coherent," with an average score of 4.46, indicating strong overall support for its relevance and usability in practice.

DS-II: Evaluating and applying the guide in a case study

To evaluate the guide's practical applicability, a case study was conducted within the partner company. The objective was to test its integration under real conditions and refine existing eco-design guidelines within a multi-criteria decision-making tool. Given the project context and availability of generic recommendations, Phase 3 (Customization) was selected as the most relevant entry point.

A specific manufacturing process was chosen in consultation with stakeholders, and Customization was implemented through three remote workshops (Figure 85), with a fourth added as needed. Two process experts and one environmental expert participated, bringing complementary experience in manufacturing development and sustainability.

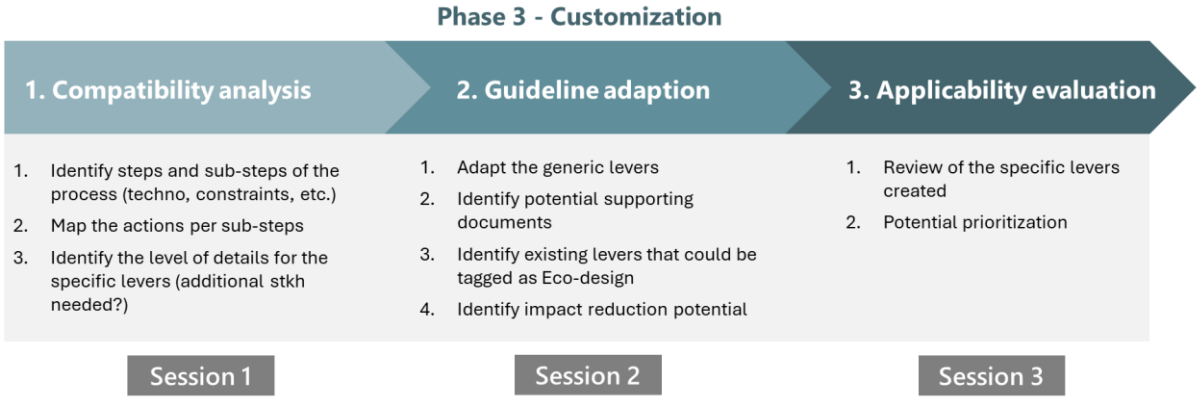

Figure 85. Initial timeline for the case study

In Workshop 1, participants reviewed the generic guidelines and process flow to identify relevant steps, technologies, and constraints. A pre-filled table listing guidelines alongside process steps structured the discussion and supported initial mapping to sub-steps.

In Workshop 2, the mapping was refined. To improve usability, the table was replaced with a visual representation of the process. Each guideline was shown as an independent element and interactively positioned along the relevant steps (Figure 86), completing the compatibility analysis.

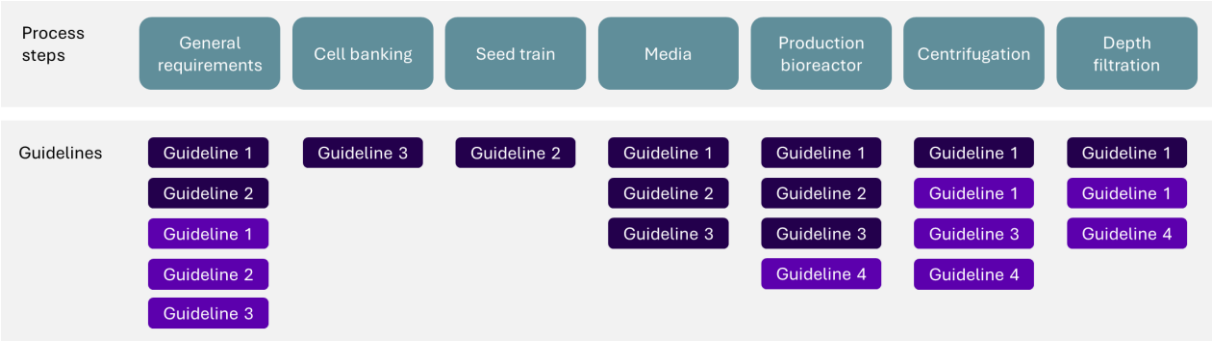

Figure 86. Mapping of generic guidelines across process steps. The names of the guidelines are not disclosed due to confidentiality. The guidelines are color-coded to reflect their categorization into two distinct groups.

Workshop 3 focused on adapting mapped guidelines into process-specific recommendations. A structured table guided the discussion, but progress was slower than expected, prompting a fourth session.

The final workshop centered on integrating the adapted guidelines into the company's decision-making tool. Existing entries were reviewed and aligned; where gaps existed, new recommendations were added. A final review ensured consistency with environmental goals, operational feasibility, and process constraints.

By the end of the case study, tailored guidelines had been developed, mapped, and adapted to technical and regulatory conditions. The process confirmed the tool's practical relevance, with success factors including stakeholder engagement, visual formats, and integration into existing systems, despite time and facilitation challenges.

5.3.4.6. Discussion

This section reflects on the main findings of this experiment, focusing on the scientific contribution of the developed tool and its empirical relevance for sustainable manufacturing. It concludes with a reflection on the study's limitations and avenues for future directions.

Scientific and empirical contributions

The main existing methodologies for developing environmental guidelines that were identified in the DS-I phase were evaluated according to their purpose and main content. A comparison to the developed guide is shown in Table 39.

Table 39. Comparison between the developed guide and other tools for guideline development. Phases covered refers to (I) Investigation, (T) Transformation, (C) Customization. Plus signs represent the level of alignment with the identified criteria (High, Medium, Low).

Methodology (authors)	Focus area	Target users	Phases covered	Custo. level	Stkh. involvement	Modularity
Guide developed in this study	Manufacturing process design	Environmental and process experts	I, T, C	+++	+++	+++
A guide for environmental improvement (McAloone and Bey, 2009)	Product design, Environmental strategy	Environmental experts, Product dev. Team	I, T	+++	+++	++
Green design guidelines (Telenko et al., 2009)	Product design	Environmental experts	I, T, C	+	++	+
Eco-knowledge tool (Rossi et al., 2019a)	Product design	Environmental experts	I, T	++	+	+
Contextual DfE Principles (Ramanujan et al., 2018)	Manufacturing process design	Environmental experts	I, T	+++	++	+
CSPD (Schöggl et al., 2017)	Product design	Environmental experts, other stakeholders	I, T	++	+++	++
EDIMS (Pochat et al., 2007)	Product design	Environmental experts, product designers	I, T	++	++	+
MSPD (Byggeth et al., 2007)	Product design	Environmental experts	T, C	+	++	+
Sustainability fingerprint (Hallstedt et al., 2023)	Product design	Environmental experts, Product dev. Team	T, C	+++	++	++

The developed guide distinguishes itself from existing methodologies by:

- **Being tailored for manufacturing process development**: Unlike most tools that focus on product design or early-stage development, this guide explicitly targets the manufacturing phase, a critical yet underexplored area in sustainability integration. It accounts for the specific decision points, constraints, and operational realities of industrialization. Both empirical findings and expert interviews reinforced the absence of structured tools to address environmental performance during process design, confirming the need for such a focused approach.

- **Connecting environmental assessments to actionable process guidelines**: A key strength of the guide is its ability to translate environmental assessments (e.g., LCA) into structured, traceable guidelines. While recent studies have explored this through case-specific or improvement-based frameworks (Maes et al., 2021; Utama and Abirfatin, 2023), the proposed approach is more generalizable across manufacturing contexts. It guides users in identifying and classifying environmental challenges to develop generic guidelines, which are then adapted to specific situations, a process experts saw as essential for turning sustainability data into action.

- **Embedding stakeholder collaboration throughout the methodology**: The guide is designed to facilitate co-creation between environmental specialists and process experts at every phase, from scoping to guideline prioritization. Many existing methods remain expert-centric, limiting cross-functional adoption. In contrast, this guide includes explicit steps for identifying and engaging stakeholders, ensuring that guidelines are relevant, feasible, and aligned with operational constraints. The case study validated this collaborative structure as critical to both quality and implementation.

- **Enabling flexible use through extensive modularity**: Given the complexity of certain manufacturing contexts, such as pharmaceuticals, modularity emerged as a key design feature. The guide can be deployed fully or partially, depending on available resources, project scope, and environmental maturity. The case study illustrated this flexibility: only Phase 3 was used, building on existing corporate guidelines. Experts recognized this layered approach, corporate-level development followed by local adaptation, as crucial for scalability and adoption across different contexts.

- **Supporting company-specific instantiation and integration**: Beyond modularity, the guide was designed for use within existing company procedures. Most required data already exist internally; the key is to identify, access, and structure them effectively. In Phase 1, for example, environmental strategies, documentation, and previous assessments form the baseline. Rather than creating new systems, the methodology encourages reusing and aligning what already exists.

  A structured instantiation framework(Sarancic et al., 2024) was used to define key integration elements:
  - Strategic alignment: early dialogue between environmental and manufacturing teams clarifies objectives.
  - Identification of key steps: the guide highlights where existing company data can be leveraged to streamline application (Figure 84).
  - Stakeholders' engagement: a structured approach supports the identification of relevant actors, roles, and communication flows throughout the process.
  - Supporting materials: an input–output table was developed to improve usability; others are proposed for future work.

  These elements support adaptation across organizational contexts by linking the guide to existing terminology, workflows, and initiatives.

- **Enabling sustainability-driven decisions across organizational levels**: The guide helps managers and practitioners act on sustainability data by translating assessments into structured, context-specific guidelines. Its modular design allows use at different levels of maturity, scale, and readiness, linking corporate goals to process decisions. This vertical integration supports alignment across strategic, tactical, and operational levels, addressing calls for frameworks that connect technology with managerial priorities (Ilgin and Gupta, 2010; Zhang et al., 2013). It can support compliance, foster innovation, and embed sustainability in daily decision-making.

In summary, this study responds to persistent calls for structured, adaptable tools that connect environmental assessments to implementation. By integrating previously dispersed approaches and emphasizing customization, the guide addresses a core methodological gap. It contributes both a robust academic framework and a practical solution for embedding sustainability into manufacturing process development.

Limitations and future directions

Limitations

A first limitation concerns the boundary conditions for effective application. Two prerequisites are essential: (1) availability of environmental data (e.g., LCA) to identify hotspots and support robust guideline development, and (2) process relevance, since not all manufacturing steps equally affect environmental performance. These conditions may limit the tool's use in contexts with limited data infrastructure or unclear impact distribution.

A second limitation is the resource intensity of guideline development. The case study showed that workshops required more time than expected, and that broader expertise was needed to tailor generic guidelines to specific processes. Despite the guide being modular and instantiable, its application depends on available time, organizational capacity, and dedicated personnel. A clear needs assessment and stakeholder engagement plan are therefore essential.

A third limitation concerns the separation between development and implementation. Although implementation is not explicitly addressed, it is critical to achieving impact. The guide's preliminary steps and needs analysis can support implementation planning, as shown in the case study where customized guidelines were embedded into a decision-making tool. However, other contexts may require different pathways, and success may depend on involving decision-makers from the outset.

The experiment's case-specific nature also limits generalizability. Conducted in a single pharmaceutical company, characterized by complexity and strict regulation, the research did not test the full methodology, as Phases 1 and 2 had already been addressed. Broader testing across industries and full applications is needed to assess scalability. Nonetheless, the structured and modular nature of the guide, its foundation in LCA, and its emphasis on cross-functional collaboration make it broadly transferable to other manufacturing industries, particularly those where manufacturing activities contribute significantly to environmental impacts. To implement the framework in other sectors, stakeholders should adapt certain inputs such as regulatory requirements, operational constraints, and internal terminology. Successful application requires coordination between environmental experts and process engineers, as well as access to impact assessment data and process knowledge. In less regulated or lower-impact industries, where the manufacturing phase contributes less to total life cycle impacts, the relevance of such a methodology may be lower, and a simplified version may be more appropriate.

Further, outcomes may vary depending on user expertise. Despite structured support, the guide's effectiveness relies on collaboration between environmental and process teams, whose differing familiarity with assessments and operations can affect results.

Finally, the methodology's reliance on LCA presents several challenges. Although LCA offers valuable insights, it has been critiqued for methodological limitations, such as narrow system boundaries, burden shifting, and the risk of rebound effects (Andrew and Pigosso, 2024; Castro et al., 2022; Finnveden, 2000; Finnveden et al., 2009; Guzzo et al., 2023; Jolliet et al., 2019; Metic and Pigosso, 2022). Translating LCA results into categorical challenges may oversimplify complex issues, and poor data quality can compromise guideline robustness. These issues underscore the need for cautious interpretation and continuous refinement.

Future work

Building on these limitations, several research avenues are proposed. First, further validation in diverse industrial settings is needed to confirm the guide's generalizability and identify context-specific refinements. Testing the methodology across different manufacturing sectors and with full deployment of all three phases would generate more comprehensive insights.

Second, research should explore the integration of the guide into existing company procedures, with a focus on instantiation. The development of tailored templates, terminology mapping, and embedding within digital tools

could improve adoption and usability. In this context, digitalization offers significant potential. Industry 4.0 technologies can facilitate real-time data collection, streamline documentation, and support dynamic guideline adaptation (Machado et al., 2020; Zheng et al., 2021).
Another promising direction involves the exploration of alternative or complementary environmental assessment methods. While LCA is widely used, its limitations suggest a need to examine other tools that might enhance or supplement the identification of environmental hotspots. In particular, the integration of Absolute Environmental Sustainability Assessment (AESA) could provide a stronger foundation for science-based, impact-driven guideline development (Hauschild et al., 2020).
Further research could also refine the guide's decision-making components. Incorporating tools such as Net Present Value (NPV), as suggested by Hallstedt (2017), may enhance prioritization by adding time and cost dimensions (Hallstedt, 2017). Balancing methodological rigor with ease of use remains essential, and future work should investigate how modularity can be leveraged to support phase-specific adaptations based on organizational needs and resource constraints.

5.3.4.7. Conclusion

Manufacturing companies are increasingly recognizing their role in addressing environmental challenges and reducing their impact. This experiment developed and tested a practical guide to support the design of environmentally sustainable manufacturing processes. The tool enables environmental and process experts to translate environmental insights into tailored, actionable guidelines through a structured three-phase approach: Investigation, Transformation, and Customization.

The research contributes to sustainable manufacturing by offering a structured, adaptable methodology focused specifically on process design, addressing key gaps in existing approaches. Drawing on a comprehensive literature review, expert feedback, and practical application, the study demonstrated the guide's potential to support environmentally informed decision-making.

However, this work was subject to certain limitations. The case study was conducted within a single company, which may limit generalizability, and the tool's reliance on assessment data raises challenges related to data availability and quality. Future research should explore broader industrial validation, cross-sector applicability, and improved data integration to enhance usability and adoption.

In conclusion, by structuring environmental guideline development into a practical methodology, this experiment provides a valuable foundation for companies seeking to systematically reduce the environmental impact of their manufacturing processes.

5.3.4.8. Synthesis of Experiment 2

This experiment resulted in the development and initial application of a structured methodology for creating environmental guidelines tailored to manufacturing process design. The work originated from an industrial project in which LCA results were translated into environmental levers and embedded in a multi-criteria decision-making tool for one GBU. Lessons learned from this experience were captured and synthesized, and their robustness was reinforced through a targeted literature analysis that provided complementary scientific insights. Together, these elements supported the formalization of a generic methodology for developing environmental guidelines.

The methodology was then applied and tested in another technologic platform, marking the first step toward its dissemination. If not yet fully institutionalized, this replication demonstrated the methodology's transferability across organizational contexts and its capacity to produce tailored guidelines adapted to process-specific constraints. The case also highlighted critical success factors for dissemination, including stakeholder engagement, modularity, and integration into existing decision-making tools.

By combining empirical learnings with reinforcement from scientific literature, and by validating the methodology through replication, this experiment illustrated how the transition framework supports the transformation of isolated insights into reusable practices. It thus shows progress across four steps of the framework, capturing, synthesizing, formalizing, and initiating dissemination, and confirms the potential of the framework to both standardize and scale sustainability practices within complex industrial environments.

5.3.5. Evaluation of the transition framework

The transition framework was evaluated through its application in two experiments: the insulin portfolio LCA (Experiment 1) and the development of an environmental guidelines methodology (Experiment 2). Both projects illustrated how isolated initiatives can evolve into systemic practices when structured through the framework's four steps (capture, synthesize, formalize, disseminate). Although neither project was originally designed as an "evaluation experiment," both progressively applied the framework's underlying logic and therefore provided a suitable ground for assessing its relevance, usability, and outcomes.

5.3.5.1. Project-level evaluation

The first step for evaluating the framework proposed was the project-level evaluation which was allowed through the experiments.

Experiment 1 - Portfolio LCA of insulin products: the framework proved useful for capturing and consolidating knowledge from existing LCAs, in order to perform a portfolio level approach. Insights were synthesized into practices related to data structuring, modeling consistency, and prioritization of impact sources. These practices were formalized into a list of strategies, that could enable more efficient and comparable LCAs across products if implemented. At the time of evaluation, dissemination into Sanofi's standard operating procedures (SOPs) had not yet been achieved, but the outputs provided a solid foundation for organizational uptake.

Experiment 2 - Methodology for sustainable manufacturing: the framework structured the transition from isolated environmental levers for a multi-criteria decision-making (MCDM) tool to a generalized methodology for developing environmental guidelines. Learnings from the initial project were captured and synthesized, complemented by targeted literature insights to reinforce scientific robustness. These were formalized into a stepwise methodology, subsequently tested in another technologic platform, thereby demonstrating early dissemination. The methodology was designed to be broadly applicable beyond MCDM tools, supporting multiple contexts.

5.3.5.2. Framework-level evaluation

To ensure a more detailed analysis, the experiments were assessed following the defined criteria (Table 40)

Table 40. Results of the assessment of the experiments

Criteria	Experiment 1 – LCA	Experiment 2 - Methodology
Relevance	**High**	**High**
	Addressed the lack of consistency across individual LCAs by structuring a portfolio-level approach	Helped transform project-based outputs into a reusable methodology with wider applicability.
Usability	**Medium**	**High**
	Capturing and synthesizing were logical, formalization required more effort, while dissemination remained pending	all steps were explicitly applied, and dissemination was initiated through replication in another GBU.
Scalability	**High**	**High**
	Methodological strategies for portfolio level LCA could be applied to future LCAs beyond insulin	Methodology was intentionally designed for generalizability, moving beyond the specific decision tool context.
Integration	**Low**	**Medium**
	Produced actionable strategies but not yet institutionalized into SOP.	Methodology tested and partially replicated in another GBU, not yet generalized company-wide.

The evaluation shows that the transition framework consistently provided high relevance across both experiments (Table 41). Usability was demonstrated in both cases, though Experiment 1 highlighted challenges in advancing

beyond formalization, whereas Experiment 2 applied all four steps more seamlessly. Scalability was strong in both projects: portfolio templates in Experiment 1 could be transferred to future LCAs, while Experiment 2 deliberately targeted generalizability across contexts. Integration emerged as the main limitation: although both experiments produced actionable outputs, their full embedding into organizational routines and SOPs is still lacking.

Table 41. Step by step analysis of the experiments according to the phases of the transition framework

Experiment	1- Capture	2-Synthesize	3-Formalize	4-Disseminate
Portfolio LCA	Consolidated insights from multiple LCAs (e.g., insulin device); identified key points for data collection.	Identified hotspots and focus points, Clustered insights (e.g., modeling consistency)	Developed a set of strategies designed for integration into LCA SOP.	Not yet disseminated; integration into SOPs is planned for the near future.
Guideline Methodology	Captured learnings from specific LCAs and from the MCDM tool project	Synthesized project-based insights with additional literature to reinforce robustness.	Formalized a methodology for developing envtl guidelines, applicable beyond decision-making tools.	Tested in another business unit, demonstrating early replication and partial dissemination.

Link with the Design Requirements (DRs)

When analyzing the two experiments against the design requirements derived from literature (DR1–DR8), several observations emerge. Both initiatives addressed the early requirements (DR1–DR3) effectively: explicit and tacit insights were systematically captured, clustered into transferable lessons, and formalized into methodological assets. However, requirements related to governance anchoring and system alignment (DR4, DR6) were only partially met, as the outputs have not yet been fully embedded within organizational structures and decision-making processes. Similarly, requirements linked to dual knowledge transfer, iterative spread, and context-fit scaling (DR5, DR7, DR8) were only partially realized: Experiment 1 did not reach dissemination, while Experiment 2 demonstrated replication potential but remained at an early stage of institutionalization.

5.4. DISCUSSION

This section interprets and contextualizes the main results obtained regarding the transformation of projects into practices. It is organized into four parts. First, the proposed transition framework is discussed, with its key theoretical and practical implications. Second, the experiments are examined in light of the framework. Third, the contribution of this work to the systemic integration of environmental sustainability is highlighted. Finally, limitations and directions for future work are presented.

5.4.1. Interpreting the transition framework: implications for theory and practice

The proposed transition framework was not introduced as a novel theoretical construct but as a structured synthesis of existing insights on organizational learning and pilot-to-practice transitions. Its main contribution lay in clarifying and operationalizing these insights into a format that could be directly applied in the pharmaceutical context. By framing the transformation of projects into practices as a sequence of four iterative steps: capture, synthesize, formalize, disseminate, the framework highlighted the mechanisms through which organizational learning supported systemic integration of environmental sustainability.

The experiments confirmed the practical relevance of the early steps of the framework. Both capture and synthesis were successfully implemented, enabling the consolidation of insights and the abstraction of generalizable lessons. Formalization was also achieved to some extent, with project outcomes translated into reusable strategies. However, dissemination proved far more challenging. In both experiments, outputs were either only partially

disseminated or remained at the stage of planned integration. This limitation reflected a widely recognized challenge in the literature, which emphasized dissemination and embedding as the most complex aspects of organizational learning (Boscherini et al., 2010; Duffield and Whitty, 2015).

These findings suggested that while the framework provided a simple and actionable guide for structuring transitions, its application was neither linear nor uniform. Tailoring was necessary to fit the specificities of different types of initiatives. In the case of LCAs, the focus was on methodological streamlining and consistency, whereas for the guideline methodology, emphasis was placed on turning insights into a generalizable design method. This reinforced the need for flexibility: although the same framework was applied, the way capture, synthesis, formalization, and dissemination were operationalized varied depending on project goals and organizational context.

5.4.2. Key insights from the experiments

The two experiments provided complementary tests of the framework. The portfolio LCA experiment demonstrated the value of capture and synthesis across multiple product-level LCAs, leading to the formalization of strategies that could eventually inform operating standards for LCA execution at Sanofi. The manufacturing methodology experiment went further by integrating project-based learnings with scientific insights and formalizing them into a generic method for developing environmental guidelines. This methodology was subsequently tested in another technologic platform, thereby moving into early stages of dissemination.

