Universiteit Utrecht

Master's Thesis – Master Sustainable Business and Innovation

Harmonizing Transformations: Key Considerations for Implementing AI-Driven Sustainability in Pharmaceutical Manufacturing

Sophia Ester Neudeck, BSc.

University-Supervisor:	Dr. Susan van Hees
Second Assessor:	Prof. Dr. Wouter Boon
Internship Company:	Boehringer Ingelheim RCV GmbH & Co KG Dr.-Boehringer-Gasse 5-11 | 1120 Vienna | Austria
Company-Supervisor:	Natalie Egreteau, MSc.

Boehringer Ingelheim

ABSTRACT

This master's thesis investigates the role of artificial intelligence (AI) in enhancing sustainability within the pharmaceutical manufacturing sector. As environmental concerns intensify globally, the pharmaceutical industry is under increasing societal and regulatory pressure to adopt sustainable practices that minimize its ecological footprint. Meanwhile, the adoption of Industry 4.0 technologies, including AI, becomes increasingly relevant due to their potential to optimize manufacturing processes and enhance sustainability. However, there currently is a significant lack of practical guidance for the successful integration of these technologies, specifically within the pharmaceutical industry. To address this, the study aims to identify key considerations for integrating AI methods to optimize sustainability parameters, such as energy efficiency, carbon emissions, water usage, resource efficiency, and raw material optimization.

Employing a mixed-methods approach, the research combines a semi-systematic literature review with qualitative interviews and a quantitative survey involving industry stakeholders and subject matter experts. The findings reveal that machine learning (ML), a subset of AI, is the most prevalent technique applied for sustainability optimization of manufacturing processes. The most feasible parameter to optimize with AI was found to be energy consumption, highlighting the importance of prioritizing energy efficiency within the manufacturing domain. The importance of adopting AI for sustainability purposes was highlighted by the survey results, which indicate a strong consensus among participants regarding the benefits of AI integration, including improved operational efficiency, enhanced decision-making, and significant cost savings.

The findings underscore the necessity of fostering sustainability literacy among professionals involved in AI implementation, such as data scientists and manufacturing experts. Furthermore, the research highlights the need to reevaluate pharmaceutical intellectual property rights to facilitate knowledge sharing and collaboration, which are essential for advancing sustainable practices across the industry.

This thesis contributes to the existing body of knowledge by addressing the limited exploration of AI's transformative potential in pharmaceutical manufacturing sustainability. It provides actionable insights and practical guidance for industry stakeholders, emphasizing the importance of aligning AI integration with sustainability goals. By offering targeted recommendations, particularly in prioritizing energy efficiency and leveraging machine learning techniques, this research empowers pharmaceutical firms to navigate the complexities of sustainable manufacturing effectively. Ultimately, this study supports the industry's transition towards greener production methods, aligning with societal expectations for responsible innovation and environmental stewardship.

Keywords: Artificial Intelligence; Sustainability; Biopharmaceutical Manufacturing; Pharmaceutical Manufacturing; Industry 4.0; Machine Learning; Energy Efficiency; Resource Optimization; Process Optimization; Responsible Innovation; Pharmaceutical Industry Transformation.

TABLE OF CONTENT

INTRODUCTION

The global pharmaceutical industry stands at a critical juncture, grappling with multifaceted challenges, such as the growing demand for pharmaceutical products, driven by an aging population and evolving healthcare needs, that extend beyond the conventional realms of drug development and manufacturing (Bünder, 2022). Meanwhile, concerns related to the industry's environmental impact have intensified (Schneider et al., 2010).

While playing an essential role in enhancing global well-being, the pharmaceutical industry also has a significant negative impact on the environment due to its emissions and resource intensive manufacturing processes (Belkhir and Elmeligi, 2018; Richie, 2022). Furthermore, it has been recognized as a reservoir for aquatic pollution with antibiotics (Wang et al., 2021) and other metabolites (Gonzáles et al., 2021), which pose a significant threat to the environment (Shashi, 2022; Paulick et al., 2022; Larsson, 2014).