Together, these experiments showed how different types of initiatives instantiated the framework in different ways. The first emphasized methodological consolidation and comparability, while the second highlighted replication and cross-unit application. Both, however, converged on a common limitation: dissemination remained partial, constrained by issues of organizational alignment, governance, and resource prioritization. This indicated that the framework could structure transitions effectively but did not in itself resolve the organizational barriers that hindered full embedding.

5.4.3. From projects to systemic integration: contribution to environmental sustainability

The results provided an answer to Sub-Research Question 2.1: validated projects could indeed be transformed into systemic practices, therefore partially confirming Hypothesis 2. However, the transformation required more than the structured capture and formalization of lessons, it also depended on dissemination mechanisms and organizational alignment. Without these, practices risked remaining fragile and temporary.

This finding reflected what organizational learning research had described as the difficulty of applying lessons learned in practice (Duffield and Whitty, 2015). It also resonated with critiques of the “linear fallacy,” which assumed that scaling up automatically ensured sustainability. In reality, scale-up without institutionalization rarely secured long-term positive impact. The experiments illustrated this risk: both generated tangible reusable practices, but neither achieved full institutionalization.

This study therefore demonstrated that systemic integration of environmental sustainability in the pharmaceutical sector could be effectively supported by the proposed framework, though dissemination and institutionalization remained incomplete. The transition framework enabled the transformation of isolated projects into systemic practices, yet dissemination and institutionalization required further effort. The findings showed that dissemination was not only a matter of standardizing good practices, but also of ensuring their effective use in day-to-day operations. This underlined that improving the positive impacts of validated projects through their transformation into scaled and standardized practices was necessary but not sufficient. This points to a broader challenge of organizational change: without mechanisms that build alignment, learning, and ownership, scaled practices risk remaining underutilized. In the literature, this challenge is framed through the lens of organizational capabilities (Amui et al., 2017; Teece, 2007), which emphasize the routines, learning processes, and cultural shifts that allow organizations to reconfigure practices and embed sustainability into strategy. This provides a direct bridge to the

next part of this chapter, which will explore how capability development can support the institutionalization of environmental sustainability over time.

5.4.4. Limitations and future work

Three main limitations and associated research opportunities were identified.

Proposed transition framework
The framework, while useful as a structuring approach, was relatively generic and not specific to the pharmaceutical sector, thereby potentially limiting its usability and usefulness. Future work could refine each step and associate activities by linking it more closely to pharma-specific requirements, such as regulatory compliance, patient safety, and quality assurance. Doing so would increase its operational relevance and value for practitioners.

Performed experiments
Only two experiments were conducted, both within the same company. This limited the generalizability of findings. Moreover, the projects were not initially designed as evaluation experiments, and the active involvement of the researcher may have introduced bias. Future studies should test the framework across a broader range of initiatives and organizations, ideally in settings where evaluation was planned from the outset.

Systemic practices dissemination
As already emphasized, dissemination remained the most challenging step. The experiments stopped short of full integration, largely due to organizational constraints. This limitation mirrored findings in the literature, where dissemination and embedding were recognized as the most complex dimensions of organizational learning. Future research should therefore focus on identifying governance mechanisms, incentive structures, and cultural enablers that could support the transition from reusable practices to institutionalized routines.

5.5. CONCLUSION

This part of Chapter 5 aimed to address Hypothesis 2 and, more specifically, **Sub-Research Question 2.1**: *How can validated environmental projects be consolidated and standardized into practices that support systemic integration across pharmaceutical product and process development?* The transition framework developed and tested in this part provided a structured means of capturing, synthesizing, formalizing and disseminating project learnings into reusable practices across the organization. Applied through two experiments, it demonstrated that isolated initiatives, such as LCAs or specific eco-design levers, can indeed be transformed into systemic practices that extend beyond their initial project scope.

However, the results also showed that this transformation was only partial. Although the framework supported the move from projects to systemic practices, dissemination and institutionalization remained limited. This reflects a broader challenge observed in organizational learning literature: the difficulty lies less in creating new practices than in embedding and sustaining them across diverse organizational contexts.

At a higher level, these findings highlight that systemic integration of environmental sustainability in the pharmaceutical sector cannot rely solely on the standardization of project outcomes. Instead, it requires complementary organizational mechanisms that ensure practices are absorbed, aligned with strategic objectives, and renewed over time. Organizational learning processes are strongly shaped by people: stakeholder engagement, cross-functional collaboration, and knowledge-sharing mechanisms are central to capturing insights from projects and embedding them into routines. This points to the importance of developing organizational capabilities as one possible next step, which could enable the institutionalization of the environmental sustainability strategy, thereby fostering both the dissemination of developed practices and the broader systemic integration of environmental sustainability within the organization.

PART B: INSTITUTIONALIZING THE STRATEGY THROUGH ORGANIZATIONAL CAPABILITIES

This second part of Chapter 5 shifts the focus from project-level learning to the institutionalization of the environmental sustainability strategy, and its practices, through the development of organizational capabilities. Part A showed that while isolated initiatives can be scaled into systemic practices, however practices alone are not sufficient to guarantee lasting integration. Even when formalized, they remain fragile if not embedded within broader organizational structures and cultures.

The objective here is to address Sub-Research Question 2.2 (SRQ2.2): *How can the environmental sustainability strategy and its components be institutionalized across functions to become durable organizational capabilities?* To do so, this part builds on insights from organizational change management (OCM), maturity models, and sustainable product development practices, and develops a capability model tailored to the pharmaceutical sector. The framework is designed both as a diagnostic tool and as a roadmap for strengthening the conditions that enable environmental sustainability to become embedded across strategy, people, culture, processes, and skills.

In this sense, Part B moves beyond identifying what practices are deployed to examine how the organization develops the underlying capabilities that allow these practices to be institutionalized, sustained, and renewed over time.

5.6. CONTEXT

As highlighted in Part A, the application of lessons learned remains one of the most difficult steps in organizational learning (Duffield and Whitty, 2015). Scaling up practices without embedding them into organizational structures risks falling into the "linear fallacy," where expansion occurs without institutionalization, and outcomes quickly dissipate (SC4CCM, 2014). In highly regulated and complex industries such as pharmaceutical industries, this risk is amplified: sustainability practices may emerge in pilot form or be adopted in isolated parts of the organization, but without durable capabilities they struggle to survive leadership changes, shifting priorities, or resource constraints.

This makes capability building a critical complement to practice development. Operational capabilities focus on the execution of day-to-day tasks and the replication of existing routines, and dynamic capabilities refer to the firm's ability to purposefully create, extend, or modify its resource base to respond to a changing environment (Teece, 2018, 2007). They represent the organizational "infrastructure for change," enabling companies not only to perform current operations but also to sense opportunities and threats, seize them through action, and reconfigure assets and processes accordingly (Hutchinson, 2024; Teece, 2007).

From this perspective, the institutionalization of environmental sustainability requires more than replicating validated practices across functions. It requires the creation of dynamic capabilities that ensure sustainability is systematically integrated into structures, cultures, and decision-making routines. Such capabilities span multiple dimensions: leadership sponsorship, cross-functional collaboration, communication strategies, incentive systems, tools, and workforce upskilling. Together, they provide the agility needed for pharmaceutical firms to sustain compliance while innovating and adapting to new sustainability requirements.

For the pharmaceutical industry, this challenge is particularly important. Strict regulatory requirements, safety imperatives, and complex global supply chains mean that sustainability cannot remain an "add-on." It must be embedded into the very capabilities that underpin organizational functioning. Building such capabilities is therefore essential to move beyond isolated projects and standardized practices, ensuring that environmental sustainability becomes part of the organization's long-term strategic resilience.

In this light, Part B develops a capability model that translates the environmental sustainability strategy into measurable pillars and maturity levels. By diagnosing current capability profiles, identifying gaps, and providing

pathways for progression, the framework offered a structured means to institutionalize sustainability in a way that is both systemic and durable.

5.7. MATERIAL AND METHODS

Consistent with the overall methodology adopted in this thesis, the work presented here followed the DRM (Blessing and Chakrabarti, 2009a) and focused on two stages: the Descriptive Study I (DS-I) and the Prescriptive Study (PS). The DS-I stage aimed to develop a detailed understanding of organizational change management and capability building, complemented by empirical insights drawn from internal documentation and discussions with key stakeholders. Building on this foundation, the PS stage sought to define the desired future state and to conceptualize a support tool designed to strengthen environmental sustainability capabilities within pharmaceutical organizations.

5.7.1. Literature review

A semi-systematic literature review was conducted (Snyder, 2019) using a thematic approach, with the objective of identifying the organizational conditions, mechanisms, and frameworks that support capability building for sustainability integration. The review focused on two complementary bodies of literature: Organizational Change Management (OCM) and (dynamic) capabilities, with additional insights from maturity models and eco-design integration approaches. The process followed a structured protocol to ensure methodological rigor.

First, a set of guiding questions was formulated to frame the review:

- How do organizations build the capabilities required to achieve strategic transformation?
- What mechanisms enable or hinder organizational change in the context of sustainability?
- What insights do maturity models provide for structuring capability development?

Second, a targeted search strategy was developed, using Boolean combinations of keywords grouped into conceptual clusters aligned with the research focus. The first cluster targeted organizational change management, using terms such as “organizational change,” “change management,” “transformation processes,” “cultural change.” The second cluster emphasized capabilities, with keywords including “capability”, “organizational capabilities”, “dynamic capabilities”, “capability building”. The third cluster addressed maturity models, using terms like “maturity model,” “capability maturity,” “capability model” Searches were conducted using Scopus and Google Scholar to ensure coverage of both academic and applied perspectives.

Third, articles were selected based on their relevance to the research objective. Inclusion criteria emphasized peer-reviewed publications, in English, that addressed one or more aspects of organizational change and capability development. Backward and forward snowballing was applied to identify foundational references.

Finally, the selected literature was reviewed and organized thematically into two main perspectives: (1) organizational change management as the overarching lens for embedding new practices; (2) capabilities and maturity models as structuring elements for understanding organizational readiness and progression. Together, these strands informed the synthesis of key requirements for capability building, which underpinned the development of the proposed capability model.

5.7.2. Empirical study: internal documentation review

An empirical study was conducted at Sanofi to identify existing resources, practices, and initiatives relevant to structuring the integration of environmental sustainability within the organization, with a particular focus on elements linked to OCM. Data were collected primarily through the review of internal documentation (slide decks, project reports, guidelines). This was complemented by targeted discussions with key stakeholders, including members of the eco-design team and the Sanofi Learning Center, in order to contextualize the documents and clarify their application.

5.7.3. Conceptualization of a support

Insights derived from the literature review and the empirical data analysis (DS-I) were consolidated to inform the development of a capability model. This step corresponds to the Prescriptive Study (PS) stage of the DRM (Blessing and Chakrabarti, 2009a), where the objective is to define a desired future state and to conceptualize potential solutions grounded in prior findings.

The DS-I outcomes led to the identification of structural elements for capability building. Literature findings informed the key principles of how capabilities are developed and institutionalized, while the internal capability initiative at Sanofi provided dimensions and components already recognized by the company as essential. In parallel, existing eco-design tools and documents (e.g., maturity model, eco-design standard) were used as structuring references to identify practices that could be embedded within the framework.

The development process included a series of workshops with eco-design team members, where iterative refinements were made to ensure clarity, feasibility, and alignment with ongoing initiatives. Discussions with the Learning Center further ensured that the framework remained consistent with Sanofi's broader vision of capability building, striking a balance between comprehensiveness and usability.

The resulting support took the form of a capability model structured around several core elements. It first defined a set of pillars or dimensions representing the main areas where capabilities needed to be built. Within each pillar, specific items were identified, each corresponding to a concrete aspect of capability development. For every item, maturity levels were described to capture progression from initial to advanced states of implementation. Additionally, some KPIs were defined to improve the maturity level identification.

In addition, workshops and alignment discussions with key stakeholders (e.g., business partners, eco-design leads) led to the identification of practical ways of using the framework in organizational contexts, ensuring it could be applied as both a diagnostic and developmental tool.

Ultimately, the role of the support developed was to:

- Provide a structured approach for building organizational capabilities in environmental sustainability.
- Translate abstract strategic objectives into actionable elements and measurable progress indicators.
- Facilitate alignment across teams and functions, fostering organizational learning and embedding sustainability into everyday practices.

5.7.4. Application of the support

Due to time constraints, the developed support was not evaluated through a full systematic DS-II evaluation. However, during its development, and to ensure iterative feedback loops, the framework was applied at several stages in an incomplete but progressive manner. This allowed the identification of strengths, points for improvement, and directions for future use.

The application focused on a few core functions of the company, each directly connected to environmental sustainability and the product and process development.

(1) The first stage of application aimed to assess the maturity of each key function in relation to the integration of environmental sustainability. An initial assessment was carried out by the eco-design team members based on their knowledge of practices within these functions. To strengthen this assessment, an online survey was distributed to key members of the functions (e.g., eco-design leads and other relevant stakeholders), providing a more robust evaluation of maturity levels. In addition, informal discussions with stakeholders uncovered actions already being implemented within functions that had not been visible to the eco-design team. The purpose of this stage was to obtain a clear understanding of the current situation and the potential pathways for improvement.

(2) The second stage of application consisted of preparing and organizing workshops to co-develop with the functions a shared vision of the desired end state for environmental sustainability and to define how it

could be achieved. Three internal workshops were held within the eco-design team to structure the sessions and ensure alignment before engaging with the functional teams.

(3) The third stage of application emerged in parallel with the development of the capability model and represented a first step in capability building through the integration of environmental sustainability requirements into technology standards for manufacturing. The process followed the four-step transition framework identified in Part A of this chapter: (1) capturing insights from LCAs, (2) synthesizing them and combining them with literature-based knowledge, (3) formalizing these insights into concrete recommendations, and (4) disseminating them by embedding the recommendations within standards. The formalization and dissemination stages were conducted in working groups with subject matter experts (SMEs), which played a central role in refining, structuring, and validating these recommendations. In parallel, the process also laid the groundwork for defining an approach with different levels of integration depth, intended to structure the progressive embedding of environmental recommendations into technological standards.

Although these three stages did not constitute a comprehensive evaluation of the proposed support, they provided valuable insights into its applicability, highlighted opportunities for refinement, and informed subsequent steps for embedding environmental sustainability within organizational practices.

5.8. RESULTS

5.8.1. Insights from the literature review

The literature review conducted identified organizational change management (OCM) as a central field for understanding how change can be effectively achieved within organizations. OCM provided valuable perspectives on the processes, structures, and human factors that influence change. In the following, key insights from OCM are presented and connected to the specific challenges of sustainability integration. Building on this, the review then turned to a critical dimension of OCM, capabilities and dynamic capabilities, and examined related perspectives such as dynamic capabilities, maturity models, and sustainable product development practices.

5.8.1.1. Organizational Change Management and Sustainability

Integrating sustainability into organizations cannot be achieved through isolated initiatives alone. While Part A highlighted the limits of pilots and the importance of organizational learning, research on organizational change management (OCM) shows that deeper transformation requires the creation of capabilities that embed sustainability into the very fabric of an organization.

Classic OCM models, from Lewin's (1947) unfreeze–change–refreeze to Kotter's (1996) stepwise approach, emphasize that change unfolds over time and requires both structural and cultural anchoring (Alas, 2007; Kotter, 1996; Lewin, 1947). Later reviews stress leadership, communication, and employee commitment as critical determinants of successful change (Armenakis and Bedeian, 1999; Ramos-Maçães and Román-Portas, 2022). Applied to sustainability, these insights underline that beyond technical tools, organizations must establish the conditions that allow new practices to be accepted, routinized, and reinforced.

Human and cultural factors are equally central. Change management research highlights that employee attitudes, values, and mental models can accelerate or block integration (Boks, 2006; Lozano, 2008; Verhulst et al., 2007). Leadership sponsorship, empowerment, and psychological safety emerge as enablers of change, while resistance, if unmanaged, often undermines transformation (Klein et al., 2022; Millar et al., 2012). Recognition, participation, and collaboration across functions are therefore indispensable for embedding sustainability at scale (Kiesnere and Baumgartner, 2019).

Finally, incentive and reward systems are recognized as structural enablers or barriers. OCM studies note that short-term performance pressures often impede sustainability (Siegrist et al., 2020). Aligning incentives, integrating sustainability objectives into performance management, and rewarding long-term contributions are

repeatedly identified as prerequisites for durable change (Baumgartner and Ebner, 2010; Kiesnere and Baumgartner, 2019).

5.8.1.2. Dynamic Capabilities and Maturity

The strategic dimension of OCM is frequently highlighted. Strategy provides orientation, but it only becomes effective when operationalized through organizational capabilities (Ford and Evans, 2001). Dynamic capabilities refer to a firm's ability to sense opportunities and threats, seize them through strategic actions, and reconfigure its resources accordingly (Teece, 2007). This perspective emphasizes that sustainability integration is not a one-off initiative, but a continuous process of learning, transformation, and renewal.

In parallel, maturity models have emerged as practical tools to structure such evolution. Defined as sequential levels of increasing capability, maturity models enable organizations to assess their current practices and identify pathways for improvement (Kohlegger et al., 2009; Korsten et al., 2025; Stoiber et al., 2023). Widely applied since the 1970s, maturity models exist for domains such as quality, project management, and IT, with the CMMI and OPM3 as widely recognized examples. More recently, maturity models specifically dedicated to eco-design and sustainability have been developed, such as EcoM2 (Pigosso et al., 2013), Eco-Mi (Xavier et al., 2020), or the Maturity Grid assessment tool for environmentally conscious design (Moultrie et al., 2016). These models typically structure sustainability integration into progressive levels and distinguish between managerial and technical dimensions of eco-design, highlighting the need to combine strategic alignment with operational practices.

Taken together, the dynamic capabilities perspective and maturity models underscore that sustainability integration requires both continuous adaptation and structured evaluation mechanisms. They demonstrate the importance of developing organizational capabilities across multiple dimensions, while also revealing that existing models are often domain-specific and may not fully address the broader systemic integration challenges faced by industries such as pharmaceuticals.

5.8.1.3. Sustainable Product Development practices

Building on the eco-design maturity models introduced above, Vilochani et al. (2024) consolidated 61 sustainable product development (SPD) practices, structured across the product development process (PDP) and associated support functions (Vilochani et al., 2024). Their work explicitly builds on the EcoM2 (Pigosso et al., 2013), extending it by providing a comprehensive repository of practices that can be systematically linked to different stages of product development and organizational functions.

The SPD practices are organized into key focus areas such as sustainability evaluation, management, improvement, knowledge, legislation and regulation, process integration, decision support, and value chain collaboration. They also highlight the importance of multifunctional organizational involvement, identifying eleven core functions, from market intelligence and strategic management to supply chain, compliance, and change management, that are critical to embedding sustainability into PDP.

This consolidation demonstrates both the breadth, and the depth of practices required for sustainability integration. It reinforces the idea that capability building cannot be reduced to technical tools or design methods alone but must involve strategy, governance, cross-functional collaboration, and continuous learning. In this sense, SPD practices provide a detailed operational complement to the maturity model perspective, illustrating the types of concrete activities and organizational functions that underpin higher maturity levels.

5.8.1.4. Synthesis of the literature review

The literature reviewed highlights that integrating sustainability into organizations requires a combination of change management, adaptive capabilities, and structured practices. Organizational change management provides the levers for mobilizing people, aligning strategy, and overcoming resistance to change. The dynamic capabilities perspective emphasizes the need for continuous sensing, seizing, and reconfiguring to adapt to evolving sustainability challenges, while maturity models offer practical pathways to evaluate and structure this progression. Finally, sustainable product development practices consolidate a wide range of concrete activities and organizational functions that must be addressed to embed sustainability throughout product development processes. Taken together, these perspectives underline that capability building for sustainability is inherently

multidimensional. It spans strategy, people, processes, and governance, requiring both high-level alignment and operational practices.

5.8.2. Insights from the empirical study

The analysis of internal documentation at Sanofi revealed several initiatives that contributed to building capabilities and strengthening maturity in the field of eco-design and environmental sustainability. Three key elements stood out: the development of an eco-design maturity model, the creation of an eco-design standard, and the introduction of a capability model initiative. Together, these efforts illustrated the progressive shift from tool-based eco-design practices toward systemic approaches, and they provided an important basis for the development of the capability model proposed in this research.

5.8.2.1. Previous eco-design initiatives

Within Sanofi, several initiatives have been undertaken in recent years to foster eco-design and embed related practices across the company's product development processes. Two elements were identified as particularly relevant to the present research, as they directly inform the foundations of capability building for environmental sustainability.

Eco-design maturity model (DEimeter)

In 2022, Sanofi's eco-design team developed an Eco-design Maturity Model (DEimeter) with the aim of assessing and guiding the integration of eco-design within R&D projects (Luu, 2023a). The design process followed a structured methodology inspired by Design Thinking and the DRM, progressing through four stages: Discover, Define & Ideate, Develop & Test, and Deliver.

The purpose of the maturity model was twofold: (1) to track the integration of eco-design in R&D projects across the pharmaceutical development phases, and (2) to guide practitioners in selecting and applying appropriate eco-design tools (Figure 87). The model also incorporated an assessment of eco-design management practices, grouped into three categories: leadership and tactical integration, training and resources, and collaboration and communication.
Implemented in Excel, the tool enabled users to navigate by project phase and function, access relevant eco-design tools, and evaluate management practices at the end of each phase. Results were expressed as maturity levels (1–5) and visualized through radar diagrams to support comparison across projects and phases.
Despite its structured design, the model faced limitations in uptake, as awareness of eco-design remained uneven across functions, and training was necessary to foster its use. Consequently, the maturity model was not deployed systematically within Sanofi.