In this context, the United Nations' 2030 Agenda for Sustainable Development defines sustainability as "meeting present needs without compromising the chances of future generations to meet their needs." (United Nations, 2023) This concept is increasingly pivotal as it integrates economic growth, social inclusion, and environmental protection. Recent interpretations emphasize the need for a holistic approach that balances these three dimensions to ensure long-term well-being (Glavič and Lukman, 2007). Additionally, sustainability involves making choices that avoid immediate rewards at the expense of long-term environmental health.

Manufacturing, driven by humanity's desire for continuous development (Malshe et al., 2015), is increasingly recognizing the need for environmental sustainability. According to Rosen and Kishawy (2012), there are three key factors influencing the environmental impact of manufacturing operations:

Product: The strategy for creating environmentally friendly products often involves a design process that considers environmental impacts throughout the product's life. This typically includes Design for Environment (DFE) and Life Cycle Analysis (LCA) methods. Designing products to be environmentally friendly can enhance their success and longevity. Flexibility in product design allows for environmental improvements, such as material substitution, while maintaining competitiveness (Ahmad et al., 2018; Rosen and Kishawy, 2012).

Process: Environmental enhance-ments in manufacturing processes are tied to reduction, reuse, recycling, and remanufacturing. Zero-emission manufacturing, which views the system as an industrial ecosystem, necessitates waste reuse within the system. This requires capabilities for pollution prevention and waste reuse. Flexible manufacturing also demands material flexibility, and equipment that can handle variations in material flows can boost sustainability while preserving competitiveness (Azapagic et al., 2006; Rosen and Kishawy, 2012).

Practices: ISO 14000[1] certification significantly influences manufacturing practices. While it can support organizational practices, it doesn't guarantee environmental improve-ments (Sarkis, 2001). Practices such as benchmarking and performance measurement can be strategically used to improve manufacturing, as they assist managers in developing and maintaining new environmental programs and technology (Rosen and Kishawy; 2012).

In the context of this master's thesis, a focus on enhancing the sustainability of processes has been chosen as it directly addresses the

[1] *ISO Certifications validate a business's adherence to international standards set by the International Organization for Standardization (ISO, n.d.).*

environmental impact of manufacturing operations. By improving processes, companies can achieve significant reductions in emissions and resource consumption, leading to more sustainable production methods (Panagiotopoulou et al., 2021). This approach not only aligns with regulatory requirements and stakeholder expectations but also ensures long-term operational efficiency and competitiveness. Enhancing process sustainability is a practical and impactful way to integrate environmental considerations into the core of manufacturing activities, driving meaningful progress towards overall sustainability goals (Abubakr et al., 2020).

REGULATORY ENVIRONMENT

Globally, regulatory bodies are increasingly responding to societal expectations for corporate sustainability by tightening reporting requirements (Milanesi et al., 2020), such as the Corporate Sustainability Reporting Directive (CSRD) which will mandate Environmental, Social, and Governance (ESG) reporting for over 50.000 companies starting in 2024 (European Parliament, 2022). This underscores the urgent need for the pharmaceutical industry to address its environmental impact and adopt sustainable practices, while also considering broader aspects such as corporate governance, human rights, and societal impacts (Bade et al., 2023).

Within the pharmaceutical manufacturing sector, the imperative for sustainable practices is particularly pronounced (Weaver et al., 2022), as data suggests that the industry produced 52 million tons of CO_2-equivalent in 2018 – about 5.5 million tons more than the automotive manufacturing industry in the same year (Belkhir and Elmeligi, 2018).

The significance of sustainable pharmaceutical practices is highlighted in the 'Pharmaceutical Strategy for Europe,' a document published by the European Commission in 2020, which addresses the various challenges and opportunities in the pharmaceutical industry to ensure better access to affordable medicine, promote innovation, and strengthen the EU's role in global health (European Commission, 2020).

One of the four pillars, which the strategy addresses, aims to increase awareness of the sustainable use of pharmaceutical products and therefore aligns with the European Green Deal's ambition for climate neutrality and a toxic-free environment. It emphasizes the need for high-quality, safe, and environmentally sustainable medicine. Furthermore, the strategy emphasizes the importance of detecting and managing quality issues in the pharmaceutical industry and calls for strengthening oversight of the global manufacturing chain, ensuring transparency across the entire supply chain. In this context, the EU plays an active role in promoting good manufacturing and distribution practices internationally (European Commission, 2020).

The 'Pharmaceutical Strategy for Europe' underlines the need for innovation in environmentally sustainable and climate-neutral pharmaceuticals and manufacturing by encouraging the application of best available techniques, such as the use of artificial intelligence, to reduce emissions and contribute to the EU's climate goals.

Overall, the pharmaceutical industry has witnessed an upsurge in attention towards the sustainability of its activities, particularly in relation to Corporate Social Responsibility (CSR) measures and sustainability reporting (Schneider et al., 2010). However, the upkeep and enhancement of these practices are frequently overlooked by pharmaceutical managers due to a deficiency in effective strategies for their implementation (Shashi, 2022). One example for this oversight is that the industry has predominantly focused on linear approaches and short-term objectives, such as waste reduction, rather than adopting holistic, circular methodologies and longer-term goals like waste mitigation, resource efficiency, and closed-loop models (Ang et al., 2021).

In December 2023, the EU commission has reached a provisional agreement with the EU Parliament and the Council on the Ecodesign for Sustainable Products Regulation (ESPR). This agreement aims to make sustainable products the new norm in the EU by promoting longer product lifespans, energy and resource efficiency, easier repair and recycling, reduced use of harmful substances and increased recycled content (European Commission, 2023). Even though pharmaceutical products are not yet covered by the proposal, several large pharmaceutical companies have announced their commitment to Ecodesign (Sanofi, 2023; Boehringer Ingelheim, n.d.; Biomérieux, n.d.; Lilly, 2024).

BIOPHARMACEUTICAL MANUFACTURING

Biopharmaceuticals represent a distinct category of pharmaceuticals that differ significantly from other types of pharmaceuticals, such as small molecule drugs and traditional chemical-based medications. Unlike small molecule drugs synthesized through chemical processes, biopharmaceuticals are derived from living organisms or biological sources, including proteins, peptides, nucleic acids, and complex carbohydrates. The manufacturing of biopharmaceuticals involves biotechnological techniques like cell culture, fermentation, and genetic engineering to produce therapeutic molecules with high specificity and biological activity. Biopharmaceuticals are often larger, more complex molecules that target specific receptors or pathways in the body, making them suitable for personalized medicine and targeted therapies (Szkodny & Lee, 2022).

The manufacturing process of biopharmaceuticals can be broadly categorized into upstream and downstream processing. Upstream processing begins with selecting a suitable host organism, such as bacteria, yeast, or mammalian cells, and introducing the gene of interest into these cells using recombinant DNA technology (Berlec & Štrukelj, 2013). The engineered cells are then cultured in bioreactors under controlled conditions to promote growth and protein expression. Upstream processing therefore focusses on optimizing cell growth and protein production. In downstream processing, the harvested cells or fermentation broth undergo a series of purification steps to isolate and purify the desired biopharmaceutical product from cellular components and impurities. This includes techniques such as filtration, chromatography, and precipitation to achieve high purity and yield. Finally, the purified product is formulated into the desired dosage form, such as injectables, and undergoes rigorous quality control measures to ensure safety, efficacy, and consistency (Walsh, 1999).