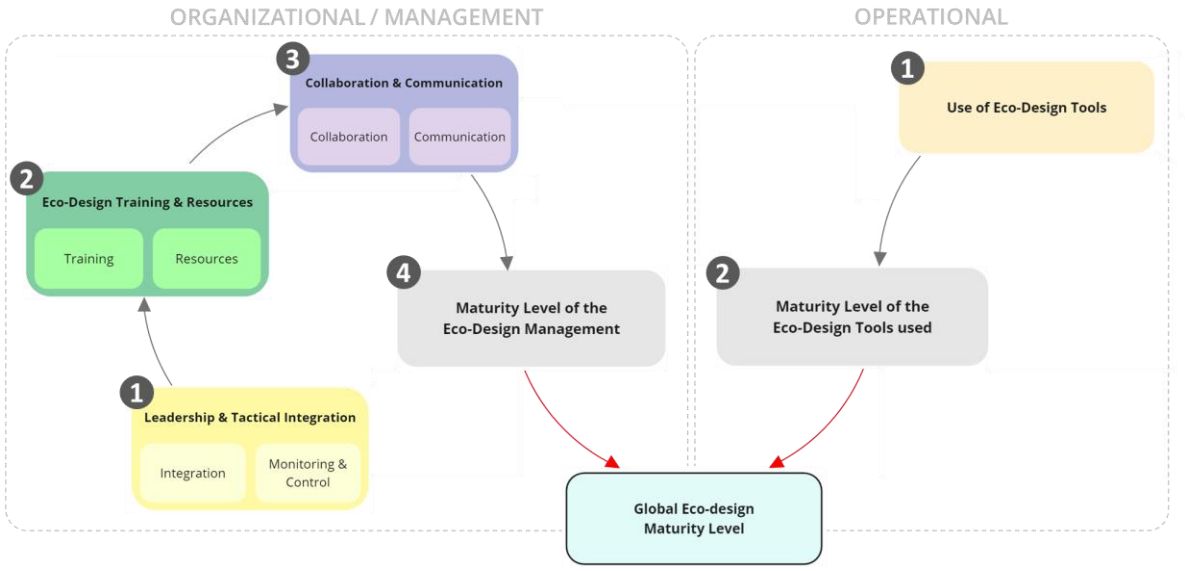

Figure 87. Structure of DEimeter

Although the eco-design maturity model was never fully implemented, its development represented a significant milestone in the company's eco-design journey. It combined insights from literature with internal testing to clarify what "maturity" means for eco-design in pharmaceutical R&D. Despite the specific maturity levels, practices, and tool lists not being directly reused, the model laid an important foundation for understanding the organizational dimensions of eco-design maturity. These insights now inform the development of broader organizational capabilities for environmental sustainability.

Eco-design standard

Building on earlier initiatives, Sanofi introduced an internal eco-design standard in 2024 to formalize eco-design management across the company. The standard defined minimum requirements to ensure a systemic approach and included provisions for:

- Eco-design organization and governance.
- Product environmental assessment.
- Eco-design improvement levers.
- Reporting processes.
- Communication and claims.
- Stakeholder engagement and training.

In practice, the standard became the backbone of the company's eco-design management system, providing a foundation for the institutionalization of processes that had previously been fragmented across projects and functions.

By codifying responsibilities and processes, the eco-design standard represented a foundational element of Sanofi's environmental sustainability approach. It not only aligned eco-design practices with corporate and regulatory requirements but also created the structural conditions necessary for building organizational capabilities. In this sense, it constituted a key building block upon which subsequent capability development could be anchored.

5.8.2.2. Capability framework initiative

In 2025, Sanofi launched an initiative on capability building aimed at strengthening organizational learning and aligning business functions with strategic objectives. This marked a shift from a skills-based perspective, focused on individual competencies, toward the broader notion of capabilities, understood as what an organization collectively needs to achieve a strategy.

The initiative, supported by a generic framework and associated scorecards, emphasized several dimensions such as strategy, upskilling, people, stories, or symbols. These elements were designed to track progress, measure maturity, and guide functions toward desired end-states. The approach reflected the company's ambition to build capability models around key topics and functions. Although not originally developed for environmental sustainability, the generic elements provided a relevant basis for informing the capability model proposed in this research, as they fully align with the broader Organizational Change Management (OCM) field of research and with the institutionalization of the developed strategy.

By framing capabilities as the organizational means to achieve strategic goals, and by emphasizing measurement, alignment, and cultural change, the initiative highlighted the elements necessary for a structured approach. At the same time, it also underscored a gap: while the need for building capabilities in environmental sustainability was recognized, no dedicated tool or roadmap had yet been developed in this area. This gap provided a direct opportunity for the present research, which advances a tailored capability model to operationalize this ambition.

5.8.2.3. Synthesis of the empirical study

The empirical analysis showed that several initiatives had laid important foundations for capability building in environmental sustainability at Sanofi. The eco-design maturity model provided initial insights into assessing and guiding maturity in R&D, while the eco-design standard established minimum requirements for managing eco-design across the company. More recently, the capability model initiative emphasized the organizational need to develop capabilities as a means to achieve strategic objectives. Together, these initiatives demonstrated progress toward structuring environmentally sustainable practices but also revealed the absence of a dedicated tool tailored

to sustainable capability building, at Sanofi and more broadly within the pharmaceutical sector, an identified gap that this research addressed.

5.8.3. Building sustainable capabilities in the pharmaceutical industry

The insights gathered from both the literature and internal analyses informed the development of the proposed support: a capability model for environmental sustainability, together with a method for its application.

5.8.3.1. Structuring insights for capability development

The analysis of the literature and internal documentation confirmed that building organizational capabilities is essential for embedding environmental sustainability in the pharmaceutical sector. The review of organizational change management (OCM) literature emphasized the importance of strategy alignment, leadership support, cultural anchoring, performance systems, and skills development, all dimensions that mirror the pillars identified in Sanofi's internal capability initiative. This convergence reinforced the relevance of using these pillars as the backbone for structuring capability development in environmental sustainability.

In parallel, the empirical work on eco-design tools provided concrete foundations for defining the scope of capabilities to be developed. The eco-design maturity model laid the groundwork by highlighting dimensions of progression and management practices necessary to embed sustainability in product development. The eco-design standard was then systematically analyzed against the structuring components of capability building. Out of the 61 items included in the standard, 31 were identified as directly connected to capability development for environmental sustainability, while the remaining 30 were considered out of scope. The relevant items were consolidated into higher-level elements, which helped clarify what practices and mechanisms should be integrated into the support.

Taken together, these findings show that the literature and internal initiatives not only align in their recognition of capabilities as central to organizational change but also provide complementary foundations: the literature offers theoretical and conceptual guidance, while the empirical insights identify concrete practices already in place and gaps still to be addressed. This dual perspective directly informed the development of the capability model presented in the following section, ensuring that it is both theoretically grounded and practically relevant.

5.8.3.2. Capability model for environmental sustainability

This section presents the capability model developed to guide the building of environmental sustainability capabilities in pharmaceutical organizations. The capability model proposed is composed of six pillars, reflecting key insights from the literature. Figure 88 below presents the overall structure and pillars defined.



Figure 88. Overview of the capability model

Each pillar is composed of several items with a total of 21 items. The items cover the range of key components within a pillar, with the aim of being comprehensive enough but also simple enough so it can be used efficiently across the organization.

Framework pillars and items

The following section provides a detailed description of the six pillars of the capability model, along with their associated items. Each pillar represents a key dimension of capability building, while the items specify the concrete components that collectively structure the framework (the detailed version of each pillar is presented in Appendix ?)..

Pillar 1: Developing the right strategy

This pillar defines how environmental sustainability is positioned as a core strategic lever. It encompasses the rationale for action (business case), the articulation of ambitions (vision and narrative), the operationalization through measurable targets (business targets), and the alignment of daily practices (sustainable behaviors). Together, these elements determine whether sustainability is treated as compliance or as a driver of innovation, competitiveness, and long-term value creation.

Pillar 2: Engaging the right people

This pillar captures the human and relational dimension of capability building. It includes leadership commitment (sponsorship), the existence of a dedicated and structured Eco-design team (core team), the mobilization of advocates (champions network), and the overall readiness of functions and stakeholders to engage in change. Collectively, these items determine the depth of ownership, alignment, and influence needed to embed sustainability across and beyond the organization. The pillar is structured around five items (Table 43).

Pillar 3: Shaping the right stories, rituals, and symbols

This pillar reflects how sustainability becomes visible, shared, and meaningful within and outside the organization. It covers the formalization of communication strategies, the sharing of stories and best practices, the integration of rituals into everyday work, and the use of external claims to signal value creation. These mechanisms act as cultural carriers, shaping identity, reinforcing behaviors, and enhancing both internal alignment and external legitimacy. The pillar is structured around four items (Table 44).

Pillar 4: Reinforcing with the right rewards and recognition

This pillar addresses how sustainability is reinforced and incentivized. It integrates the definition of sustainability goals in performance management, the recognition of contributions both formally and informally, and the promotion of a culture of experimentation. By linking sustainability to performance and rewarding innovative efforts, this pillar ensures that environmental practices are not only adopted but also sustained and continuously improved. The pillar is structured around three items (Table 45).

Pillar 5: Enabling with the right tools and processes

This pillar ensures that sustainability is operationally enabled. It covers the embedding of Eco-design considerations into tools, templates, and workflows (decision support) and the integration of sustainability into people-related processes (HR and talent systems). By institutionalizing sustainability into the organization's infrastructure, this pillar moves sustainability from intention to routine practice. The pillar is structured around two items (Table 46).

Pillar 6: Building the right skills

This pillar focuses on the development of knowledge and competencies required for long-term transformation. It includes a structured upskilling strategy, systematic needs analysis, and tailored training content and methods. Its role is to move from generic awareness to dynamic, role-specific learning that fosters continuous improvement and equips employees with the skills to drive sector-wide change. The pillar is structured around three items (Table 47).

Maturity assessment levels

The evaluation of each item was based on a four-level maturity scale, ranging from initial awareness (Level 1) to advanced, systemic integration (Level 4). For every item, specific definitions of each maturity level were

developed to ensure consistent and detailed assessment. In addition, tailored indicators (KPIs) were proposed to facilitate evaluation and provide measurable criteria.

As an illustration, Item #17 ("Tools & Decision Support") is presented below:

- **Level 1:** Eco-design is not considered in tools or templates; systems may not enable relevant Eco-design choices; they are not use
- **Level 2:** Some qualitative and quantitative tools exist, but tools require extra effort to make Eco-design choices and do not provide holistic understanding
- **Level 3:** Key Eco-design prompts and data are integrated into tools, templates, and workflows.
- **Level 4:** Tools are intuitive and nudge-by-design: Eco-design is the default, embedded through smart automation, visualizations, and AI-supported recommendations.

To further illustrate, the KPIs developed for evaluating Item #17 are presented in Table 48.

Table 42. KPIs used to evaluate Item #17 ("Tools & Decision Support") across maturity levels

KPIs	Level 1	Level 2	Level 3	Level 4
Data availability	Tool relies mainly on qualitative insights or databases filled with secondary data (including generic economic datasets).	Database (e.g., LCA tool) integrates both internal primary data and complementary secondary datasets (including economic data).	Database integrates robust internal primary data with limited use of secondary datasets (excluding generic economic proxies).	Database is predominantly based on high-quality, supplier-specific primary data across the value chain.
Decision making outcome	Tool supports decisions based on basic environmental aspects (e.g., material choices, waste streams).	Tool enables decision-making based on quantified environmental impacts, but with limited scope (e.g., partial life cycle, selected indicators).	Tool allows comprehensive LCA, covering multiple impact categories, detailed steps, and comparisons across alternatives.	Tool supports advanced decision-making, including consequential LCA, prospective scenario modeling (e.g., PCP assessment), identification of optimal solutions, and alignment with planetary boundaries.
Tool engagement	Function does not actively use Eco-design tools.	Function uses Eco-design tools, but with external support; usage is not yet autonomous.	Function independently and systematically applies Eco-design tools in decision-making.	Eco-design tools are fully embedded into the function's workflows; teams actively contribute to the continuous development and improvement of tools.

5.8.3.3. Framework application method

To operationalize the capability model and support the systemic integration of environmental sustainability, an application method was proposed. The method builds on the continuous improvement logic of PDCA (Plan–Do–Check–Act), adapts insights from the EcoM2 logic (Pigosso et al., 2013) to the pharmaceutical context, and brings insights from the FSSD and its ABCD-process (Broman and Robèrt, 2017b) . It is structured in six iterative steps (Figure 89), which can be tailored to the specific ambitions and resources of the organization.

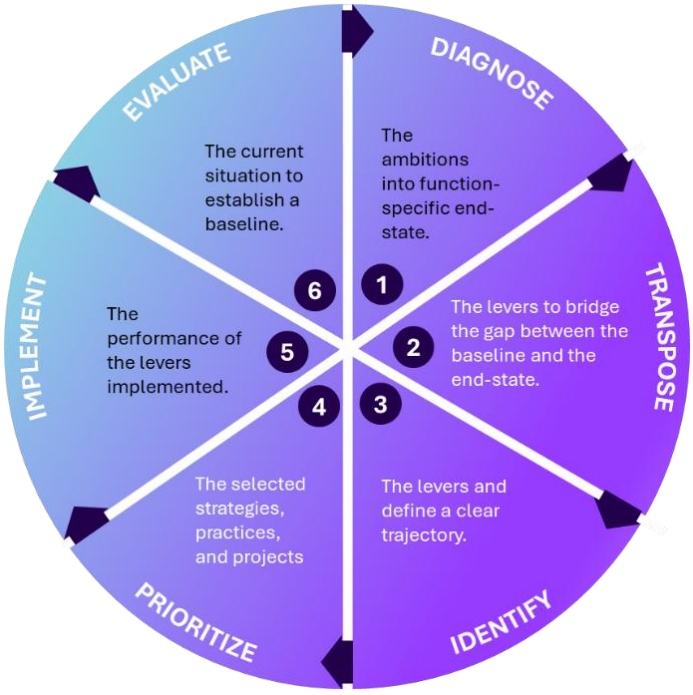

Figure 89. Application method of the capability model

Step 1 – Diagnosis of the current situation: The first step is to establish a baseline. Each function is assessed across the six pillars and 21 items of the capability model to determine its current maturity profile. This diagnostic provides a structured overview of strengths, weaknesses, and priority areas.

Step 2 – Transposition of ambitions and vision: Once the current state is mapped, the organization transposes its overall sustainability ambitions into function-specific visions for each pillar. This allows the definition of a desired "end state" (e.g., 2030 horizon) tailored to key functions.

Step 3 – Identification of levers: For each function and pillar, the gap between current maturity and desired end state is analyzed. The required enablers to bridge this gap are identified and translated into candidate strategies, management practices, and improvement projects.

Step 4 – Prioritization and roadmapping: The proposed strategies and projects are prioritized based on strategic alignment, feasibility, and expected impact. A roadmap is then established, linking short-term actions to long-term objectives and providing a clear trajectory toward the defined end state.

Step 5 – Planning and implementation: Each function then plans and implements the selected strategies, practices, and projects. This step includes detailing responsibilities, allocating resources, and integrating initiatives into existing governance and workflows. Special attention is given to change management, cross-functional coordination, and stakeholder engagement, ensuring that sustainability practices are effectively embedded in day-to-day operations.

Step 6 – Performance evaluation: The implemented strategies, practices, projects, or tools are evaluated in terms of their specific performance indicators, as well as their contribution to reducing environmental impacts and achieving the organization's sustainability ambitions. This assessment ensures that outcomes are measured both at the project level and in relation to the broader sustainability objectives.

Finally, and following the PDCA logic, the evaluation results feed back into the capability model. The maturity profile is reassessed to capture progress, update the baseline, and identify new opportunities for improvement. This cyclical process ensures that each iteration not only delivers tangible environmental impact but also reinforces organizational capabilities, driving the organization toward higher levels of maturity in environmental sustainability.

5.8.4. Application of the framework

As presented in Section 5.7.4., the capability model could not be fully evaluated within the timeframe of the doctoral thesis. Nevertheless, several applications were conducted that demonstrate its potential and provide preliminary results. Three examples are presented: first, a maturity evaluation (step 1), second, the preparation of workshops to translate ambitions into functional pathways (step 2, 3, 4), and third, the integration of environmental recommendations into technology standards (step 5).

5.8.4.1. Diagnostic of the current situation (step 1)

Workshops with members of the eco-design team, complemented by discussions with key stakeholders from different functions, enabled the identification of actions that were being undertaken or planned within each function. Within each pillar, and its associated items, several actions were mapped. The first step was therefore to systematically identify and classify these actions. Each was categorized according to its status (ongoing or planned), and for planned actions the expected year of initiation was also recorded. Figure 90 illustrates the number of identified actions for one specific function and their distribution over time. The end state was defined for 2030.

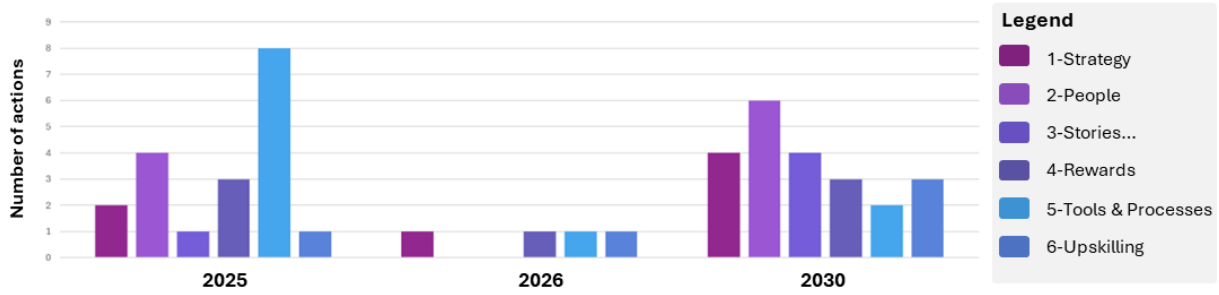

Figure 90. Number of actions identified per pillar over time, for one specific function

Once actions were identified, each was further analyzed, and a maturity level was assigned. This process revealed that some actions were sufficient to reach higher maturity levels, while others restricted the function to lower levels unless additional actions were introduced or existing ones improved. For example, Item #17, Tools & Decision Process, highlighted that not all tools were positioned at the same level of maturity (Figure 91).

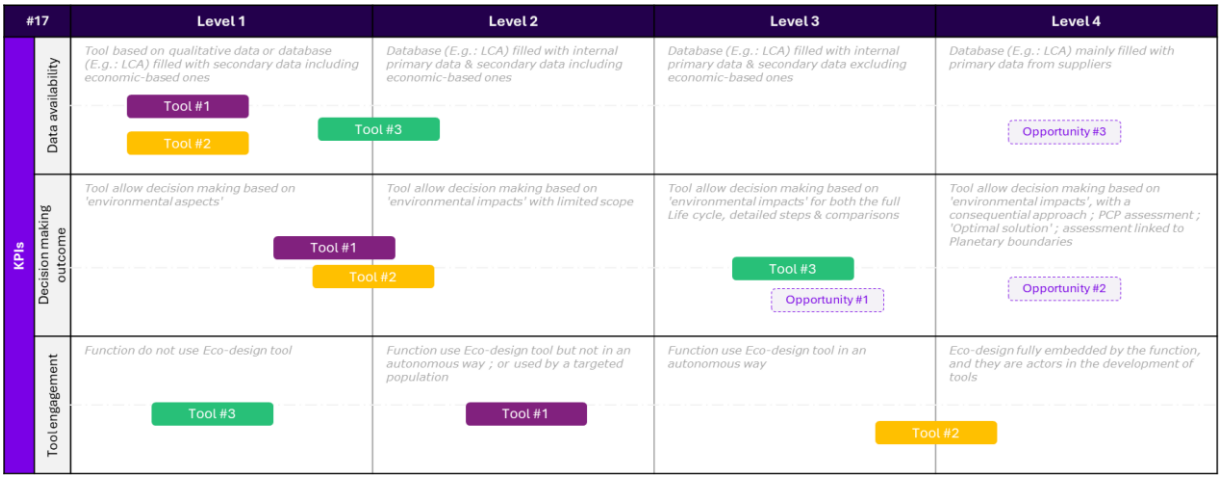

Figure 91. Maturity mapping of existing tools

This detailed evaluation of individual actions allowed an in-depth analysis at both the item and pillar levels. By aggregating the results, global maturity scores were established for each pillar and function. Figure 92 presents the overall maturity evaluation for one function.

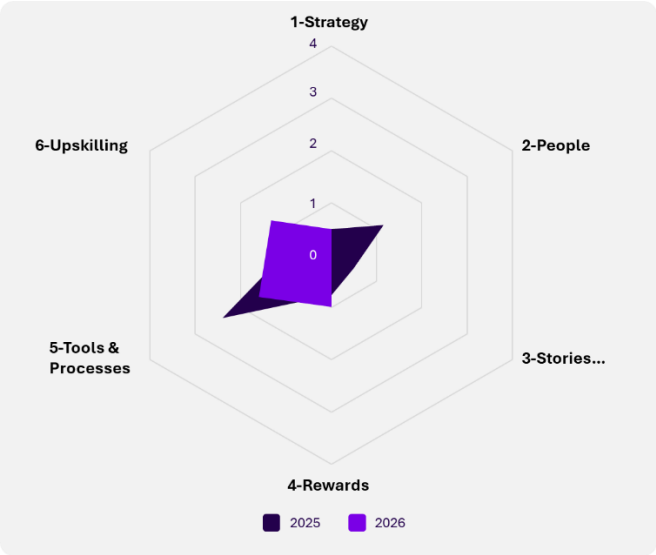

Figure 92. Current maturity profile of Function A

The diagrams showed that several actions within the identified pillars were ongoing, with maturity levels between 2 and 3 for Pillar 5 (Tools & Processes), while Pillar 2 (People) remained between levels 1 and 2. For the other pillars, maturity was situated between levels 0 and 1. The actions planned for 2026 were expected to improve maturity in the Upskilling and Governance pillars. With the target end state set for 2030, where all pillars were expected to reach maturity level 4, the analysis clearly highlighted the gap between the current situation and the desired future state.

5.8.4.2. Workshops with key functions (step 2, 3, 4)

Once the diagnostic of the current situation had been completed, the next objective was to move to the next steps and translate the strategy associated with the global environmental sustainability vision and ambitions into specific pathways and actions for each key function. This step aims to define the expected end state for each function in order to contribute to the overall sustainability strategy. To achieve this, a series of workshops are being planned with each function. Given time constraints, the initial focus will be placed on two selected pillars: Pillar 1 (Strategy) and Pillar 5 (Tools & Processes).

Backcasting is widely regarded as the most appropriate approach for planning in sustainability contexts, as it begins from the desired future and works backward to identify the necessary steps. In line with this, the workshops are designed as backcasting exercises, drawing on the ABCD-procedure and funnel metaphor of the Framework for Strategic Sustainable Development (FSSD) (Broman & Robèrt, 2017).

The global corporate vision already defined the long-term ambition, and the diagnosed maturity profiles provided the baseline of the current reality. The workshops were therefore intended to transpose the global vision into function-specific visions (A), use the maturity assessment as a baseline (B), explore solutions through creativity (C), and prioritize (D) the actions that can bridge the gap.

Within each 30-minute block, the ABCD logic will be applied in a tailored way:

- **Strategy (30 min):** covers the full ABCD sequence. Participants will begin with a reminder of the company's global vision and will be invited to co-create a function-specific end state (A). The current maturity profile will then be reviewed and refined (B), followed by a creativity session to generate potential strategies and end-state (C), and prioritization of solutions based on strategic guidelines such as flexibility, pace, and return on investment (D).
- **Tools (30 min) and Processes (30 min):** build on the end state already defined in the Strategy session. Here, the "A" step is limited to a short reminder of the vision, while the focus shifts to reviewing and enriching the maturity profiles (B), identifying gaps and opportunities for tools and processes to evolve (C), and prioritizing actions into potential roadmaps (D).

The workshops are designed to last approximately two hours, with 30 minutes allocated to each pillar (Strategy, Tools, Processes), complemented by a 15-minute introduction and 15-minute wrap-up. The introduction will cover participants, objectives, creativity tools (e.g., online whiteboard), and a reminder of Sanofi's environmental sustainability principles. The conclusion will synthesize outcomes and define next steps.

By embedding the ABCD-procedure into the capability model workshops, even in a simplified form, the planned sessions aim to ensure that actions are not only grounded in functional maturity profiles but also systematically aligned with the company's long-term sustainability vision through a principle-based backcasting logic.

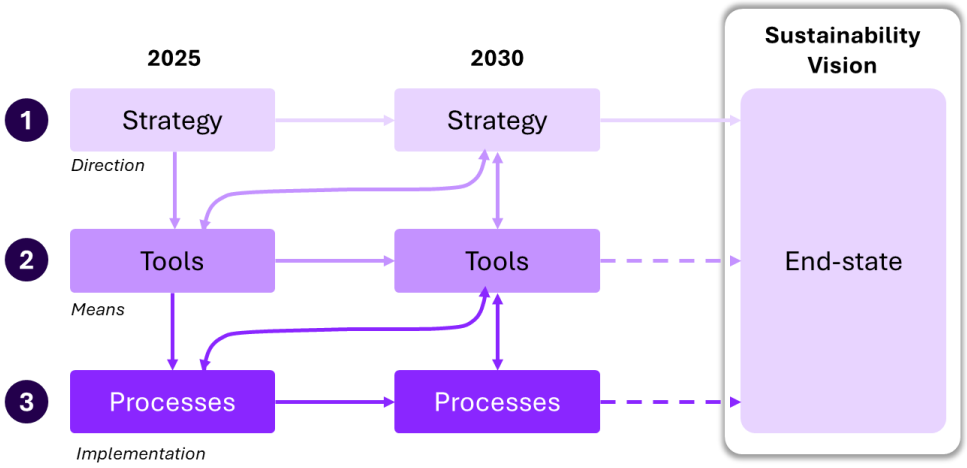

Figure 93. Logical flow and organization of the workshops

To support the design of these workshops, Figure 93 was developed to illustrate how the pillars of the capability model interact over time and how they build on each other in a coherent trajectory, moving from the current state (2025 horizon) toward the desired end state (2030 horizon). The Strategy pillar provides the overall direction by defining visions and objectives, which then cascade into the Tools pillar, where methods, systems, and enablers are designed to operationalize the strategic intent. In turn, these tools shape the Processes pillar, where practices are embedded in daily operations and governance. Arrows moving downstream represent this cascade logic (direction → means → implementation), while the feedback arrows upstream emphasize that processes also generate insights that inform the refinement of tools and, ultimately, adjustments to strategy. This dynamic reflects the continuous improvement logic of the PDCA cycle, where each iteration builds on both top-down ambition and bottom-up learning. By aligning the pillars along both a temporal axis (from current state to end state) and a hierarchical axis (from strategy to processes), the diagram conveys how sustainability integration requires coherence across levels and functions, ensuring that strategic visions translate into tools and processes that are both effective and adaptive.

5.8.4.3. Improving manufacturing technology standards (step 5)

The absence of environmental considerations in manufacturing technology standards was identified as a critical gap under Pillar 5 (Tools & Processes), Item 17 (Tools & Decision Support). To address this, environmental recommendations were integrated into selected standards as a pilot project. The experience also led to the formulation of a structured process for guiding future integration. These two elements are presented below.

Integrating environmental recommendations into standards

The preliminary application of the capability model highlighted the absence of environmental considerations within manufacturing technology standards as a key gap under Pillar 5 (Tools & Processes), Item 17 (Tools & Decision Support). These standards are structured documents that define internal practices for using specific technologies and serve as mandatory references when designing industrialization processes. At the time of analysis, they did not include any reference to environmental sustainability. This was considered as an important foundational step toward strengthening capabilities and reaching the end state, as it would ensure that environmental considerations were embedded systematically and at the same level as traditional requirements such as quality or cost. This gap was revealed in parallel with the development of the capability model, which was built iteratively from literature, internal documentation, and feedback loops with functions' stakeholders.

The use of the capability model as a diagnostic tool (step 1) allowed the identification of this gap, which was then prioritized for action. Because the manufacturing function already had strong environmental ambitions, it was possible to move directly to step 3, with the integration of environmental recommendations into selected technology standards. To carry out this action, the transition framework developed in Part A was applied.

Step 1 – Capture: this step was divided into two parts:

a. **Prioritization of standards**: existing LCAs were reviewed to identify priority technologies based on their importance in the manufacturing process and their potential environmental impacts. This information was combined with the manufacturing function's technology roadmap, which specified the standards scheduled for revision. Together, these elements enabled the selection of two priority standards for update.
b. **Hotspot analysis of selected technologies**: for the chosen technologies, LCAs were analyzed in greater detail to identify environmental hotspots within manufacturing processes. As the manufacturing stage of pharmaceutical products is known to account for the majority of life cycle impacts, this deep dive focused on pinpointing specific process steps driving impacts (e.g., a particular step associated with high energy consumption or material use). This analysis provided the key environmental levers to be addressed through recommendations.

Step 2 – Synthesize: the captured learnings were analyzed to derive general insights. Although LCAs provided useful direction, it was sometimes difficult to attribute impacts to individual technologies (e.g., data such as energy consumption was typically aggregated at the building level). To overcome these limitations, complementary insights were gathered from scientific literature to identify known hotspots and potential recommendations.

Step 3 – Formalize: insights from internal and external sources were translated into draft recommendations for integration into the standards. The standards were analyzed to determine where recommendations should be positioned, and the content was adapted to the required format and wording. Drafts were iteratively refined through working sessions with SMEs to ensure clarity, feasibility, and alignment with existing practices.

Step 4 – Disseminate: once finalized and validated, the recommendations were integrated into the standards. Meetings with the standards' core team and end users ensured understanding and paved the way for effective implementation. Since the use of standards was mandatory whenever the relevant technologies were applied, this step ensured that the recommendations would be systematically embedded into practice.

Through this process, environmental recommendations were successfully integrated into two technology standards. This action was subsequently recorded in the capability model under Pillar 5, Item 17, with a maturity level of 3 - "*Key environmental prompts and data are fully integrated into tools, templates, and workflows*".

Developing a structured approach for standard integration

Beyond the integration of environmental recommendations into two manufacturing technology standards, the pilot also led to the formulation of a structured approach for systematically embedding environmental considerations into standards. This approach was derived from the pilot experience by applying the steps of the transition framework (capture - synthesize - formalize - disseminate) not only to the recommendations themselves, but also to the process of integration.

The resulting approach supported both tracking of the current state of integration, and improvement by guiding further actions. It was structured into four stages:

1. **Framing**: through the standard analysis, and generic knowledge of environmental impacts, identify integration opportunities and determine where in the standard environmental recommendations should be placed.
2. **Qualitative integration**: introduce recommendations based on generic, non-company specific data, primarily from literature.
3. **Quantitative integration**: refine and substantiate recommendations with company-specific evaluations (e.g., LCA) supported by primary data. Not all recommendations need to be quantitatively assessed.

4. **Collaboration**: transfer or adapt recommendations when they are more relevant to another function's standards (e.g., energy-related recommendations integrated into engineering or facility management standards rather than manufacturing).

This approach was embedded into the eco-design team's way of working, providing a structured pathway for future collaborations with functions revising their standards. Table 49 illustrates its application across selected technologies, showing the level of integration achieved at each stage

Table 43. Progress of environmental integration across technology standards

Steps	Framing	Qualitative integration	Quantitative integration	Collaboration
Techno standard A	✓	✓	✓	~
Techno standard B	✓	✓	~	~
Techno standard C	✓	~		
Techno standard D	✓	✓		~

5.9. DISCUSSION

5.9.1. Capability model as a lever for organizational change

The findings showed that the capability model acted as a lever for organizational change. Research in organizational change management (OCM) had long emphasized that technical tools or isolated initiatives were insufficient to drive transformation unless they were accompanied by enabling structures, leadership commitment, and cultural reinforcement (Armenakis and Bedeian, 1999; Kotter, 1996; Ramos-Maçães and Román-Portas, 2022). Applied to sustainability, this meant that eco-design methods, LCA tools, or technical guidelines remained underused if the organizational conditions for change were not deliberately cultivated (Brones et al., 2017; Lozano, 2008).

The capability model operationalized these insights by embedding classical OCM levers: sponsorship, communication, incentives, and cultural alignment, into measurable items structured across six pillars. By doing so, it translated the often intangible "soft side" of change (attitudes, behaviors, narratives, recognition) into tangible elements that could be assessed, developed, and monitored alongside the "hard side" (tools, KPIs, processes). This dual focus addressed the gap repeatedly noted in the eco-design literature, where integration models tended to privilege technical practices while overlooking cultural and behavioral enablers (Boks, 2006; Kiesnere and Baumgartner, 2019; Verhulst et al., 2007).
The empirical applications reinforced this perspective. For instance, the diagnostic of maturity revealed that the People and Recognition pillars generally lagged behind Tools & Processes, highlighting that cultural and behavioral enablers were less developed than technical practices. Similarly, the integration of environmental recommendations into manufacturing standards illustrated how technical elements could be formalized but also showed the need for strong sponsorship and cross-functional alignment to ensure their effective uptake.

In this sense, the framework provided a structured way to mobilize people and align strategy while also institutionalizing practices. It acted not only as a diagnostic tool but also as a roadmap for reinforcing change at multiple levels, linking leadership sponsorship with team behaviors, aligning incentives with desired outcomes, and embedding sustainability narratives into everyday rituals. As such, it extended OCM insights into the

sustainability domain, demonstrating how organizational change could be deliberately structured and measured to support systemic environmental integration.

5.9.2. Advancing capabilities and maturity

The capability model developed in this thesis advanced existing perspectives on dynamic capabilities and maturity models while complementing recent work on sustainable product development (SPD) practices (Vilochani et al., 2024). Maturity models, originating from CMMI and OPM3 (Fahrenkrog, 2004; SEI, 2006), demonstrated how structured, staged progression could support organizational improvement. Like CMMI, the framework recognized the centrality of process capability as the infrastructure for continuous improvement. Like OPM3, it emphasized the alignment between strategic intent and functional deployment. Building on this lineage and inspired by EcoM2's translation of maturity models into the field of product eco-design (Pigosso et al., 2013), the framework proposed here offered a sector-specific instantiation adapted to the requirements of the pharmaceutical industry. By structuring sustainability integration into six pillars, 21 items, and four maturity levels, it provided both a diagnostic view of current practices and a roadmap for incremental improvement.

This contribution also connected with dynamic capabilities theory, which emphasized the need for organizations to sense opportunities, seize them through action, and reconfigure their structures accordingly (Franco et al., 2024; Teece, 2007). The capability model operationalized this perspective by translating abstract processes into concrete, assessable items that enabled pharmaceutical firms and their core functions to measure where they stood, identify gaps, and progressively build the capabilities needed to integrate sustainability.

The framework further complemented SPD practices (Vilochani et al., 2024), which provided a comprehensive repository of what should be done across product development and support functions. Although SPD practices mapped the technical and managerial activities needed for sustainability, they did not address the organizational capabilities required for their uptake. The capability model filled this gap by shifting the focus from tools and practices alone toward the maturity of organizational conditions (e.g., leadership, incentives, culture, and integration) that determine whether such practices could take root. This perspective was reinforced in 2024, with the investigation of the extent to which these 61 SPD practices are actually implemented in manufacturing companies, using a capability-based maturity scale derived from CMMI and EcoM2 (Vilochani et al., 2025). Their study revealed a strong theory–practice gap: while corporate sustainability strategy and performance monitoring practices scored higher due to regulatory and reputational pressures, most other areas, such as product requirements, organizational communication, data management, and sustainable technologies, remained at ad-hoc or only partially formalized levels. These findings confirmed that the challenge is not the availability of practices, but rather the organizational capability to embed them systematically across functions. The uneven profiles observed in their cross-sectoral sample mirrored those identified in this thesis, where technical enablers scored higher maturity than people- and culture-related dimensions. In this sense, the proposed capability model directly responded to the shortcomings highlighted by Vilochani et al. (2025), by providing a structured, sector-specific model that allows pharmaceutical functions to profile capabilities, identify gaps, and develop roadmaps for improvement (Vilochani et al., 2025).

This point reinforced the limitations identified by Rossi et al. (2016), who showed that the limited industrial uptake of eco-design tools was due less to their availability than to capability gaps in integration, cross-functional collaboration, and alignment with strategy (Rossi et al., 2016). The capability model directly responded to these barriers by providing a structured means to assess such gaps, translate them into measurable items, and guide targeted improvement strategies.

The preliminary application of the framework demonstrated the value of this combined perspective. The diagnostic application revealed uneven capability profiles: technical enablers such as tools and processes reached higher maturity, while people- and culture-related dimensions lagged behind.

5.9.3. Positioning the capability model within existing frameworks

The capability model and its application method developed in this thesis draw inspiration from established frameworks in the sustainability and organizational change fields. In particular, three reference points stand out:

the Framework for Strategic Sustainable Development (FSSD) (Broman and Robèrt, 2017a), the EcoM2 and its PDCA-inspired application method (Pigosso et al., 2013), and the consolidation of Sustainable Product Development (SPD) practices (Vilochani et al., 2024). Each brings complementary insights: FSSD provides the principle-based logic for backcasting, EcoM2 structures the improvement cycle through PDCA, and SPD practices offer a repository of concrete activities that organizations may implement. The proposed framework combines and extends these traditions in ways tailored to the pharmaceutical sector.

FSSD: from principles to backcasting.
The FSSD is one of the most established approaches for guiding sustainability transitions (Broman and Robèrt, 2017a) . It is grounded in sustainability principles and operationalized through the "funnel" metaphor and the ABCD procedure: (A) articulate a vision of success consistent with sustainability principles, (B) assess the current reality, (C) brainstorm pathways forward, and (D) prioritize actions. The key innovation of FSSD lies in its backcasting logic: instead of extrapolating from current trajectories, organizations define a desired end state and then work backward to identify necessary steps.

The capability model builds directly on this principle-based reasoning. The application workshops designed in this thesis replicate the ABCD cycle within each functional block. However, because Sanofi had already defined a global sustainability vision at corporate level, the sequencing was pragmatically adapted. In practice, the process begins with B (diagnosis of maturity profiles), then moves to A (translation into function-specific visions), before proceeding with C (creativity to identify levers) and D (prioritization). This preserves the essence of FSSD while reflecting governance realities of large organizations: global direction first, functional translation second. The capability model therefore positions FSSD not as an abstract visioning exercise, but as a structured, repeatable mechanism to cascade principles into functional pathways, anchored in measurable maturity profiles.

EcoM2 and PDCA: structuring improvement cycles.
The EcoM2 (Pigosso et al., 2013) represents another cornerstone. Building on PDCA and business process management, it defines a six-step method: (1) diagnose maturity, (2) propose practices/projects, (3) manage project portfolio, (4) plan, (5) implement, and (6) assess results. Its strength lies in combining maturity assessment with continuous improvement cycles, enabling organizations to track progress over time and embed eco-design systematically.

The capability model and its application method mirror this cadence but extend it in three ways:

- Anchoring actions in an explicit capability system (six pillars, 21 items, KPI-linked maturity levels), beyond the eco-design domain.
- Embedding the ABCD logic of FSSD within each step, making backcasting part of the improvement rhythm rather than a one-off strategy exercise.
- Emphasizing cultural and human enablers (leadership, incentives, recognition, rituals), which are often underrepresented in eco-design maturity models.

In this way, the framework combines the principle-based orientation of FSSD with the operational discipline of EcoM2/PDCA, ensuring both direction and continuous improvement.

SPD practices: what to do vs. how to sustain it.
SPD practices (Vilochani et al., 2025, 2024) consolidate a wide range of sustainability-oriented activities across product development and support functions. They specify what should be done in areas such as evaluation, process integration, compliance, and value chain collaboration. Yet, their industrial uptake remains limited, with most practices applied only ad hoc or partially formalized. The capability model responds to this gap by focusing on the conditions for uptake: leadership sponsorship, recognition, rituals, training, and governance. In short, SPD specifies practices, while the capability model specifies the capability infrastructure required to make those practices stick.

Positioning among other frameworks.
Beyond these three main references, other frameworks also provide useful comparisons. Eco-Mi (Xavier et al., 2020) extends maturity thinking to eco-innovation, while DEimeter (Luu, 2023a) adapts maturity assessment to pharmaceutical drug development. The CE Maturity Model (Uhrenholt et al., 2022) applies a multi-dimensional

maturity lens to circular economy transformation. Finally, generic frameworks such as CMMI (SEI, 2006) and OPM3 (Fahrenkrog, 2004) demonstrate how capabilities and maturity have long been used to structure organizational improvement, though without a sustainability or pharmaceutical focus. To position the proposed framework relative to these models, Table 50 synthesizes their emphases across four criteria.

Table 44. Positioning of the proposed capability model relative to existing frameworks

	Envtl. Sust. focus	Capability focus	Maturity focus	Pharma focus
FSSD	High	Low	Medium	Low
EcoM2	Medium	Medium	High	Low
Eco-Mi	Medium	Medium	High	Low
DEimeter	Medium	Low	High	High
CEMM	Medium	Low	High	Low
CMMI	Low	High	High	Low
OPM3	Low	High	Medium	Low
Proposed CM	High	High	High	High

This comparison shows that while existing models provide valuable building blocks, none combines principle-based backcasting (FSSD), PDCA-based continuous improvement (EcoM2), and a pharmaceutical-specific capability framework. The proposed model advances this integration by embedding cultural enablers alongside technical practices, and by tailoring capability development to the realities of pharmaceutical product and process development.

5.9.4. Systemic practices and Organizational capabilities

The integration of environmental recommendations into manufacturing technology standards illustrated how the capability model and the transition framework developed in Part A could be used together. The capability model identified the gap (absence of environmental considerations in standards), while the transition framework provided the process to address it (capture, synthesize, formalize, disseminate). Together, the two frameworks formed a complementary approach, one defining what capabilities were needed, the other guiding how they could be institutionalized in practice.

The case of the technology standards exemplified this interaction. The capability model highlighted a structural deficiency under Pillar 5 (Tools & Processes, Item 17), which revealed that standards did not embed environmental sustainability alongside cost and quality requirements. Using the transition framework, this gap was addressed through a structured process: environmental hotspots were identified through LCA, insights were synthesized with literature, recommendations were formalized in standard-compatible formats and finally disseminated and embedded into mandatory documents.

This case showed that the two frameworks worked in tandem: the capability model diagnosed the organizational need, while the transition framework provided the pathway to act upon it. It also demonstrated that the transition framework was not merely theoretical but applicable to embedding sustainability into core operational tools such as standards. In this sense, the integration into standards represented a bridge case between Part A and Part B, validating that diagnosing capabilities and enabling their institutionalization are inseparable components of systemic sustainability integration.

5.9.5. Contributions and implications

This research made contributions at several levels.

Theoretical implications: the thesis extended OCM and maturity model perspectives into the domain of pharmaceutical sustainability. By combining insights from OCM, dynamic capabilities, and sustainability maturity models (e.g., EcoM2), the capability model provided a novel, structure that captured both the technical and cultural

dimensions of capability building. Unlike existing models, the proposed framework offered a sector-specific instantiation adapted to the highly regulated and complex pharmaceutical industry. It advanced the academic conversation by bridging the gap between tools/practices (e.g., SPD) and the organizational conditions required for their effective uptake.

Practical and managerial implications: for practitioners, the framework provides a diagnostic and prescriptive tool that enables functions to evaluate their current maturity, identify gaps, and design roadmaps for improvement. By structuring capabilities across strategy, people, processes, recognition, and upskilling, the framework supports managers in prioritizing where to act and in aligning technical enablers with cultural and organizational change levers. The pilot application in manufacturing demonstrated its potential to identify overlooked gaps (e.g., the absence of environmental considerations in technology standards) and to guide integration in a systematic way. In this context, the transition framework developed in Part A complemented the capability model by providing the process through which identified gaps could be addressed, moving from diagnosis to action. Together, the two frameworks offered a combined approach: one defining what capabilities needed to be built, and the other guiding how they could be embedded into organizational practice.

Sectoral implications: the pharmaceutical industry faces unique challenges due to its strict regulatory environment, patient safety requirements, and stakeholders diversity. By tailoring a capability-based framework to this context, this research provided a model that could accelerate the integration of environmental sustainability without compromising compliance or product quality. An illustration of this tailoring is the incorporation of the Patient Care Pathway (Schrijvers et al., 2011) as part of a higher maturity level in the Tools & Processes pillar. The care pathway is a concept that can be used to link environmental sustainability directly to patient-centric journeys in healthcare systems. This highlighted how sector-specific logics could be integrated into a generic capability approach, ensuring that sustainability becomes embedded in the industry's own language and practices. At a broader level, the framework contributed to the operationalization of sustainability strategies in a structured, maturity-oriented way, aligned with both regulatory requirements and societal expectations.

5.9.6. Limitations and future work

Although the proposed capability model represented a significant step toward structuring the integration of environmental sustainability in the pharmaceutical industry, several limitations must be acknowledged.

First, the framework remained in a preliminary stage of application. Although initial maturity assessments were conducted and specific elements, such as the integration of environmental recommendations into manufacturing standards, were tested, a complete systematic DS-II evaluation could not be conducted within the timeframe of the doctoral thesis. As a result, the effectiveness, scalability, and long-term impact of the framework still require empirical validation through broader and deeper applications.

Second, the maturity evaluation (step 1) relied partly on the knowledge and perceptions of members of the eco-design team and selected stakeholders. Even though these actors had substantial expertise, the absence of a systematic data-collection process introduced potential bias and limited the comprehensiveness of the diagnostic. Similarly, the online survey distributed to selected functions was a good idea but remained exploratory in nature. Future work should therefore focus on strengthening the robustness of the diagnostic phase, by deploying the framework more widely, engaging diverse roles and geographies, and triangulating self-reported data with objective performance indicators.