Exploring how the sustainability of biopharmaceutical manufacturing processes can be enhanced is crucial for several reasons. First, the biopharmaceutical industry has a significant environmental impact due to the resource-intensive nature of bioprocessing, including ecotoxicity, human toxicity and water consumption (Etit et al., 2024). By improving sustainability, such as reducing energy and water consumption, optimizing raw material usage, and implementing green chemistry principles, the environmental footprint of biopharmaceutical manufacturing can be minimized. Moreover, sustainable manufacturing practices can lead to cost savings through increased efficiency and resource utilization, benefiting both the industry and society (Lalor et al., 2019).

In this thesis, the terms pharmaceutical and biopharmaceutical manufacturing have been used synonymously. This approach is intended to streamline the discussion and should not influence the validity of the findings in any way. The principles and processes discussed are applicable to any pharmaceutical manufacturing process, ensuring that the insights and recommendations provided can be implemented across the industry, regardless of the specific type of pharmaceutical being produced.

INDUSTRY 4.0 TRANSFORMATION

The application of artificial intelligence (AI) in pharmaceuticals spans from drug discovery to manufacturing processes and supply chain management (Nishant et al., 2020). AI is commonly referred to as *“a system's ability to interpret external data correctly, to learn from such data, and to use those learnings to achieve specific goals and tasks through flexible adaptation*” (Kaplan & Haenlein, 2019). In the context of this research, artificial intelligence can be explained as the integration of advanced computational algorithms into manufacturing operations, enabling systems to learn from data, make informed decisions, and optimize processes autonomously (Kulkov, 2021).

Specifically within the pharmaceutical industry, AI applications may range from predictive maintenance and quality control to drug discovery processes, offering the potential to enhance efficiency, accuracy, and innovation (Shiammala et al., 2023; Schneider et al., 2019).

Furthermore, it can enhance lead optimization, which is the iterative process of refining and enhancing the pharmacological and physicochemical properties of initial drug candidates to optimize their efficacy, safety, and overall therapeutic profile (Sarkar et al., 2023), reducing time-to-market and research costs (Mariani et al., 2023; Kulkov, 2021). The manufacturing landscape benefits from AI through process optimization, where smart systems equipped with AI algorithms continuously monitor and analyze operations, identifying patterns and adjusting parameters in real-time (Bhattamisra et al., 2023). This predictive and adaptive approach can minimize errors, reduce waste, and enhance overall operational efficiency (Nishant et al., 2020).

The pharmaceutical supply chain, intricate and involving multiple stakeholders, including government agencies, wholesalers, community and hospital pharmacies, and advocacy organizations (Latonen et al., 2023), stands to gain from AI applications improving forecasting accuracy, inventory management, and distribution logistics (Debnath et al., 2023), which can contribute to overall resource efficiency and waste minimization (Waltersmann et al., 2021). Predictive analytics powered by AI mitigate the risk of drug shortages, enhancing the resilience of the supply chain.

Pharmaceutical companies that are capable to acquire sufficient investments in technological advancements, are progressively adopting the principles of the fourth industrial revolution (Industry 4.0). This term is used to describe the ongoing digital transformation which utilizes advanced technologies such as AI, the Internet of Things (IoT), big data, and automation to develop smarter, more efficient, and interconnected industrial systems (Sarkis et al., 2021). In this context, the incorporation of AI into manufacturing processes emerges as a crucial factor for elevating sustainability and competitiveness (Debnath et al., 2023).

Despite the numerous opportunities presented by AI for enhancing the efficiency, optimization, monitoring, and control of pharmaceutical manufacturing processes, its actual implementation remains rare due to a limited understanding of AI concepts in this domain (Rathore et al., 2023). According to Weaver et al. (2022), it is crucial to identify modifiable factors that can improve the environmental sustainability of pharmaceutical manufacturing. However, there is currently limited research on the use of AI for sustainability in manufacturing, particularly within the pharmaceutical sector. Although it is recognized that AI has the potential to increase resource efficiency in manufacturing processes, practical frame-works for achieving this goal are currently lacking (Patel & Rabizadegan, 2021; Arias et al., 2023). Therefore, there is an urgent need to address these knowledge gaps and develop clear strategies for leveraging AI to optimize sustainability in pharmaceutical manufacturing processes.

AIM OF THE RESEARCH

To address the identified lack in guidance for implementing AI methods to enhance the sustainability of (bio)pharmaceutical manufacturing processes, the following research question has been formulated:

"What are the key considerations for successfully integrating AI methods for optimizing sustainability in (bio)pharmaceutical manufacturing processes?"

In addition, two sub-questions have been developed to provide practical guidance for initiating this implementation:

A. Which sustainability parameters in (bio)pharmaceutical manufacturing can feasibly be adjusted or optimized with the help of AI?

B. Which AI methods are most likely to optimize the identified sustainability parameters in (bio)pharmaceutical manufacturing processes?

By addressing these research questions, this study aims to identify key considerations for integrating AI methods to enhance the sustainability of (bio)pharmaceutical manufacturing processes. The intended outcome is to provide actionable insights and practical guidance for industry stakeholders, enabling them to optimize resource utilization, reduce environmental impact, and improve overall efficiency. This research holds significant societal and practical relevance as it seeks to contribute to the development of more sustainable and resilient (bio)pharmaceutical manufacturing practices, fostering innovation, and supporting the industry's transition towards greener and more responsible production methods. By aligning with societal expectations for innovative solutions to address environmental challenges, this study underscores the importance of improving manufacturing processes towards sustainable practices (EFPIA, 2023; Milanesi et al., 2020).

This study adds to scientific knowledge by bridging the gap between AI and sustainability in the pharmaceutical manufacturing sector, addressing the critical issue of the industry's environmental footprint (Okeke et al., 2022). By contributing to the scientific understanding of AI integration in sustainable manufacturing, this research underscores the importance of applying research-based knowledge to practical applications in the field. The emphasis on sustainability aligns with global efforts to reduce environmental impact across industries (Rissman et al., 2020). Previous research has explored sustainability challenges in the pharmaceutical industry and the transformative potential of AI in specific manufacturing processes (Weaver et al., 2022). However, a comprehensive exploration of integrating AI for the sustainability of (bio)pharmaceutical manufacturing remains limited (Patel & Rabizadegan, 2021).

THEORY

The following section establishes the theoretical groundwork for this study, providing a solid foundation for the research and guiding the methodology. This section draws on insights from the sustainability transitions theory, the responsible innovation framework, and the dynamic sustainability framework. These theoretical frameworks have been selected because they collectively address the complex and multifaceted nature of the research questions. Specifically, they offer a comprehensive approach to understanding and integrating sustainability, innovation, and dynamic adaptation in (bio)pharmaceutical manufacturing.

The sustainability transitions theory helps to explore long-term changes and shifts towards sustainable practices by providing insights into socio-technical systems (Petrović, 2023). The responsible innovation framework emphasizes the ethical and societal implications of innovation, ensuring that technological advancements align with broader societal values. The dynamic sustainability framework focuses on the continuous adaptation and improvement of sustainable practices over time. Together, these frameworks provide a robust theoretical foundation to holistically explore what needs to be considered when integrating AI in sustainable manufacturing practices, ensuring that the research is both thorough and relevant.

SUSTAINABILITY TRANSITIONS THEORY

The Sustainability Transitions Theory (STT) is a framework that examines how large-scale, long-term changes towards sustainable practices occur within socio-technical systems, focusing on the interactions between technology, society, policy, and innovation. It provides a comprehensive lens through which the dynamics of societal shifts towards sustainability can be examined (Petrović, 2023). By recognizing the multi-dimensional aspects of sustainability and the necessity for radical innovations, STT guides the exploration of AI integration towards transformative change. Understanding the micro-, meso-, and macro-level dynamics within the industry facilitates the identification of leverage points for sustainable transitions.