Third, the framework focused primarily on internal capabilities within core functions such as R&D, manufacturing, and the device and packaging unit. Although this scope reflected a deliberate boundary aligned with the environmental sustainability priorities, it excluded other functions, which could play a critical role. Future research could extend the framework to cover additional functions and cover inter-organizational capabilities, for instance by adapting certain pillars (e.g., stakeholder engagement, supply-chain collaboration) to upstream and downstream partners.

Fourth, while the framework's design sought to balance comprehensiveness and usability, the granularity of 21 items and four maturity levels might still represent a cognitive and operational challenge, particularly for functions

with limited prior exposure to sustainability. Additional work is needed to refine guidance materials, digitalize the framework for easier navigation, and develop training modules or facilitation tools to support its implementation. At the same time, the 21 items may also prove overly simplified to fully capture and develop the internal capabilities required for systemic sustainability integration. Future research should therefore examine this dimension through detailed applications, in order to assess whether the current level of granularity is sufficient or whether further refinement and expansion of items is necessary.

In summary, the capability model laid the foundations for a structured, maturity-based approach to building sustainability capabilities in pharma. The main limitations highlighted key next steps involving testing, refining, and extending the model to ensure it becomes a practical, scalable tool that supports continuous improvement and systemic integration of environmental sustainability across pharmaceutical systems.

5.10. CONCLUSION

This part of Chapter 5 aimed to address Hypothesis 2 and, more specifically, Sub-Research Question 2.2: *How can the environmental sustainability strategy and its components be institutionalized across organizational functions to develop durable capabilities?* To answer this, a capability model tailored to the pharmaceutical sector was developed.

The framework structured sustainability integration into six pillars, 21 items, and four maturity levels, offering both a diagnostic lens and a roadmap for improvement. Each pillar captured a critical dimension of capability building: strategy, people, stories and rituals, rewards, tools and processes, and upskilling, thus providing a comprehensive view of the organizational conditions required to embed sustainability. The maturity levels allowed functions to assess their current situation, define an end state, and identify pathways for progression. The application method linked these assessments to concrete actions such as defining strategies, management practices, and improvement projects, thereby operationalizing the framework as both an evaluative and prescriptive tool.

Preliminary applications highlighted its potential but also some limitations. Uneven capability profiles were observed across functions, with technical enablers (e.g., tools and processes) showing higher maturity than people- and culture-related dimensions. The framework's level of granularity (21 items across six pillars) might present a limitation. Additionally, its validation remained partial, with applications spanning step 1 to 3 and focused only on selected functions and specific cases such as the integration of environmental recommendations into technology standards.

Despite these limitations, the results underscored that embedding environmental sustainability across pharmaceutical product and process development depends on the deliberate building of organizational capabilities. The capability model provided here offers a structured basis to evaluate current conditions, identify gaps, and guide functions toward higher levels of maturity, thus supporting the institutionalization of the environmental sustainability strategy.

SYNTHESIS OF CHAPTER 5

This chapter addressed **Hypothesis 2**: *Systemic integration of environmental sustainability in the pharmaceutical industry can be achieved by consolidating validated projects into standardized practices and institutionalizing the sustainability strategy as enduring organizational capabilities, thereby enhancing the environmental performance of products and processes*. To investigate this, Chapter 5 was structured into two complementary parts, each designed to answer one of the sub-research questions supporting H2.

Part A addressed Sub-Research Question 2.1: *How can validated environmental projects be consolidated and standardized into practices that support systemic integration across pharmaceutical product and process development?*

Drawing on organizational learning and transition management perspectives, Part A developed a transition framework structured into four steps: capture, synthesize, formalize, and disseminate. This framework was tested through two experiments, a portfolio-level LCA of Sanofi's insulin products and the development of environmental guidelines for manufacturing processes. The results demonstrated that isolated initiatives, when systematically processed through the framework, could be transformed into standardized practices with broader applicability. However, the experiments also revealed limits: while project learnings could be captured and formalized, dissemination and embedding into organizational routines remained partial, reflecting the well-known challenge of sustaining change across functions. Part A therefore highlighted the value of structured mechanisms for project-to-practice transformation, while showing that practices alone were insufficient to ensure durable systemic integration.

Part B addressed Sub-Research Question 2.2: *How can the environmental sustainability strategy and its components be institutionalized across organizational functions to develop durable capabilities?*

Building on insights from organizational change management, maturity models, and sustainable product development practices, Part B developed a capability model tailored to the pharmaceutical sector. Structured into six pillars, twenty-one items, and four maturity levels, the framework provided both a diagnostic tool and a roadmap for capability development. It shifted the focus from what practices are deployed to how organizations develop the underlying conditions (e.g., leadership, incentives, culture, tools, skills) that allow practices to be institutionalized, sustained, and renewed. Preliminary applications, including maturity assessments, preparatory workshops, and the integration of environmental recommendations into manufacturing technology standards, demonstrated its usability as both an evaluative and a guiding instrument. The link between the capability model and the transition framework further showed how the two approaches complemented each other: the former identified capability gaps, while the latter provided the process to address them.

Overall synthesis

In conclusion, the findings from Parts A and B validate H2. Together, the two frameworks proposed in this chapter, the transition framework and the capability model, offered structured pathways to move from isolated initiatives and strategic intentions toward systemic and durable integration of environmental sustainability. The transition framework demonstrated that validated projects can be transformed into standardized practices, while the capability model showed how the strategy and its components can be institutionalized through organizational conditions.

These findings highlighted that systemic integration requires dual mechanisms: on the one hand, processes that transform project outcomes into standardized practices (Part A), and on the other hand, capability-building approaches that allow these practices to be embedded, aligned with strategy, and sustained over time (Part B). The capability model thus provided the foundations for turning sustainability from an accumulation of practices into organizational capabilities, thereby advancing the institutionalization of the environmental sustainability strategy in the pharmaceutical sector.

At the same time, the evaluation revealed limitations: both frameworks remain at an early stage of development, tested only in partial applications, and require further validation through broader DS-II evaluations. Nevertheless, they provide complementary and transferable approaches to operationalize environmental sustainability in the pharmaceutical sector. These conclusions directly inform the overall discussion of the thesis, which reflects on the role of dynamic capabilities and organizational learning as essential enablers of systemic integration of environmental sustainability in the pharmaceutical industry.

Résumé en français - Chapitre 5 : Transition systémique et changement organisationnel

Ce chapitre répond à l'Hypothèse 2 (H2) en examinant comment la soutenabilité environnementale peut être intégrée systémiquement dans le développement des produits et procédés pharmaceutiques. Il se structure en deux parties : la Partie A s'intéresse à la transformation de projets validés en pratiques systémiques (SRQ2.1), la Partie B vise à institutionaliser la stratégie via la création de capacités organisationnelles (SRQ2.2).

PARTIE A - De la pratique de projet à la pratique systémique
Contexte et méthode : S'appuyant sur les constats du chapitre 4 (pilotes prometteurs mais peu intégrés), cette partie explore comment l'apprentissage organisationnel peut transformer des initiatives isolées en pratiques réutilisables. Une revue semi-systématique de littérature couvre trois domaines : la gestion des connaissances (KM), l'apprentissage organisationnel (OL), et les transitions pilote-vers-pratique.

Constats de littérature : Un schéma récurrent émerge : les organisations excellent à capturer la connaissance, mais peinent à l'interpréter, la formaliser et l'ancrer dans les routines. Le modèle Syllk (Duffield et Whitty) souligne la nécessité d'aligner facteurs humains et techniques. Cinq lacunes transversales sont identifiées : biais de capture, déséquilibre tacite/explicite, désalignement outil-système, écart stratégie-processus, et aveuglement contextuel.

Pour faire face à ces manques, un cadre de transition est proposé. Huit exigences de conception (DR1-DR8) sont synthétisées, débouchant sur un cadre en quatre étapes itératives : Capturer (collecter les enseignements), Synthétiser (dégager des schémas généralisables), Formaliser (traduire, standardiser et simplifier), Disséminer (transférer et intégrer dans l'organisation).

Expérimentation 1 - ACV de portefeuille d'insulines : Cette étude applique une approche d'Analyse de Cycle de Vie (ACV) au portefeuille d'insulines de Sanofi (Toujeo®, Lantus®, Soliqua®, etc.), selon une approche « cradle-to-grave » conforme à la méthodologie PEF. Les résultats montrent que trois étapes dominent l'impact environnemental (81-93% selon l'indicateur, hors transport patient) : la fabrication de l'API, le packaging primaire, et le dispositif d'injection (stylo à insuline). Pour l'API (insuline glargine), l'énergie (vapeur, ~65% pour le changement climatique) et quatre substances chimiques (glucose, agent dénaturant, hydroxyde de sodium, agent réducteur) sont les principaux contributeurs. La comparaison Toujeo SoloStar®/DoubleStar® montre une réduction de 24-42% en faveur du format à plus grande capacité. Sur le plan méthodologique, l'approche portefeuille permet de standardiser la collecte de données et d'améliorer la comparabilité, malgré des risques de sur-simplification. Sept stratégies sont proposées pour mener des ACV de portefeuille efficace dans le secteur pharma.

Expérimentation 2 - Méthodologie pour la fabrication durable : Issue d'un projet industriel où des leviers éco-conception ont été intégrés dans un outil d'aide à la décision multicritère, cette expérimentation développe un guide structuré en trois phases : Investigation (comprendre le contexte et les impacts), Transformation (convertir les impacts en recommandations génériques), Customisation (adapter les recommandations au contexte spécifique). Développé selon la DRM et validé par 13 experts (score moyen de cohérence : 4,46/5), l'outil a ensuite été testé et répliqué au sein de Sanofi via des workshops, confirmant sa transférabilité.

Les deux expérimentations montrent une forte pertinence et une bonne évolutivité, mais une intégration limitée : les résultats restent en attente d'intégration formelle dans les procédures standards (SOP) de Sanofi. L'analyse par rapport aux exigences DR1-DR8 confirme que les premières étapes (capture, synthèse, formalisation) sont bien maîtrisées, tandis que la gouvernance et la dissémination restent partielles, confirmant partiellement H2 mais soulignant qu'au-delà de la standardisation, l'institutionnalisation exige des capacités organisationnelles complémentaires.

PARTIE B - Institutionnaliser la stratégie via les capacités organisationnelles
Contexte et méthode : Cette partie répond à SRQ2.2 en s'appuyant sur la gestion du changement organisationnel (OCM), les capacités dynamiques (e.g., Teece), et les modèles de maturité. Une revue de littérature et une étude empirique (analyse de trois initiatives Sanofi : le modèle de maturité éco-conception

DEimeter, la norme éco-conception, et une initiative de cadre de capacités) alimentent le développement du modèle.

Le modèle de capacités développé est composé de six piliers, totalisant 21 items, chacun évalué sur 4 niveaux de maturité avec KPI associés :

1. Développer la bonne stratégie (business case, vision, cibles, comportements durables)
2. Engager les bonnes personnes (sponsoring, équipe dédiée, réseau de champions)
3. Façonner les bonnes histoires, rituels et symboles (communication, partage de bonnes pratiques)
4. Renforcer par les bonnes récompenses et reconnaissance (intégration dans la gestion de la performance)
5. Permettre par les bons outils et processus (aide à la décision, etc.)
6. Construire les bonnes compétences (montée en compétences, formation)

Méthode d'application : Un processus en six étapes, inspiré du PDCA, d'EcoM2 (Pigosso et al., 2013) et de la procédure ABCD du FSSD (backcasting) : Diagnostic → Transposition de la vision → Identification des leviers → Priorisation → Mise en œuvre → Évaluation de la performance, le tout formant un cycle itératif.

Applications préliminaires : Au sein de Sanofi : (1) un diagnostic de maturité par fonction révèle un profil inégal : les Outils & Processus (Pilier 5) atteignent des niveaux 2-3, tandis que les Personnes (Pilier 2) restent à 1-2, et la plupart des autres piliers entre 0 et 1, avec un objectif de niveau 4 fixé pour 2030. (2) Des workshops de planification stratégique sont en préparation pour traduire la vision globale en trajectoires spécifiques par fonction. (3) L'intégration de recommandations environnementales dans deux strandards technologiques de fabrication illustre la combinaison des deux cadres (capacités + transition) : le modèle de capacités identifie la lacune (absence de critères environnementaux dans les normes), le cadre de transition fournit le processus pour la combler (capture des points chauds via ACV → synthèse avec la littérature → formalisation en recommandations → dissémination dans les normes obligatoires), atteignant un niveau de maturité 3.

Apports et limites

Le modèle proposé se distingue en combinant simultanément une forte orientation soutenabilité environnementale, capacités, maturité, ET spécificité pharmaceutique, une combinaison absente les cadres existants (FSSD, EcoM2, Eco-Mi, DEimeter, CEMM, CMMI, OPM3). Le modèle agit comme levier de changement organisationnel en rendant mesurables les dimensions « soft » (culture, comportements) aux côtés des dimensions techniques. Il comble le fossé théorie-pratique identifié par Vilochani et al. (2025) concernant les pratiques de développement durable de produits. Toutefois, l'évaluation reste préliminaire : absence de DS-II complète, biais potentiel du diagnostic reposant sur la perception d'experts internes, périmètre limité à certaines fonctions clés (R&D, manufacturing, dispositifs), et granularité des 21 items possiblement à affiner.

Conclusion

Les deux parties valident conjointement H2 : le cadre de transition démontre que des projets validés peuvent devenir des pratiques standardisées, tandis que le modèle de capacités montre comment la stratégie peut être institutionnalisée à travers des conditions organisationnelles durables (leadership, incitations, culture, outils, compétences). L'intégration systémique de la durabilité environnementale nécessite ainsi une double mécanique : la transformation des résultats de projets en pratiques (Partie A) et la construction de capacités permettant d'ancrer, d'aligner et de pérenniser ces pratiques (Partie B). Ces conclusions alimentent directement la discussion générale de la thèse sur le rôle des capacités dynamiques et de l'apprentissage organisationnel comme leviers essentiels de l'intégration systémique de la soutenabilité environnementale dans l'industrie pharmaceutique.

Chapter 6. Contributions & Limits

This chapter presents the main contributions of the doctoral research carried out at the LCPI in collaboration with Sanofi. Conducted through action research in a pharmaceutical company, the work generated contributions simultaneously at the scientific and industrial levels. Therefore, they are not treated separately but discussed together and later synthesized in a final mapping. The results were developed both to support Sanofi in integrating environmental sustainability across its organization and to provide insights for the broader pharmaceutical sector. The research explored several dimensions of sustainability implementation, resulting in a methodological proposal for structuring the systemic integration of environmental sustainability in the pharmaceutical industry. Building on the literature and empirical studies, this proposal articulates how strategy, organizational learning, and organizational change can be combined into a coherent pathway toward systemic integration.

Each section of this chapter describes the contributions linked to this research, all of which address the central research question of the thesis: **How can the systemic integration of environmental sustainability be structured in the pharmaceutical industry?**

The structure of the chapter follows the logic of the thesis: the first section focuses on the CE strategy developed for pharmaceuticals, including its supporting elements and case projects, and situates CE in relation to existing eco-design approaches. The second section addresses systemic transition and organizational change, highlighting contributions related to the transformation of projects into practices and the development of organizational capabilities. These contributions are illustrated with empirical experiments such as the Portfolio LCA and the Manufacturing guide. The third section combines these elements into an overarching methodological proposal for structuring systemic sustainability integration in pharmaceuticals. Finally, the chapter concludes with a synthesis of all contributions.

The contributions summarized in this chapter represent key aspects that pharmaceutical companies should consider when aiming to reduce their environmental impacts and implement sustainability in a systemic manner. Alongside each contribution, the main limitations are also presented, which open pathways for future research and practice.

6.1. A SECTOR-SPECIFIC STRATEGY FOR CE IN PHARMA

The development of a CE strategy took root in the field of corporate strategy and integration models, with the aim of identifying how the crucial elements of CE can be structured for the pharmaceutical sector. This addressed the first hypothesis of the thesis:
H1: *A structured Circular Economy strategy, enabling internal and external collaboration and alignment, can foster the emergence and reinforcement of circular initiatives in the pharmaceutical sector, ultimately contributing to the reduction of environmental impacts across the organization.*

This hypothesis was explored through the proposal of a CE strategy for the pharmaceutical industry and through the design and implementation of pilot projects across the company and product life cycle.

6.1.1. Designing a CE strategy

To address SRQ1.1: What are the key elements of a Circular Economy strategy in the pharmaceutical sector, and how can they be effectively implemented?, this thesis developed and consolidated a set of contributions that together form a sector-specific CE strategy.

The first contribution lies in the systematic **mapping of pharmaceutical CE literature**, which revealed a polarized focus between upstream manufacturing (e.g., solvents, green chemistry, and post-industrial waste) and downstream healthcare activities (e.g., device reuse, hospital waste). This observation, consistent with Ang et al. (2021) and Saha et al. (2025), shows that the two literatures address different ends of the life cycle without connecting them: pharmaceutical studies concentrate on short loops and eco-design principles, while healthcare studies emphasize end-of-life management and hospital practices, with limited attention to pharmaceutical product and process development (K.L. Ang et al., 2021; K. Saha et al., 2025). As a result, CE in pharmaceuticals risks being reduced to incremental design strategies, while CE in healthcare risks overlooking the sector’s specificities

and upstream impacts. Addressing this dual gap motivated the positioning of eco-design maturity at the center of the CE strategy developed here, while deliberately extending its scope to integrate medium- and long-loop strategies, organizational mechanisms, and healthcare system dynamics.

Building on these insights, the **Circular Economy Integration Model (CEIM)** was developed as an evidence-based framework for structuring CE in pharmaceuticals. By positioning eco-design at its core and extending outward to encompass organizational, policy, and healthcare system dimensions, the CEIM responds to the narrow, short-loop focus of existing literature and provides a structured way to link pharmaceutical product and process strategies with broader system-level dynamics.
The CEIM consolidates existing product-level approaches, such as green chemistry and eco-design, within a wider CE perspective, clarifying their overlaps and showing how eco-design can serve as a foundation for more advanced circular strategies. Beyond its conceptual role, the CEIM also functions as a practical tool: projects can be mapped onto the model to visualize their positioning and to anticipate barriers likely to emerge when establishing circular loops. In this way, it supports both reflection and action. Despite being generic enough to be applied across the sector, the model remains partly abstract and could gain robustness if combined with complementary frameworks that address additional system levels (e.g., (Chen et al., 2020; Evans, 2023; Scheepens et al., 2016)).

A third contribution consists in the **definition of company-wide indicators**, notably the Waste Impact Index and Waste Score, to track progress in CE implementation. These KPIs provide industry with actionable tools to compare performance across sites and foster practices sharing, while also contributing scientifically to the field of CE metrics by extending waste-hierarchy logic into weighted, normalized indicators. Their focus on post-industrial waste responds directly to pharma's materiality profile. Although not entirely novel scientifically, they represented a concrete step forward for industry by enabling Sanofi to move beyond end-of-pipe solutions (K. Saha et al., 2025), track progress across sites, and facilitate the emergence of good practices. Scientifically, they resonate with recent work on CE metrics (Shevchenko et al., 2024), positioning themselves within the domain of waste-management C-metrics and offering a weighted, normalized alternative to traditional recycling rates.

Finally, a range of **supporting tools and methods** were developed, including a CE glossary, waste standards and position papers, community of practice, and a handbook of good/best practices. These elements provided shared references and operational guidance for Sanofi employees, thereby reinforcing industrial uptake of CE concepts. Although these tools were valuable for fostering internal alignment, they represent primarily industrial contributions, as they clarified rather than expanded the scientific understanding of CE.

Overall contribution

Taken individually, the mapping of literature, the CEIM, the KPIs, and the supporting tools each represent contributions to understanding and operationalizing CE in pharmaceuticals. Taken together, however, they constitute a more significant contribution: the formulation of a **Circular Economy strategy tailored to the pharmaceutical industry**. This answers SRQ1.1 by demonstrating that it is indeed possible to implement CE in this sector, and by specifying the key elements that need to be considered to do so. The proposed strategy articulates conceptual frameworks, performance indicators, and practical enablers into a coherent pathway that organizations can adopt and adapt.

Limitations

Several limitations remain alongside these contributions. The CEIM, while evidence-based, is still relatively abstract and must be complemented with additional frameworks to fully capture macro-level dynamics and organizational transitions. The KPIs developed are valuable for operational monitoring but remain focused on waste management and are less adapted to biopharmaceutical operations, where circular options are more constrained. Supporting tools such as glossaries, standards, and best-practice handbooks proved effective for industrial alignment but represent incremental rather than scientific contributions. Finally, the overall CE strategy remains generic and has so far been validated primarily at the conceptual and corporate levels, its transferability across different pharmaceutical contexts and regulatory environments has yet to be demonstrated through systematic application.

6.1.2. Circular initiatives and case studies

To address SRQ1.2*: To what extent can a CE strategy for the pharmaceutical sector be applied in practice, and how do collaboration mechanisms enable or hinder its implementation?* the CE strategy developed in Part A was tested through a portfolio of initiatives and three detailed case studies: Single-Use Technologies (SUT) circularity, Take-Back Systems (TBS), and solvent recovery. These projects served both as pilots to operationalize the strategy and as empirical material to evaluate its applicability, usability, and outcomes in real pharmaceutical contexts.

The evaluation confirmed the **relevance of the CE strategy** across different loops and scales. SUT circularity addressed one of the key industrial challenges in large-molecule manufacturing, developing recovery loops for high-value components, site-level decision tools, and supplier engagement mechanisms. It also revealed opportunities for new business models, such as product–service systems for magnet reuse and the establishment of recycling hubs, extending circularity beyond single projects toward potential long-term organizational models. TBS tackled post-consumer waste through collaborative take-back programs for injection devices, producing governance models and validated LCA results that demonstrate their contribution to reducing product life cycle impacts. Solvent recovery addressed one of the highest-impact materials in pharmaceutical manufacturing, establishing a potential methodology for mapping, pooling, and regenerating solvents in campaign-based production. Together, these initiatives illustrated that the CE strategy is flexible enough to support projects spanning product-level design, process optimization, and system-level collaboration.

From a scientific perspective, the case studies generate three main insights. First, they confirm the **central role of pilots** in initiating CE strategies. Consistent with Zils et al. (2025), the pilots provided a necessary intermediate step between opportunity identification and large-scale implementation, enabling organizations to test feasibility, uncover systemic barriers, and refine collaboration models (Zils et al., 2023). The contribution of this thesis lies in extending these insights to the pharmaceutical sector, where empirical evidence has so far been scarce. Second, the comparative evaluation demonstrated that collaboration quality is a determinant of project success. Initiatives with deeper engagement and stronger governance (e.g., TBS) achieved higher performance, whereas technically feasible projects with weaker engagement (e.g., SUT) struggled to deliver measurable results. Third, the evaluation framework itself, combining strategy effectiveness with collaboration dynamics, constitutes a methodological contribution for assessing CE initiatives in complex, multi-stakeholder contexts.

From an industrial perspective, the projects delivered concrete outputs and operational learnings. The SUT program generated a decision tree for waste classification, ready for deployment and offering strong potential to improve waste management at Sanofi by standardizing practices and being adaptable to other complex waste streams. Other avenues, such as SOP adjustments, supplier dialogue frameworks, or potential business models like product–service systems for magnets and recycling hubs, remained exploratory, but provided useful insights into feasibility and barriers. The TBS initiatives demonstrated how cross-industry governance can be organized to manage post-consumer waste, validated through LCAs and regulatory adaptation across contexts such as Denmark and France. The solvent recovery project provided a methodology for mapping solvent streams, assessing regeneration potential, and engaging regenerators and vendors in co-developing recovery pathways, that could be replicated. In addition, the use of weighted evaluation criteria for strategy effectiveness (sector-specificity, scalability, environmental outcomes, etc.) offered a structured tool for comparing initiatives and aligning them with strategic objectives.

In conclusion, these contributions provide a direct answer to SRQ1.2. They show that a CE strategy tailored to the pharma industry is applicable and effective in guiding diverse initiatives, but that its success depends heavily on the quality of collaboration and the ability to overcome regulatory, logistical, and measurement barriers. The pilots demonstrate the potential of CE in pharma but also reveal the limits of isolated initiatives: environmental impacts were often only partially quantified, scalability was constrained by local and site-specific conditions, and integration into corporate systems remained limited.

Limitations

Despite these pilots provided valuable contributions, they also faced limitations. The SUT decision tree remains to be implemented before its full impact can be assessed. TBS projects demonstrated promising governance models but were constrained by regulatory adaptation and local infrastructures, limiting their scalability. Solvent recovery

provided a replicable methodology, yet its operational uptake is still ongoing. More broadly, environmental impacts were often only partially quantified, and the reliance on site-specific conditions restricted generalizability. These constraints reinforce that while pilots are valuable for testing CE strategies, additional mechanisms are required for systemic integration.

6.2. ORGANIZATIONAL LEARNING & CHANGE FOR ENVIRONMENTAL SUSTAINABILITY

The second part of this thesis shifts from the design of a CE strategy toward its operationalization and long-term embedding within organizations. Although Part A demonstrated that a CE strategy tailored to pharmaceuticals can be defined and tested through pilot initiatives, the next challenge was to understand how such isolated projects can evolve into systemic practices and, ultimately, become institutionalized as organizational capabilities. This addresses the second hypothesis of the thesis:

H2: *Systemic integration of environmental sustainability in the pharmaceutical industry can be achieved by consolidating validated projects into standardized practices and institutionalizing the sustainability strategy as enduring organizational capabilities, thereby enhancing the environmental performance of products and processes*.

This hypothesis was explored through two complementary lines of inquiry. The first examined how validated environmental projects can be consolidated and scaled into reusable practices, using a transition framework grounded in organizational learning theory (Part A). The second investigated how the strategy and associated practices can be institutionalized over time through the development of organizational capabilities, ensuring that sustainability integration becomes durable and scalable across the company (Part B).

6.2.1. Strategy operationalization through systemic practices

To address SRQ2.1: *How can validated environmental projects be consolidated and standardized into practices that support systemic integration across pharmaceutical product and process development?*, this thesis developed and tested a transition framework for transforming isolated initiatives into systemic practices. Grounded in organizational learning and knowledge management literature, the framework structures this transformation into four iterative steps, capture, synthesize, formalize, and disseminate, providing a pathway for consolidating project-based insights and scaling them into organizational routines (either managerial or operational).

The framework was applied and evaluated through two experiments (Figure 94). The first focused on a portfolio LCA of insulin products, which demonstrated how fragmented, project-level assessments can form the foundation of comparative, portfolio-wide LCAs. This provided novel scientific insights into the environmental performance of insulins: APIs, packaging, and delivery devices, making it the first portfolio-level LCA of multiple insulin products. Aside from the results themselves, the experiment generated methodological strategies for conducting pharmaceutical portfolio LCA, which can improve efficiency, robustness and comparability of future assessments.

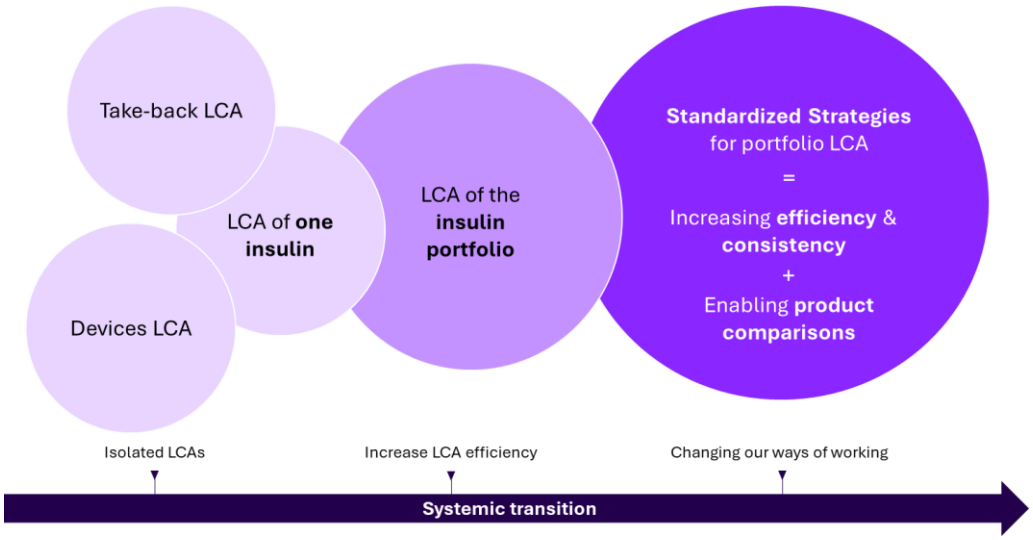

Figure 94. Application of the transition framework for insulin LCAs

The second experiment addressed the translation of environmental assessments into sustainable manufacturing practices (Figure 95). Initially, LCA results were converted into environmental levers and embedded in a multi-criteria decision-making tool for process development. Building on this experience, the research formalized a generalizable methodology for developing process-level environmental guidelines. The resulting guide follows a three-phase structure: Investigation, Transformation, and Customization, that enables the identification of challenges, translation of assessments into structured recommendations, and adaptation to process-specific constraints. Its design emphasizes modularity, cross-functional collaboration, and contextual adaptation, distinguishing it from existing methods that largely focus on product design. Validation through expert interviews and a case study in another business unit confirmed its robustness, transferability, and early dissemination potential. As such, the study contributes both a new methodological approach to sustainable manufacturing and empirical evidence on how project-based learnings can evolve into standardized practices.

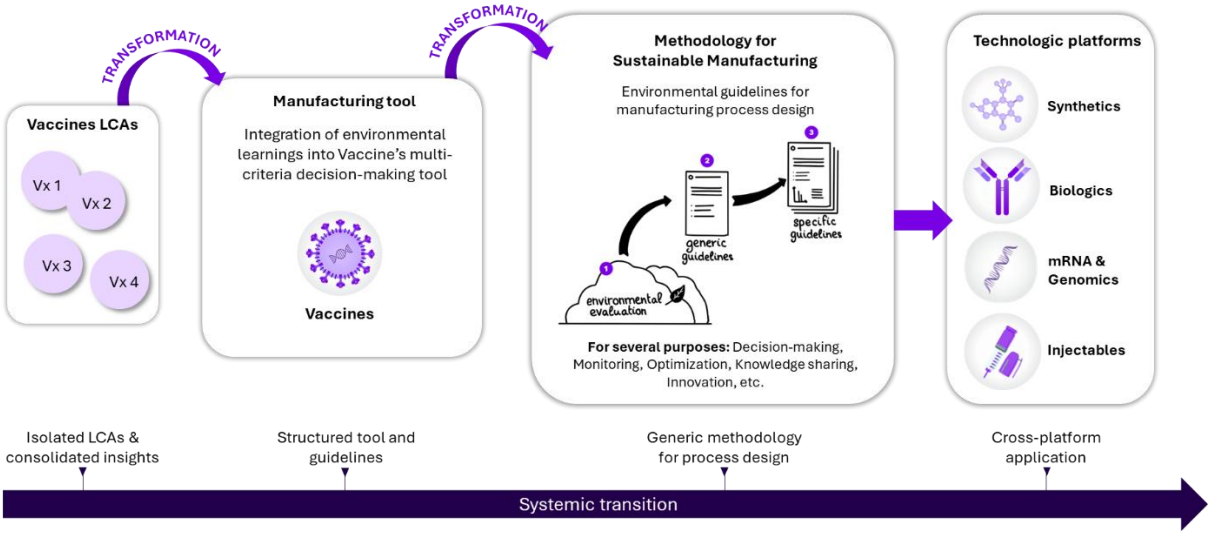

Figure 95. Application of the transition framework for sustainable manufacturing

These experiments provided concrete evidence on organizational learning mechanisms in sustainability integration. They showed that capture, synthesis, and formalization are achievable and can generate reusable outputs such as portfolio assessment strategies or structured guideline development methods. At the same time, they confirmed that dissemination and institutionalization are the most difficult steps, echoing broader findings in the organizational learning literature. Across both cases, the depth of stakeholder involvement and the presence of governance mechanisms proved decisive in enabling progress, whereas their absence limited scalability and organizational uptake.

Limitations

Despite these contributions, several limitations must be acknowledged. The transition framework, though evidence-based, remains generic and requires further tailoring to pharmaceutical regulatory and quality contexts to increase operational relevance. The portfolio LCA experiment produced novel scientific and methodological contributions, but dissemination into SOPs is not yet complete, leaving dissemination pending. The manufacturing guideline methodology was primarily tested at the Customization phase, with Investigation and Transformation less validated, and its application required significant time and expert facilitation. Both experiments were conducted within a single company, limiting external validation and raising questions about generalizability. More broadly, dissemination and embedding of the developed systemic practices into corporate routines proved partial and fragile, highlighting the persistent challenge of moving from scaled and standardized practices to fully integrated strategy.

6.2.2. Organizational change and capabilities

To address SRQ2.2: *How can the environmental sustainability strategy and its components be institutionalized across functions to become durable organizational capabilities?*, this thesis developed a capability model tailored to the pharmaceutical sector. Whereas Part A demonstrated how projects can be consolidated into reusable practices, the focus here shifts to how the overall strategy, and its associated practices, can be embedded and sustained over time across the organization. The contribution of this research lies in providing both a structured model and an application method for building the organizational capabilities that underpin systemic integration.

From a scientific perspective, the research contributes by extending existing capability and maturity frameworks into the domain of pharmaceutical sustainability. The capability model integrates cultural and behavioral enablers (leadership, incentives, narratives, recognition) with managerial and operational practices (eco-design methods, LCA, standards), bridging a gap between the organizational change literature and the eco-design maturity models. Structured into 6 pillars, 21 items, and 4 maturity levels with indicative KPIs, the model offers a novel sector-specific framework for analyzing and building sustainability capabilities. The accompanying six-step application method further advances methodological knowledge by combining PDCA logic with principle-based backcasting, thereby operationalizing capability building as an iterative process. The pilot case of embedding environmental recommendations into manufacturing standards demonstrates the complementarity of the two frameworks developed in this thesis: the capability model identifies what organizational gaps need to be addressed, while the transition framework from Part A structures how these gaps can be tackled. Together, they provide a theoretically grounded contribution to the systemic integration of sustainability in complex, regulated industries.

From an industrial perspective, the capability model provides managers with a diagnostic and prescriptive tool for institutionalizing the environmental sustainability strategy. The maturity assessment highlighted uneven profiles across functions, with technical enablers scoring higher than people- and culture-related dimensions, giving Sanofi a clear view of where to prioritize efforts. Workshops designed around the model aims to enable the translation of corporate ambitions into function-specific pathways. The pilot integration into technology standards delivered a concrete outcome: environmental recommendations were embedded into mandatory operational documents, raising the maturity of “Tools and Decision Support” and establishing a repeatable process for future updates. These applications illustrate how the model can directly inform managerial decisions, align functions, and guide integration into day-to-day routines, thereby strengthening Sanofi’s long-term capacity to embed sustainability.

In conclusion, these contributions show that capability building is essential to move from isolated practices to systemic integration. Scientifically, the thesis advances maturity and capability logic by bridging technical and organizational enablers. Industrially, it delivers a practical model and method to institutionalize the sustainability strategy within a pharmaceutical company. More broadly, the results confirm that institutionalization depends on leadership sponsorship, cross-functional engagement, aligned incentives, and cultural reinforcement, without which technical formalization remains fragile. The contribution of this thesis lies in demonstrating that it is possible to embed not only individual practices but the environmental sustainability strategy itself into the organizational capabilities of pharmaceutical companies.

Limitations

Despite these advances, several limitations must be acknowledged. First, the model remains in an early stage of application, with no full DS-II evaluation completed within the thesis timeframe. The diagnostic relied partly on expert judgment and a limited survey, which introduced potential bias and restricted representativeness. The pilot applications focused mainly on manufacturing, leaving other functions and inter-organizational dimensions unexplored. Even though the six pillars and 21 items strike a balance between breadth and usability, they may still require simplification for some contexts or greater granularity in others, supported by digital tools and facilitation materials. Finally, although designed for the pharmaceutical industry, further integration with regulatory and quality management systems is needed to ensure full operational relevance.

6.3. STRUCTURING SYSTEMIC INTEGRATION: COMBINING CONTRIBUTIONS

The research results in a methodological proposal for structuring the systemic integration of environmental sustainability in the pharmaceutical industry. Rather than three isolated contributions, the CE strategy, transition framework, and capability model form an interactive system in which strategy, practices, and capabilities mutually reinforce one another. Together, they constitute a pathway that links high-level ambitions with operational practices and long-term institutionalization.

The previous sections detailed three complementary contributions: (1) the definition of a CE strategy tailored to pharmaceuticals and validated through pilot projects, (2) the transition framework for scaling projects into systemic practices, and (3) the capability model for embedding both the strategy and its practices into organizational routines. Together, these contributions converge into a broader methodological proposal that directly addresses the central research question of this thesis: *How can the systemic integration of environmental sustainability be structured in the pharmaceutical industry?*

Although CE served as the primary entry point, the methodological proposal extends beyond CE alone. It provides a generic logic for structuring the systemic integration of environmental sustainability as a whole, contributing not only to CE implementation but more broadly to embedding sustainability into the routines, processes, and culture of pharmaceutical organizations (Figure 96).

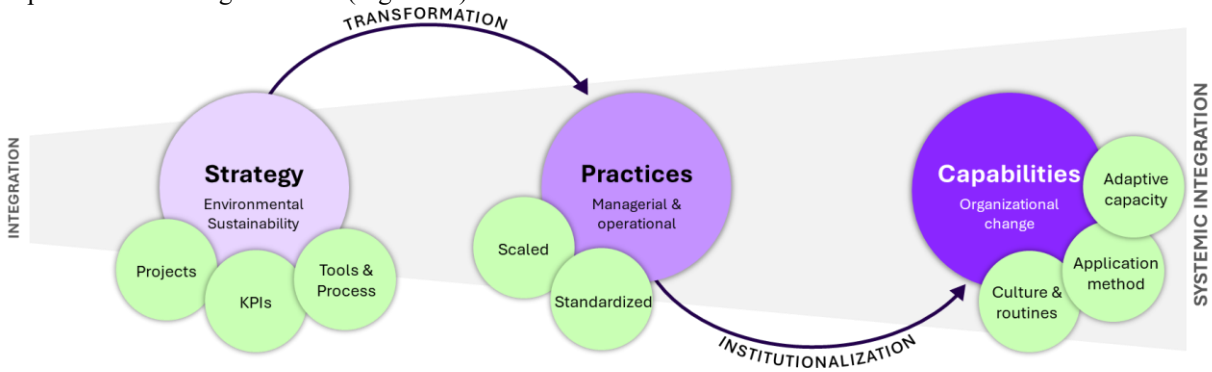

Figure 96. Methodological framework for structuring the systemic integration of environmental sustainability

Three interconnected pillars

1. **Circular Economy strategy as entry point**
   - The CEIM, company-wide KPIs, and supporting tools provide a conceptual and operational foundation for identifying opportunities, mapping barriers, and initiating circular projects across product life cycles.
   - Pilot projects validated the strategy in practice and confirmed the central role of collaboration quality in determining outcomes.
2. **Transition framework for systemic practices**
   - The four-step framework (capture, synthesize, formalize, disseminate) enables isolated initiatives to be consolidated into standardized managerial or operational practices.

- The portfolio LCA experiment, and the sustainable manufacturing guideline exemplify how this framework translates fragmented project knowledge into reusable practices, enhancing comparability, decision support, and methodological robustness.

3. **Capability model for institutionalization**
    - To ensure a complete integration, practices and strategy must become organizational capabilities. The capability model structures capability building, supported by an application method.
    - Pilot applications, such as embedding environmental recommendations into standards, illustrate how capability building reinforces institutionalization and complements the transition framework.

Interactions between the pillars

The three pillars do not operate in sequence only, they form a mutually reinforcing system of systemic integration:

- **Strategy - Practices**. The CE strategy guides the selection and framing of projects, while the transition framework transforms validated pilots into standardized practices that refine and enrich the strategy with operational evidence. For instance, the portfolio LCA not only produced scientific insights but also informed strategic prioritization of environmental hotspots across the insulin franchise.
- **Practices - Capabilities**. The transition framework generates standardized practices that can be embedded into capability structures. For example, the manufacturing guideline methodology strengthened the "Tools & Processes" pillar of the capability model by providing decision support for process design. In this way, practices serve as building blocks for dynamic capabilities.
- **Strategy - Capabilities**. Strategic ambitions (CEIM, KPIs, supporting tools) only deliver impact if supported by dynamic capabilities in leadership, incentives, and cultural alignment. Conversely, capability development ensures that strategic ambitions are institutionalized into enduring routines, as shown by the integration of environmental recommendations into technology standards.

Overall contribution

The integration of these three components constitutes the thesis's overarching methodological contribution: a coherent pathway that links strategy design, project-level validation, systemic practice development, and organizational capability building. Conceptually, it bridges multiple bodies of literature, CE, DfS, organizational learning, and organizational change, into a unified framework tailored to the pharmaceutical sector. Practically, it provides companies with tools (CEIM, KPIs, guidelines, capability model) and processes (transition framework, application method) that can be iteratively applied to move from partial integration to a systemic integration of environmental sustainability. Although CE provided the main entry point, the framework extends beyond CE to address environmental sustainability more broadly. Its originality lies in showing how ambition, practice, and institutionalization can be articulated within a single methodological pathway.

Limitations

Despite its coherence, the proposal faces several limitations. It remains partly generic and requires adaptation to regulatory and quality constraints across pharmaceutical contexts. Although individual components being validated through experiments, the full pathway has not yet been tested end-to-end within a single program. Its applicability to other companies, or to smaller firms with different resources, also remains to be demonstrated. Finally, dissemination and institutionalization, repeatedly identified as the most fragile steps, still require stronger governance mechanisms, incentive systems, and cultural alignment to ensure lasting impact. More broadly, the proposal represents one possible structuring of systemic integration, additional elements and refinements may be required.

A further limitation relates to the very notion of systemic integration: embedding sustainability across an organization does not automatically lead to significant environmental improvements or sustainable innovations. Practices can be widely diffused without being transformative, resulting in incremental rather than breakthrough reductions. The same applies to capability building: the development of dynamic capabilities for sustainability does not in itself guarantee alignment with environmental ambitions or substantial performance gains. This underlines the importance of continuously questioning not only how sustainability is integrated, but also what level of ambition and impact is pursued. Clear strategic objectives, explicitly aimed at improving environmental performance, are necessary to guide integration efforts. Likewise, maturity levels for capability building should be defined not only to support systemic diffusion but also to ensure that practices and capabilities remain aligned with long-term strategies and contribute meaningfully to environmental sustainability.

This limitation reinforces the importance of strategy as the starting point for systemic integration. Without clearly defined ambitions and measurable objectives, practices and capabilities risk being diffused without delivering meaningful impact. A strategy provides the necessary direction to ensure that practices and capabilities do not simply multiply incrementally but are aligned with long-term goals and oriented toward significant environmental improvements. In this sense, the pathway proposed in this thesis, strategy first, then practices, and capabilities, represents not only a structuring approach but also a safeguard to ensure that systemic integration contributes to genuine sustainability transitions rather than incremental adjustments.

6.4. SYNTHESIS OF CHAPTER 6

The diverse contributions of this thesis can be synthesized by mapping them onto the eco-design integration framework proposed by Brones and Monteiro de Carvalho (2015) (Brones and Carvalho, 2015). This framework distinguishes three systemic levels: macro (strategy), meso (processes), and micro (tools and projects), together with a transversal axis that captures change management (human factors, cultural and organizational enablers). Although originally developed for eco-design, its vertical and transversal logic provides a robust lens for situating the results of this thesis, which extend the scope to environmental sustainability more broadly, encompassing both Circular Economy and eco-design approaches.

Table 51 below positions the main contributions of the thesis along these four dimensions. For each level, it specifies the concrete outputs developed, together with a short description of their role in supporting systemic integration.

Table 45. Positioning of thesis contributions across macro, meso, micro, and transversal integration levels

Integration level	Main contributions	Description
Macro	CE Strategy	Defines a tailored Circular Economy strategy for the pharmaceutical sector.
	CEIM	Framework structuring CE integration across product, process, and organizational dimensions.
	CE KPIs	Indicators enabling cross-site monitoring and benchmarking of CE performance.
	Capability Model	Strategic diagnostic: identifies maturity gaps across six pillars, linking strategy to organizational change.
Meso	Transition Framework	Process for scaling project learnings into systemic practices.
	Portfolio LCA	Strategies for portfolio-wide LCAs.
	Manufacturing Guide	Methodology for embedding environmental sustainability into process design.
	Standards integration	Structured method for embedding environmental recommendations into operational standards.
Micro	Take-Back Systems (TBS)	Position paper for post-consumer device circularity (governance, LCA, etc.)
	Single Use Technologies	Waste-classification decision tree and exploration of new business models.
	Manufacturing guide	Integration of environmental recommendations into MCDM for process development.
	Portfolio LCA (templates & strategies)	Provides practical methods for efficiency, robustness, and comparability of LCAs.
	Supporting tools	Glossary, handbook, and best practices supporting internal alignment and knowledge sharing.