At its core, STT emphasizes the transformation of socio-technical systems, wherein established practices, technologies, and institutions undergo profound changes to align with sustainability imperatives. Socio-technical systems are 'dominant technologies, infrastructures, industries, supply chains and organizations responsible for delivering societal function' (Sorrell, 2018). Central to STT is the recognition of multiple dimensions of sustainability, encompassing environmental, social, and economic aspects, and the acknowledgment of the interconnectedness of these dimensions within complex systems (Loorbach et al., 2017).

Industry 4.0 has been recognized as a major driver of sustainability transitions, as it aims to connect resources, services, products, and human beings through digitalization (Asiimwe & de Kock, 2019). In their paper, Mäkitie et al. (2023) explore the contribution of digital innovation in sustainability transitions and find that the coupling between the two is becoming increasingly relevant. They propose four ways, in which digital innovation may be coupled with sustainable innovation: incremental twin innovation, digitally supported sustainable innovation, sustainability supported digital innovation, and radical twin innovation. According to the authors, the optimization of existing industrial processes through AI falls in the category of incremental twin innovation, which is described as 'the least transformative digital innovation in the context of sustainability' (Mäkitie et al., 2023). They argue that even though these innovations aim to improve existing structural configurations of production and consumption (e.g., by increasing efficiency), they do not result in fundamental change towards more sustainable patterns and may also increase certain lock-in effects of unsustainable patterns.

To create substantial changes in these patterns, radical innovations are needed, as only these can lead to fundamental reconfigurations of socio-technical systems. These innovations are linked to institutional changes, the creation of novel collaboration patterns, as well as the entry of new actors and reorientation of existing actors (Dolata, 2009) and emerge from the recombination of previously unconnected knowledge (Grashof & Kopka, 2023). Thus, radical innovations are often associated with high levels of uncertainty, large investments, risks as well as resistance and skepticism due to the limited knowledge about their application and benefits (Reinders et al., 2010). However, if successful, these innovations can lead to firms enhancing their competitive position and establish new markets. It is therefore important to recognize the use of AI technologies as a driver for potential radical innovation or the recombination of AI knowledge as a radical innovation itself. To leverage AI as a radical innovation instead of an incremental innovation, which might not lead to sufficient transformative change and promote lock-in effects, it is therefore important to develop and diffuse AI-related knowledge, especially within larger firms (Grashof and Kopka, 2023).

In the context of (bio)pharmaceutical manufacturing, applying STT involves understanding the dynamics of transitioning from conventional, resource-intensive practices towards more sustainable alternatives (Falcone and Hiete, 2019). This includes concepts such as green chemistry (GC) and sustainable chemistry (SC). The US Environmental Protection Agency (EPA) describes GC as 'the design of chemical products and processes that reduce or eliminate the generation of hazardous substances' (US EPA, 2024) and is centered around twelve leading principles, such as waste prevention and energy efficiency. SC is closely related to the concept of GC, as it 'prioritizes production processes that promote increased product value while intersecting the goals of protecting and enhancing human health and the environment' (Mutlu & Barner, 2022).

Sustainability transitions are characterized by multi-level processes, occurring across niches, regimes, and landscapes (see FIGURE 1).

In the context of AI integration in (bio)pharmaceutical manufacturing, macro-level influences may include regulatory mandates for environmental performance, industry-wide standards for sustainability reporting, and societal expectations regarding ethical AI use. Meanwhile, meso-level dynamics encompass the emergence of collaborative networks, knowledge exchange platforms, and innovation ecosystems that facilitate the diffusion of sustainable practices across the industry (Daniel, 2022). Furthermore, STT underscores the role of macro-level factors such as regulatory frameworks, policy incentives, and socio-cultural norms in shaping the direction and pace of sustainability transitions.