	Envt. Reco into standards	Specific operational requirements added to standards, anchoring sustainability at project level.
Transversal	Collab. & stkh engagement	Mechanisms for cross-industry governance (TBS) and supplier engagement (SUT).
	Collab. quality evaluation	Method for analyzing depth and effectiveness of collaboration, shown as determinant of initiative success.
	Capability Model (CM)	Transversal enabler combining cultural and technical dimensions, ensuring strategy and practices institutionalization.
	CM Application method	Process for capability building, combining PDCA logic with principle-based backcasting to iteratively plan, test, and consolidate organizational capabilities.

Macro level (strategy)
At the highest level, the thesis delivers a sector-specific CE strategy for pharmaceuticals. This includes the CEIM, indicators such as the Waste Impact Index, and the articulation of company-wide ambitions. These contributions establish the strategic direction needed to align initiatives across functions and geographies, offering both conceptual grounding and operational instruments for steering environmental sustainability.

Meso level (processes)
At the meso level, the thesis embeds sustainability into pharmaceutical development and manufacturing processes. The transition framework structures how insights from individual projects can be captured, synthesized, and formalized into standardized practices. The manufacturing guideline methodology provides a repeatable process for translating environmental assessments into actionable design rules. The integration process for technology standards demonstrates how environmental requirements can be embedded into operational procedures. Together, these contributions form the bridge between strategic intent and operationalization.

Micro level (tools and projects)
At the operational level, the research produced concrete tools and project outcomes that directly support operational decision-making. These include the portfolio LCA strategies, the SUT waste-classification decision tree, solvent recovery methodologies, and supporting tools such as glossaries and best practices handbooks. The integration of environmental recommendations into technology standards further anchors sustainability into daily operations. These outputs ensure that project teams have tangible means to implement broader strategies.

Transversal axis (culture & change management)
The transversal dimension is advanced primarily through the capability model. It integrates cultural, organizational, and technical enablers across six pillars and provides measurable indicators to diagnose maturity gaps. Coupled with its application method, it offers a structured pathway for capability building, enabling organizations to plan, test, and consolidate change iteratively. Although primarily transversal, the model also connects with the other levels: at the macro level, it institutionalizes strategic ambitions; at the meso level, it supports process alignment by revealing maturity gaps; and at the micro level, it facilitates the uptake of tools through training, incentives, and recognition.

In summary, the contributions of this thesis span all levels of integration (Figure 97): strategic direction, process embedding, operational tools, and organizational enablers. Beyond situating the results within Brones and Monteiro's framework, the thesis extends it by moving from eco-design integration to environmental sustainability integration, combining CE, eco-design, and organizational change into a coherent methodological pathway.

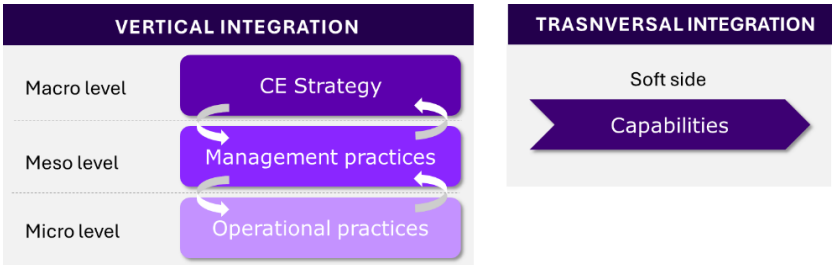

Figure 97. Mapping of the contributions on the eco-design integration model (adapted from Brones and Monterio de Carvalho, 2015)

Résumé en français - Chapitre 6 : Contributions et limites

Ce chapitre présente les principales contributions de la recherche doctorale, menée en recherche-action au sein de Sanofi, en réponse à la question centrale de la thèse. Les contributions scientifiques et industrielles sont examinées conjointement, puis synthétisées dans une cartographie finale.

Une stratégie sectorielle d'économie circulaire pour la pharma (H1). Concernant la conception de la stratégie, quatre contributions principales sont mises en avant : une cartographie systématique de la littérature révélant une polarisation entre études pharmaceutiques (amont, boucles courtes) et études des systèmes de santé (aval, fin de vie) sans connexion entre les deux ; une stratégie d'économie circulaire, basée sur un **Modèle d'Intégration de l'Économie Circulaire (CEIM)**, positionnant l'éco-conception au cœur du dispositif et l'étendant aux dimensions organisationnelles, réglementaires et systémiques ; des indicateurs à l'échelle de l'entreprise (Waste Impact Index, Waste Score), contribuant à la fois opérationnellement et au champ scientifique des métriques d'EC ; et des outils de support (glossaire, standards, communauté de pratique, manuel de bonnes pratiques), à visée principalement industrielle. Ensemble, ces éléments démontrent la faisabilité d'une EC pharmaceutique structurée, bien que le CEIM demeure relativement abstrait, que les KPI restent centrés sur la gestion des déchets et pas toujours adaptés aux opérations biopharmaceutiques, et que la stratégie globale n'ait été validée qu'au niveau corporate.

Sur le plan de l'application pratique, les trois études de cas (SUT, TBS, Régénération de solvants) confirment la pertinence de la stratégie à travers différentes boucles et échelles. Elles apportent trois insights scientifiques : la confirmation du rôle central des pilotes comme étape intermédiaire, en écho à Zils et al. ; la démonstration que la qualité de collaboration est déterminante du succès des projets (TBS surpassant nettement SUT sur ce plan) ; et un cadre d'évaluation combinant efficacité stratégique et dynamiques de collaboration qui constitue lui-même une contribution méthodologique pour analyser des initiatives d'EC en contexte multi-acteurs. Sur le plan industriel, ces projets ont produit un arbre de décision pour la classification des déchets SUT, une méthodologie de récupération des solvants réplicable, et des modèles de gouvernance intersectorielle pour les systèmes de reprise. Ces contributions restent toutefois limitées par une quantification souvent partielle des impacts environnementaux, une mise à l'échelle contrainte par les spécificités locales, et une mise en œuvre encore incomplète (l'arbre SUT n'étant pas encore déployé, la récupération de solvants restant en cours).

Apprentissage organisationnel et changement pour la durabilité environnementale (H2). Le cadre de transition en quatre étapes (capturer, synthétiser, formaliser, disséminer) a été testé via deux expérimentations. La première, **l'ACV de portefeuille d'insulines**, constitue la première évaluation comparative de plusieurs produits insuliniques et génère des stratégies méthodologiques transférables pour de futures ACV. La seconde, le **guide de développement de procédés soutenables** structuré en Investigation-Transformation-Customisation, apporte une approche méthodologique novatrice se distinguant des méthodes existantes centrées sur le produit ; validée par des experts, elle a également été testée par réplication dans une autre unité d'affaires. Ces expériences confirment que la capture, la synthèse et la formalisation des enseignements sont réalisables et génèrent des résultats réutilisables, mais que la dissémination demeure l'étape la plus difficile, faisant écho aux constats plus larges de la littérature sur l'apprentissage organisationnel. Le cadre reste néanmoins relativement générique et nécessiterait une adaptation plus poussée aux exigences réglementaires pharmaceutiques ; la dissémination des deux expérimentations demeure incomplète, et la validation s'est limitée à une seule entreprise.

Concernant l'institutionnalisation à plus long terme, le **modèle de capacités** (six piliers, vingt-et-un items, quatre niveaux de maturité) étend les cadres de capacités et de maturité existants au domaine de la soutenabilité pharmaceutique, en intégrant à la fois les facilitateurs culturels et comportementaux (leadership, incitations, reconnaissance) et les pratiques managériales et opérationnelles (méthodes d'éco-conception, ACV, standards). La méthode d'application en six étapes combine logique PDCA et backcasting fondé sur des principes, opérationnalisant ainsi la construction de capacités comme un processus itératif. Le cas pilote d'intégration de recommandations environnementales dans les standards de fabrication illustre bien la complémentarité des deux cadres développés dans cette thèse : le modèle de capacités identifie les lacunes organisationnelles à combler, tandis que le cadre de transition structure la façon de les traiter concrètement. Ce modèle reste cependant à un stade précoce d'application, sans évaluation complète réalisée dans le cadre de la thèse ; le diagnostic repose

partiellement sur le jugement d'experts internes, et l'application pilote s'est concentrée principalement sur la fonction manufacturing.

Structurer l'intégration systémique en combinant les contributions.

La recherche aboutit finalement à une proposition méthodologique globale où la stratégie d'EC, le cadre de transition et le modèle de capacités ne constituent pas trois contributions isolées, mais forment un système interactif où stratégie, pratiques et capacités se renforcent mutuellement. La stratégie guide la sélection et le cadrage des projets, tandis que le cadre de transition enrichit en retour la stratégie de preuves opérationnelles, par exemple, l'ACV de portefeuille a non seulement produit des résultats scientifiques mais a aussi informé la priorisation stratégique des points chauds environnementaux à l'échelle du portefeuille d'insulines. De même, les pratiques standardisées issues du cadre de transition deviennent les briques constitutives des capacités dynamiques : la méthodologie du guide de fabrication a ainsi renforcé le pilier « Outils & Processus » du modèle de capacités. Enfin, les ambitions stratégiques ne portent leurs fruits que si elles sont soutenues par des capacités dynamiques en matière de leadership, d'incitations et d'alignement culturel, et réciproquement, le développement de capacités garantit que ces ambitions s'institutionnalisent dans des routines durables.

Cette intégration constitue la contribution méthodologique globale de la thèse : un cheminement cohérent reliant la conception de stratégie, la validation par projets, le développement de pratiques systémiques et la construction de capacités organisationnelles, formant un pont conceptuel entre l'économie circulaire, le Design for Sustainability, l'apprentissage et le changement organisationnel. Une limite majeure est toutefois soulevée : l'intégration systémique n'entraîne pas automatiquement des améliorations environnementales significatives, la diffusion de pratiques pouvant rester incrémentale plutôt que réellement transformatrice. Ce constat renforce l'importance de la stratégie comme point de départ du processus : sans ambitions clairement définies et mesurables, pratiques et capacités risquent de se multiplier sans produire d'impact réel. La séquence proposée, stratégie, puis pratiques, puis capacités, représente ainsi non seulement une approche structurante, mais aussi un garde-fou pour garantir que l'intégration systémique contribue à une véritable transition vers la durabilité plutôt qu'à des ajustements superficiels.

Synthèse des contributions (basée sur le modèle de Brones)

Pour conclure, l'ensemble des contributions est positionné selon le cadre d'intégration macro/méso/micro/transversal de Brones et Monteiro de Carvalho (2015), initialement conçu pour l'éco-conception et ici étendu à la soutenabilité environnementale dans son ensemble. Au niveau macro (stratégique), on retrouve la stratégie d'EC, le CEIM, les KPI, et le modèle de capacités en tant que diagnostic stratégique. Au niveau méso (processus), le cadre de transition, les stratégies d'ACV de portefeuille, le guide de fabrication et la méthode d'intégration dans les standards assurent le lien entre intention stratégique et opérationnalisation. Au niveau micro (outils et projets), les études de cas TBS et SUT, le guide de fabrication comme outil MCDM, les modèles d'ACV et les outils de support fournissent des moyens concrets aux équipes de terrain. Enfin, l'axe transversal, porté principalement par le modèle de capacités et sa méthode d'application, intègre les facilitateurs culturels et organisationnels qui traversent l'ensemble des niveaux. Cette cartographie démontre que les contributions de la thèse couvrent l'ensemble du spectre de l'intégration, direction stratégique, ancrage dans les processus, outils opérationnels et facilitateurs organisationnels, et prolongent le cadre original de l'éco-conception vers une intégration systémique de la soutenabilité environnementale combinant économie circulaire, éco-conception et changement organisationnel au sein d'un même cheminement méthodologique.

Chapter 7. Conclusion & Perspectives

The work presented in this thesis set out to address a paradox at the heart of the pharmaceutical sector: the mission to protect human health while simultaneously contributing to environmental degradation. Tackling this tension requires the development of structured pathways for embedding environmental sustainability into pharmaceutical product and process development. This final chapter synthesizes the main outcomes of the research by revisiting the problem and the hypotheses, assessing their validation, and reflecting on the methodological structuring of the work. The chapter also highlights the societal, scientific, and industrial contributions of the thesis, outlines perspectives for future research and practice, and closes with the list of publications linked to the doctoral work.

7.1. CONCLUSION

The conclusions of this thesis are organized to mirror the overall logic of the research process. They begin with a restatement of the research problem and the two guiding hypotheses, before presenting their validation through the sub-research questions. The section then reflects on the methodological structuring of the work through the Design Research Methodology (DRM) (Blessing and Chakrabarti, 2009a) and ends with a general conclusion that situates the contributions within their societal, scientific, and industrial stakes.

7.1.1. Revisiting the research problem

The problematic formalized in this doctoral thesis targeted the difficulty of integrating environmental sustainability into pharmaceutical development and manufacturing processes: ***How to structure the systemic integration of environmental sustainability in the pharmaceutical industry?***

The formulation of hypotheses in response to this problematic was based on two key observations:

- Existing approaches to sustainability in pharmaceuticals often remain fragmented or pilot-based, providing isolated tools and methods without offering structured pathways for organizational integration (the strategic axis).
- There is a persistent gap between the availability of environmental methods (e.g., eco-design, LCA, Circular Economy practices) and their actual embedding into organizational routines and decision-making processes (the organizational axis).

These two axes led to the formulation of two complementary hypotheses. The first focused on the design of a sector-specific Circular Economy strategy capable of fostering collaboration and alignment across functions and stakeholders. The second focused on embedding sustainability through the development of organizational capabilities, ensuring that validated practices and strategies could evolve from isolated initiatives into systemic, long-term integration. The validation of these hypotheses is presented in the following sections.

7.1.2. Reflection on Hypothesis 1

Based on the problematic defined earlier, the first hypothesis posited that a structured CE strategy, enabling internal and external collaboration and alignment, could foster the emergence and reinforcement of circular initiatives in the pharmaceutical sector, ultimately reducing environmental impacts across the organization. This hypothesis was explored through two sub-research questions.

Review of SRQ1.1

The first sub-research question examined: *What are the key elements of a CE strategy in the pharmaceutical sector, and how can they be effectively implemented?*

Part A of Chapter 4 responded to this question by combining a systematic literature review and an empirical study of industry practices. The results highlighted that although numerous technical solutions already exist (e.g., green chemistry, solvent recovery, eco-design), they remain fragmented, isolated, and rarely connected to organizational governance. To overcome these gaps, the research developed a Circular Economy Integration Model (CEIM),

which positioned eco-design as the foundation of CE implementation, while also extending to organizational, policy, and healthcare system levels.

The CEIM was complemented by practical tools: performance indicators such as the Waste Impact Index and Waste Score to track progress, as well as glossaries, roadmaps, and best-practice documentation to guide implementation. Together, these components structured CE across both vertical integration (linking site-level actions to corporate strategies) and horizontal integration (aligning diverse internal and external stakeholders). This validated SRQ1.1 by demonstrating that it is possible to define the essential building blocks of a CE strategy tailored to the specificities of pharmaceuticals, including regulatory constraints, product safety, and multi-stakeholder complexity.

Review of SRQ1.2

The second sub-research question investigated: *To what extent can the designed CE strategy be effectively applied and generate value in pharmaceutical contexts, and how do collaboration mechanisms influence its implementation and outcomes?*

Part B of Chapter 4 addressed this question through the evaluation of three case studies: Single-Use Technology (SUT) circularity, insulin device Take-Back Systems (TBS), and Solvent recovery project, supplemented by a broader set of CE-related initiatives. These projects operationalized the CE strategy and tested its robustness in practice.
The evaluation confirmed the relevance and adaptability of the strategy: it could be applied across diverse CE loops, from material recovery to cross-industry collaborations, while remaining usable as a guiding framework under stringent regulatory conditions. Importantly, collaboration dynamics emerged as decisive enablers of success. Projects characterized by strong stakeholder diversity, deep engagement, and effective barrier management achieved significantly better outcomes. Conversely, limited collaboration often constrained scalability and long-term impact.

At the same time, several limitations were identified: gaps in environmental performance measurement, partial integration into governance systems, and the persistence of isolated pilot projects disconnected from organizational learning processes. These findings underscored that even though the CE strategy is applicable and useful, its transformative potential remains underexploited without mechanisms for systemic integration.

Synthesis of Hypothesis 1

Together, the findings from SRQ1.1 and SRQ1.2 validated Hypothesis 1. The research demonstrated that a structured CE strategy can indeed foster relevant circular initiatives in the pharmaceutical sector, while collaboration mechanisms were shown to be critical determinants of success. However, the persistence of fragmentation and the difficulty of scaling initiatives revealed the need to move beyond strategy and pilots toward systemic organizational integration. This transition challenge became the focus of Hypothesis 2.

7.1.3. Reflection on Hypothesis 2

The second hypothesis extended beyond the design of a CE strategy to address the broader challenge of embedding environmental sustainability into the organization itself. It posited that systemic integration could be achieved by consolidating validated projects into standardized practices and by institutionalizing the sustainability strategy as enduring organizational capabilities, thereby enhancing the environmental performance of products and processes. This hypothesis was explored through two sub-research questions.

Review of SRQ2.1

The first sub-research question examined: *How can validated environmental projects be consolidated and standardized into practices that support systemic integration across pharmaceutical product and process development?*

Part A of Chapter 5 addressed this question through the development of a transition framework designed to transform isolated sustainability initiatives into systemic practices. Grounded in organizational learning and

knowledge management literature, the framework structures this transformation into four steps: capture, synthesize, formalize, and disseminate.

The framework was tested in two empirical applications. The first was a portfolio-level Life Cycle Assessment (LCA) of insulin products, the first of its kind in the pharmaceutical sector. It demonstrated that fragmented, product-specific LCAs could be consolidated into a comparative, portfolio-wide perspective, enabling the identification of environmental hotspots across APIs, devices, and packaging. In addition to the scientific novelty of conducting a therapeutic portfolio LCA, this experiment provided methodological strategies for efficiency, robustness, and comparability in pharmaceutical LCA.
The second experiment focused on translating environmental assessments into process-level practices. Building on an LCA-driven case, the thesis formalized a generalizable methodology for developing environmental guidelines for sustainable manufacturing. Structured around three phases: Investigation, Transformation, and Customization, the guide enabled the translation of LCA results into structured, modular, and adaptable recommendations for process design. Its validation through expert interviews and replication confirmed both robustness and transferability.

Together, these results validated SRQ2.1 by showing that project outcomes can be scaled into reusable practices, generating methodological advances (portfolio LCA, guideline development process) and tangible industrial tools (manufacturing guide, portfolio strategies). At the same time, the experiments highlighted the persistent difficulty of dissemination and uptake into corporate routines, underscoring the need for organizational embedding mechanisms.

Review of SRQ2.2

The second sub-research question asked: *How can the environmental sustainability strategy and its components be institutionalized across organizational functions to develop durable capabilities?*

Part B of Chapter 5 explored this question by developing a capability model for environmental sustainability in the pharmaceutical sector. The model integrates cultural and behavioral enablers (leadership, incentives, narratives, recognition) with managerial and operational practices (eco-design tools, LCA, standards). Structured across six pillars, 21 items, and four maturity levels, it provides both a diagnostic and prescriptive framework for building sustainability capabilities.

The model was paired with a six-step application method, combining PDCA logic with principle-based backcasting. This operational pathway allows organizations to iteratively plan, test, and consolidate sustainability capabilities over time. Its application at Sanofi revealed uneven maturity across functions, with higher technical readiness compared to cultural enablers. Pilot integration into manufacturing standards demonstrated how environmental recommendations could be embedded into mandatory operational procedures, raising capability maturity and establishing repeatable processes for future updates.

These results validated SRQ2.2 by confirming that organizational capabilities can be intentionally built to sustain systemic integration. They also revealed that institutionalization depends on more than technical tools: leadership sponsorship, cross-functional engagement, and cultural alignment emerged as essential factors for durable change.

Synthesis of Hypothesis 2

The findings from SRQ2.1 and SRQ2.2 validated Hypothesis 2. The transition framework showed how validated projects can be scaled into standardized practices, while the capability model demonstrated how strategy and practices can be institutionalized into enduring organizational routines. Together, they advanced scientific knowledge on sustainability integration in complex, regulated industries and delivered practical tools for industry practitioners.

At the same time, the results highlighted the fragility of dissemination and institutionalization. Despite pilots demonstrating feasibility, their embedding into organizational routines remained partial, requiring stronger governance, incentives, and cultural reinforcement. These limitations underscore that systemic integration is possible but contingent on sustained organizational commitment and capability development.

7.1.4. Revisiting the methodological structuring of the work

The scientific methodology chosen to frame this research was the Design Research Methodology (DRM), which recommends an iterative progression through four main phases: Research Clarification, Descriptive Study I, Prescriptive Study, and Descriptive Study II (Blessing and Chakrabarti, 2009). This structure ensured both conceptual rigor and practical applicability, also allowing for iterative feedback between theory and empirical evidence.

The entirety of the doctoral work can be decomposed and synthesized through these DRM phases:

- **Research Clarification (RC)**: During this initial phase, the research problem was defined through targeted literature reviews and exploratory interviews. This stage established the paradox facing the pharmaceutical sector, its mission to protect human health while contributing significantly to environmental degradation, and identified the fragmented, ad hoc nature of existing eco-design and CE initiatives. These insights laid the groundwork for formulating the main research question and associated hypotheses.

- **Descriptive Study I (DS-I):** The DS-I phase deepened the understanding of the pharmaceutical context by characterizing the drivers, barriers, and stakeholder perspectives that shape sustainability integration. This was achieved through literature analyses and empirical investigations, including interviews and internal documentation studies. Findings confirmed the persistence of fragmented initiatives and highlighted the absence of structured strategies and organizational mechanisms for scaling environmental projects.

- **Prescriptive Study (PS):** Building on these insights, the prescriptive phase focused on the development of three key supports tailored to the pharmaceutical sector:
  (1) A Circular Economy strategy and integration model (CEIM), supported by KPIs and operational tools.
  (2) A transition framework for transforming isolated initiatives into systemic practices, tested through portfolio LCA and guideline development.
  (3) A capability model for institutionalizing environmental sustainability, paired with an application method for capability building.
  These prescriptive outputs were co-developed with the industrial partner and designed to be both scientifically grounded and operationally applicable.

- **Descriptive Study II (DS-II):** The DS-II phase evaluated the proposed supports in real-world contexts. The CE strategy was tested through pilots such as Single-Use Technology circularity, take-back systems, and solvent recovery initiatives. The transition framework was validated through the insulin portfolio LCA and the manufacturing guideline methodology. The capability model was examined through workshops, surveys, and a pilot integration into manufacturing standards. These evaluations confirmed the relevance of the supports, while also revealing the challenges of dissemination, scalability, and institutionalization.

By aligning the research with the DRM framework, the thesis demonstrated a progressive construction of knowledge, moving from problem exploration to prescriptive development and practical validation. Each phase built upon the previous one, ensuring a cumulative and coherent research trajectory. At the same time, the iterative nature of DRM allowed empirical findings to refine prescriptive outputs, reinforcing both their scientific robustness and industrial relevance.

7.1.5. General conclusion

Through the exploration of the societal, scientific, and industrial contexts, this doctoral research addressed a paradox central to the pharmaceutical sector: protecting human health while significantly contributing to environmental degradation. The central research question: *How to structure the systemic integration of environmental sustainability in the pharmaceutical industry?*, guided the development of frameworks, experiments, and organizational tools that together respond to this challenge.

Three major stakes guided the research and its contributions:

- **Societal stake**: **addressing the environmental crisis.**
  This thesis contributes to the urgent need to align healthcare innovation with planetary boundaries. By proposing ways to embed sustainability directly into pharmaceutical product and process development, it supports the long-term goal of reducing the environmental burden of human activity without compromising access to life-saving medicines. The work demonstrates that reconciling health objectives with environmental responsibility is not only possible but necessary for ensuring the resilience of healthcare systems in the decades to come.

- **Scientific stake: understanding integration pathways in the pharmaceutical industry.**
  The originality of this research lies in articulating fragmented approaches, DfS, CE, and organizational change, into a coherent methodological pathway for systemic integration. By combining conceptual frameworks with empirical validation in a highly regulated sector, the thesis advances knowledge on how sustainability can be operationalized in complex industrial contexts. It clarifies both the enablers (e.g., collaboration quality, capability building) and the persistent barriers (e.g., regulatory rigidity, cultural resistance), thereby extending the scientific understanding of sustainability integration.

- **Industrial stake: structuring environmental sustainability in practice.**
  The thesis delivered actionable outputs: the CE strategy and its components, the transition framework, the portfolio LCA strategies the methodology for developing environmental manufacturing guidelines, and a capability model for organizational embedding. These tools were co-developed and tested within Sanofi, providing concrete pathways for translating sustainability ambitions into operational practices and long-term capabilities. They demonstrate that environmental considerations can be reconciled with pharmaceutical development priorities, ultimately supporting the sector in aligning its environmental responsibilities with its mission to deliver safe and effective medicines.

In conclusion, this doctoral thesis shows that the systemic integration of environmental sustainability in pharmaceuticals is both necessary and achievable. It requires structured strategies to provide direction, mechanisms to consolidate projects into systemic practices, and capability-building processes to ensure institutionalization. The proposed methodological pathway, linking strategy, practices, and capabilities, contributes to bridging the gap between ambition and institutionalization. By aligning the protection of human health with the respect of planetary boundaries, the research provides both conceptual advances and practical instruments that can guide the pharmaceutical industry toward more resilient, responsible, and sustainable futures.

7.2. PERSPECTIVES

Far from being an endpoint, this thesis opens new avenues for both research and practice. Perspectives are presented in three parts: those linked to the contributions of the thesis, broader research perspectives, and their suggested temporality.

7.2.1. Perspectives on the contributions

The contributions developed in this thesis should be viewed as initial or complementary steps within a longer-term process of sustainability integration. They provide foundations that require further validation, refinement, or extension over time. For this reason, the following perspectives are presented for each contribution.

CE Strategy perspectives

- Improve the link between CE and environmental approaches and concepts.
- Move beyond environmental sustainability to sustainability.
- Validate the CEIM across a wider range of therapeutic platforms (biologics, vaccines, small molecules), geographies, and companies.

- Refine the CE KPIs with biopharma-specific waste streams and foster their integration into corporate and site-specific dashboards.
- Explore how the strategy and the CEIM could be extended to healthcare system actors (hospitals, distributors, waste operators), capturing system-level loops.
- Investigate how new business models could be developed (e.g., product–service systems, recycling hubs) and embedded into CE strategy to support long-term adoption.

Pilot initiatives

- Scale up pilot projects to multi-site or industrial deployment, assessing long-term environmental and economic outcomes.
- Conduct comparative studies across regulatory environments to identify enabling conditions and bottlenecks.
- Increase the number of pilots to tackle key pressing challenges in pharma.
- Explore governance models for cross-industry collaboration (e.g., recycling hubs, shared solvent recovery facilities).
- Develop structured evaluation methods (e.g., pre/post LCA, performance scorecards) to monitor pilot evolution over time.

Transition framework and systemic practices

- Apply the framework to other projects and beyond manufacturing
- Further validate the three-phase guideline methodology.
- Explore digitalization of the framework through knowledge platforms or AI-assisted tools to support capture, synthesis, and dissemination.
- Integrate the framework more explicitly into corporate governance mechanisms such as stage-gates or design reviews.

Capability model for environmental sustainability

- Broaden application of the model across other functions (R&D, procurement, quality, supply chain) to test its robustness.
- Simplify and digitalize the maturity assessment for larger-scale benchmarking and easier routine use.
- Integrate capability model outcomes into existing management processes to foster the development of dynamic capabilities.
- Develop facilitation materials (training, workshops, narratives, recognition schemes) to reinforce the cultural dimensions of capability building.

7.2.2. Broader research perspectives

In addition to contribution-specific perspectives, the thesis raises broader questions that frame future research directions:

Axe 1: Structuring CE strategy in pharmaceuticals

How can CE strategies be deployed consistently across business units and management layers in large pharmaceutical firms? How can CE be reconciled with product-level safety and efficacy constraints? How can circular business models generate environmental and financial benefits, and under which conditions can these be scaled?

Axe 2: LCA and sector-specific metrics

How can pharmaceutical-specific datasets (e.g., API synthesis, excipients, bioreactor operations) be developed to strengthen LCA robustness? How can LCAs and CE metrics be integrated into decision-making? How can the positive effects of circularity in pharma be accurately measured?

Axe 3: From pilots to systemic change

What governance mechanisms are most effective for transforming pilots into institutionalized practices? How can organizational learning loops be designed to reduce the fragility of dissemination and embedding?

Axe 4: Governance, collaboration, and regulation
What regulatory adaptations are needed to facilitate CE loops (e.g., take-back systems) while safeguarding patient safety? How can cross-industry collaborations be structured to manage shared infrastructures (e.g., recycling hubs, solvent recovery)?

Axe 5: From environmental sustainability to sustainability
How can the pharmaceutical industry integrate environmental and social dimensions in their products and processes? How to ensure absolute sustainability of pharmaceutical products? What is a sustainable pharmaceutical company? What is a sustainable healthcare system?

Axe 6: Transferability to other regulated industries
To what extent can the frameworks developed here (CEIM, transition framework, capability model) be transferred to other highly regulated sectors, and what adaptations are required?

7.2.3. Temporality of perspectives

Not all perspectives can or should be addressed on the same timescale. The perspectives are categorized into different temporalities.

- **Short-term**: Further testing and refinement of CE strategy, improve the link with other approaches, improve and adapt KPIs, completion of pilot implementations, validation of guideline methodology. Scope extension to sustainability.
- **Mid-term**: Scaling pilots to multiple sites, broadening transition framework applications, deploying capability model across functions, integrating sustainability into governance and regulatory systems. Considering absolute sustainability to ensure the respect of planetary boundaries.
- **Long-term**: Developing robust pharmaceutical-specific datasets and metrics, embedding CE and sustainability into healthcare system-level governance, and adapting the methodological pathway to other sectors.

7.3. PUBLICATIONS LINKED TO THE DOCTORAL THESIS

The results of the research presented in this manuscript allowed scientific publications and communications listed below.

International journal

- Massot, S., Luu, D-N., Maier, C-J., Maranzana, N., Aoussat, A., Pigosso C. A., D. Translating environmental impacts into cleaner manufacturing practices: a structured methodology and practical guide. Cleaner Engineering and Technology *(Available online from 14/02/2026)*.
- Massot, S., Luu, D-N., Maier, C-J., Grau, S., Arias-Zeballos, S., Haubrich, A., Gunne, M., Schatz, M., Pommereau, C., Maranzana, N., Aoussat, A. Life Cycle Assessment of Insulin Products: Hotspots Identification and Opportunities for Sustainable Pharmacy *(Submitted in Sustainable Chemistry & Pharmacy in June 2026).*

International conference

- Massot, S., Luu, DN., Maier, CJ., Maranzana, N., Aoussat, A. (2024). How to Foster the Circular Economy Within the Pharmaceutical Industry? A Research Framework Proposition. In: Danjou, C., Harik, R., Nyffenegger, F., Rivest, L., Bouras, A. (eds) Product Lifecycle Management. Leveraging Digital Twins, Circular Economy, and Knowledge Management for Sustainable Innovation. PLM 2023. IFIP Advances in Information and Communication Technology, vol 702. Springer, Cham. https://doi.org/10.1007/978-3-031-62582-4_3
- Massot, S., Luu, DN., Maier, CJ., Maranzana, N., Aoussat, A. (2023). A Circular Economy Integration Model for the Pharmaceutical Industry. Life Cycle Management Conference (Conference poster).
- Massot, S., Monge, M. (2024). Innovative Solutions for an Agile and Sustainable Facility: Recycling of SUT. France Bioproduction Congress (8th edition)

Others

- Massot, S., Monge, M., Lozano, J. (2024). Mechanical recycling of Post-use bioprocessing plastic containers. International Society for Pharmaceutical Engineering (ISPE) Webinar.
- Massot, S., Luu, DN., Maranzana, N., Aoussat, A. (2022). Eco-design maturity model: Proposal to foster Eco-design integration in Drug development. CONFERE22.

Résumé en français - Chapitre 7 : Conclusion et perspectives

Ce chapitre final synthétise les résultats de la thèse en revisitant la problématique et les hypothèses, en évaluant leur validation, en réfléchissant à la structuration méthodologique du travail, puis en présentant les contributions sociétales, scientifiques et industrielles ainsi que les perspectives de recherche.

Rappel de la problématique : La thèse visait à répondre à la question : *Comment structurer l'intégration systémique de la soutenabilité environnementale dans l'industrie pharmaceutique ?* Deux constats fondateurs ont motivé les hypothèses : d'une part, les approches existantes de soutenabilité restent fragmentées ou limitées à des projets pilotes (axe stratégique) ; d'autre part, il existe un écart persistant entre la disponibilité des méthodes environnementales et leur ancrage réel dans les routines organisationnelles (axe organisationnel).

Validation de l'Hypothèse 1 : Concernant SRQ1.1 (les éléments clés d'une stratégie d'EC), le Chapitre 4 (Partie A) a démontré, via une revue systématique et une étude empirique, qu'il est possible de définir les briques essentielles d'une stratégie d'EC adaptée aux spécificités pharmaceutiques : le CEIM, positionnant l'éco-conception comme fondation, complété par des KPI (Waste Impact Index, Waste Score) et des outils opérationnels, structurant l'intégration verticale et horizontale. Concernant SRQ1.2 (l'applicabilité de la stratégie), le Chapitre 4 (Partie B) a confirmé, via trois études de cas (SUT, TBS, Régénération de solvants), la pertinence et l'adaptabilité de la stratégie, tout en révélant que la qualité de collaboration constitue un déterminant décisif du succès. Des limites persistent néanmoins : lacunes de mesure, intégration partielle à la gouvernance, et persistance de pilotes isolés. L'Hypothèse 1 est ainsi validée : une stratégie d'EC structurée favorise effectivement l'émergence d'initiatives circulaires pertinentes, mais la fragmentation persistante appelle une intégration organisationnelle systémique, objet de l'Hypothèse 2.

Validation de l'Hypothèse 2 : Concernant SRQ2.1 (la consolidation de projets en pratiques), le Chapitre 5 (Partie A) a développé et testé un cadre de transition en quatre étapes (capturer, synthétiser, formaliser, disséminer), validé par deux expérimentations : l'ACV de portefeuille d'insulines (première du genre dans le secteur) et le guide méthodologique pour développement de procédés soutenables (Investigation-Transformation-Customisation). Ces expérimentations ont montré que les résultats de projets peuvent être transformés en pratiques réutilisables, tout en révélant la difficulté persistante de la dissémination. Concernant SRQ2.2 (l'institutionnalisation en capacités durables), le Chapitre 5 (Partie B) a développé un modèle de capacités (6 piliers, 21 items, 4 niveaux de maturité) associé à une méthode d'application en six étapes combinant logique PDCA et backcasting. Son application chez Sanofi a révélé une maturité inégale entre fonctions techniques et facilitateurs culturels, tout en démontrant, via le cas pilote d'intégration dans les standards de fabrication, la faisabilité d'un ancrage opérationnel. L'Hypothèse 2 est ainsi validée : le cadre de transition et le modèle de capacités montrent conjointement que projets validés et stratégie peuvent être institutionnalisés, bien que la dissémination reste fragile et dépendante d'une gouvernance, d'incitations et d'un renforcement culturel soutenus.

Structuration méthodologique : La thèse s'appuie sur la Design Research Methodology (DRM), déployée en quatre phases itératives : la Research Clarification a établi le paradoxe du secteur pharmaceutique et le caractère fragmenté des initiatives existantes ; la Descriptive Study I a approfondi la compréhension du contexte pharmaceutique (freins, leviers, parties prenantes) ; la Prescriptive Study a produit trois supports majeurs (stratégie EC, cadre de transition, modèle de capacités) codéveloppés avec le partenaire industriel ; la Descriptive Study II a évalué ces supports en conditions réelles, confirmant leur pertinence tout en révélant les défis de dissémination et de mise à l'échelle.

Conclusion générale

La thèse répond au paradoxe pharmaceutique via trois enjeux majeurs : sur le plan sociétal, elle contribue à concilier développement de médicaments et réduction d'impact environnemental ; sur le plan scientifique, son originalité réside dans l'articulation d'approches fragmentées (DfS, EC, changement organisationnel) en un cheminement méthodologique cohérent, validé empiriquement dans un secteur fortement réglementé ; sur le plan industriel, elle livre des outils concrets et testés (stratégie d'EC, cadre de transition, modèle de capacités) permettant de traduire les ambitions de soutenabilité en pratiques pérennes. En définitive, l'intégration

systémique de la soutenabilité environnementale dans l'industrie pharmaceutique est à la fois nécessaire et réalisable, à condition d'articuler stratégie, pratiques et capacités.

Perspectives de recherche
Les perspectives se déclinent selon deux dimensions, scientifique et industrielle, chacune sur trois horizons temporels.

- **Sur le plan scientifique** : à court terme, valider les modèles développés, affiner les KPI pour les procédés pharmaceutiques, et multiplier les études de cas ; à moyen terme, améliorer la disponibilité des données, permettre la comparaison inter-cas, et explorer la soutenabilité absolue au regard des limites planétaires ; à long terme, définir ce que serait un système de santé soutenable (pas seulement produit) et évaluer la transférabilité des cadres à d'autres secteurs.
- **Sur le plan industriel :** à court terme, passer à l'échelle les projets pilotes, déployer des tableaux de bord, et appliquer le modèle de capacités ; à moyen terme, intégrer la démarche aux jalons de développement (stage-gates), la déployer à travers les fonctions de l'entreprise, et renforcer partenariats et collaboration ; à long terme, développer des infrastructures partagées entre entreprises, anticiper l'évolution réglementaire, et opérer un basculement culturel du curatif vers le préventif.

Le chapitre se conclut par la liste des publications scientifiques issues de la thèse.

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APPENDICES

Appendix A
Detailed view of the Capability Model pillars and their corresponding items and descriptions.

Pillar 1: Developing the right strategy

#	Item	Description
1	Business case	Represents how environmental sustainability is justified as part of organizational value creation. It evolves from a compliance-driven rationale toward a strategic driver of innovation, competitiveness, and industry leadership.
2	Vision and Narrative	Captures how sustainability ambitions are articulated. It develops from vague, generic statements into a compelling, function-specific narrative that is embraced by teams, embedded in culture, and used to guide behaviors and innovation.
3	Business Targets	Reflects the extent to which sustainability KPIs are defined, measured, and embedded in operations. It progresses from minimal or fragmented compliance metrics to fully integrated, real-time data driving continuous Eco-design improvements.
4	Sustainable Behaviors	Describes the adoption of sustainability-oriented practices across roles. It advances from scattered awareness to widespread, reinforced habits that become second nature and embedded in daily routines.

Pillar 2: Engaging the right people

#	Item	Description
5	Sponsorship	Represents leadership commitment to sustainability. It moves from minimal, compliance-driven involvement toward transformational leadership that inspires innovation and drives organizational and industry-wide change.
6	Core Team	Defines the structure and role of the dedicated Eco-design team. It shifts from ad hoc, uncoordinated efforts toward a fully established, strategic team aligned with organizational objectives.
7	Champions Network	Represents the breadth and depth of advocacy across employees. It transitions from fragmented or skeptical engagement to a fully aligned, influential network driving transformation and innovation.
8	Function's readiness for change	Reflects the openness and preparedness of teams to adopt sustainability. It develops from resistance and disengagement to a cohesive, transformational culture of proactive change.
9	Function's stakeholders	Captures stakeholder engagement and influence. It evolves from disconnected and passive involvement to stakeholders driving systemic change and influencing industry standards.

Pillar 3: Shaping the right stories, rituals, and symbols

#	Item	Description
10	Communication Strategy	Represents the planning and deployment of communication efforts. It grows from informal, ad hoc communication to structured, optimized strategies ensuring transparency and comprehensive engagement.
11	Stories & Best Practices	Reflects how knowledge and successes are shared. It matures from isolated, local learning to widespread sharing across functions, fueling pride, identity, and organizational momentum.
12	Rituals in the Flow of Work	Describes the embedding of sustainability into routines. It progresses from absence of rituals to formalized, organization-wide practices that signal values and reinforce behaviors.

13	External Claims & Value Creation	Represents how sustainability is used externally. It evolves from no environmental claims to fully embedding them in strategy, strengthening value creation and competitive positioning.

Pillar 4: Reinforcing with the right rewards and recognition

#	Item	Description
14	Performance & goals	Captures how sustainability objectives are linked to individual and team performance. It advances from absent or unclear expectations to role-specific, stretch-oriented goals embedded at all levels.
15	Recognition (Formal & Informal)	Represents how sustainability efforts are acknowledged. It matures from rare recognition to cultural and strategic celebration of achievements, fueling motivation and identity.
16	Culture of Experimentation	Describes the openness to innovate and learn through sustainability pilots. It shifts from risk aversion to a growth mindset where experimentation and learning from failure are celebrated.

Pillar 5: Enabling with the right tools and processes

#	Item	Description
17	Tools & Decision Support	Reflects the integration of Eco-design into organizational tools and workflows. It evolves from absence of tools to intuitive, automated systems where Eco-design is the default choice.
18	Integration in HR processes	Represents the embedding of Eco-design into HR and talent systems. It develops from being absent in processes to becoming a fully institutionalized element of workforce planning and leadership development.

Pillar 6: Building the right skills

#	Item	Description
19	Upskilling Strategy	Captures the overall approach to learning. It moves from informal or optional learning to a fully strategic, continuous, and sector-influencing capability development system.
20	Upskilling Needs Analysis (knowledge & skills)	Represents how knowledge gaps are assessed. It progresses from no formal assessment to dynamic, real-time analysis embedded in workforce and business planning.
21	Upskilling Content & Methods	Reflects the design of training and learning experiences. It evolves from generic awareness content to continuous, role-specific, applied learning embedded in daily practice.

Simon MASSOT

Methodological framework for the systemic integration of environmental sustainability in the pharmaceutical industry

Résumé : La soutenabilité environnementale constitue un enjeu majeur pour l'industrie pharmaceutique, dont la mission d'amélioration de la santé humaine entre en tension avec ses impacts environnementaux. Malgré des avancées récentes, les initiatives restent fragmentées et insuffisamment intégrées aux processus de développement des produits et des procédés. Cette thèse étudie comment structurer l'intégration systémique de la soutenabilité environnementale dans l'industrie pharmaceutique. La recherche s'appuie sur la *Design Research Methodology* et combine revue de littérature, investigations empiriques et études menées au sein de Sanofi. Elle propose une stratégie d'économie circulaire et un modèle d'intégration favorisant le déploiement de pratiques circulaires à l'échelle de l'organisation. Sur cette base, un cadre de transition est développé afin de transformer des initiatives isolées en pratiques reproductibles et de soutenir leur déploiement à travers les différentes fonctions de l'entreprise. Enfin, un modèle de capacités organisationnelles est proposé pour favoriser l'institutionnalisation de la soutenabilité environnementale et son intégration durable dans le développement des produits et des procédés. Cette thèse fournit ainsi un ensemble cohérent de modèles, de méthodes et de leviers d'intégration reliant les dimensions stratégiques et opérationnelles de la soutenabilité environnementale, afin d'accompagner la transition vers un développement pharmaceutique plus durable.

Mots clés : Soutenabilité environnementale ; industrie pharmaceutique ; économie circulaire ; intégration systémique ; analyse de cycle de vie ; éco-conception ; capacités ; transition ; processus et produits.

Abstract: Environmental sustainability has become a major challenge for the pharmaceutical industry, whose mission to improve human health increasingly conflicts with its environmental impacts. Despite recent progress, sustainability initiatives remain fragmented and insufficiently integrated into product and manufacturing process development. This thesis investigates how environmental sustainability can be integrated systemically within the pharmaceutical industry. The research follows the Design Research Methodology and combines a literature review, empirical investigations, and studies conducted at Sanofi. It proposes a Circular Economy strategy and an integration model to support the deployment of circular practices across the organization. Building on this work, a transition framework is developed to transform isolated initiatives into repeatable practices and support their deployment across organizational functions. Finally, an organizational capability model is proposed to facilitate the institutionalization of environmental sustainability and its long-term integration into product and process development. Overall, this thesis provides a coherent set of models, methods, and integration levers linking the strategic and operational dimensions of environmental sustainability, thereby supporting the transition toward more sustainable pharmaceutical development.

Keywords: Environmental sustainability; pharmaceutical industry; Circular Economy; systemic integration; Life Cycle Assessment; Eco-design; Capabilities; sustainability transition; manufacturing processes.