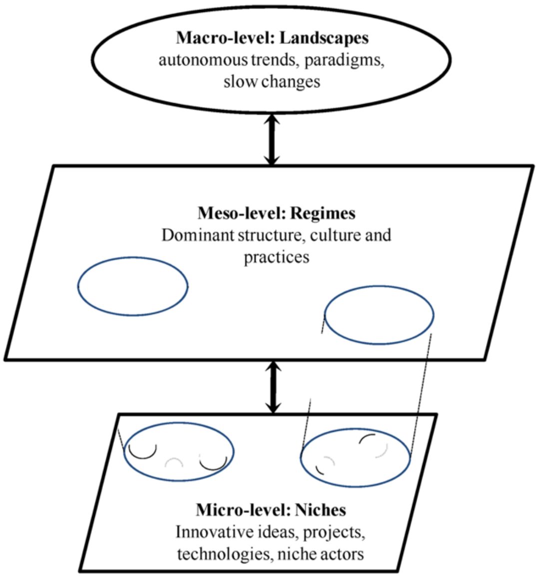


FIGURE 1: MLP FRAMEWORK BASED ON LOORBACH AND WIJSMAN (HÖRISCH, 2015)

In the realm of (bio)pharmaceutical manufacturing, the development of AI tools aimed at enhancing sustainability primarily unfolds at the micro-level, focusing on process optimizations and efficiency improvements. However, it is imperative to recognize and account for the broader meso- and macro-level dynamics that exert considerable influence over the entire manufacturing ecosystem. Only by considering and accommodating these broader influences can AI-driven processes truly maximize their impact on sustainability while remaining resilient in the face of evolving external factors.

Overall, Sustainability Transitions Theory and its related concepts offer a robust analytical framework for understanding the complexities of transitioning toward sustainable practices in (bio)pharmaceutical manufacturing. By highlighting the interplay between technological innovations, societal dynamics, and institutional contexts, STT can be utilized to inform the development of a practical framework by pinpointing areas which need to be focused on.

RESPONSIBLE INNOVATION

Transitioning toward sustainable practices in fields such as (bio)pharmaceutical manufacturing necessitates not only technological advancements but also ethical considerations and societal engagement. While Sustainability Transitions Theory (STT) provides a comprehensive framework for understanding the dynamics of such transitions, Responsible Innovation offers a normative approach to guide technological development and deployment in socially desirable, ethically acceptable, and environmentally sustainable ways. Rooted in the philosophy of science and technology studies, RI goes beyond traditional risk-based approaches to innovation governance by emphasizing broader societal values, stakeholder engagement, and anticipatory governance (Roy, 2021). Von Schomberg (2011) defines Responsible Research and Innovation (RRI) as:

'A transparent, interactive process by which societal actors and innovators become mutually responsive to each other with the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advancements in our society).'

Stilgoe et al. (2013) define RI more broadly, as a 'means taking care of the future through collective stewardship of science and innovation in the present'. Based on that, the authors propose four relevant dimensions: anticipation, reflexivity, inclusion, and responsiveness. They suggest that responsible research and innovation must anticipate potential outcomes, involve stakeholders, critically reflect on assumptions and practices, and adapt actions based on insights gained from these processes (Stahl, 2022).

Given that this study examines an innovation process within the commercial context of a (bio)pharmaceutical company, it is imperative to also consider RI from an organizational standpoint. Ceicyte and Petraite (2018) underscore the significance of prioritizing RI within commercial contexts, advocating for a Networked Responsibility Approach (NRA). They argue that a commercial enterprise must consider responsibility criteria from diverse stakeholder viewpoints, including both internal and external stakeholders, and execute innovation in a mutually responsible manner. This egocentric approach may offer greater practicality in analyzing innovation processes within firms, as it acknowledges their primary objectives of establishing competitive advantage and generating economic profit. Based on their findings, the authors propose a conceptual framework for RI at the firm level (see Figure 2). They define RI in the industry as:

'(...) a strategic concept that requires forward-thinking by having a long-term vision about the innovation and its impact on society and the environment, and also specifically including the socio-ethical aspects of the innovation, and requiring the integration of related stakeholders through the innovation development process from the initial phases and onward.'' (Ceicyte and Petraite, 2018, p.9)

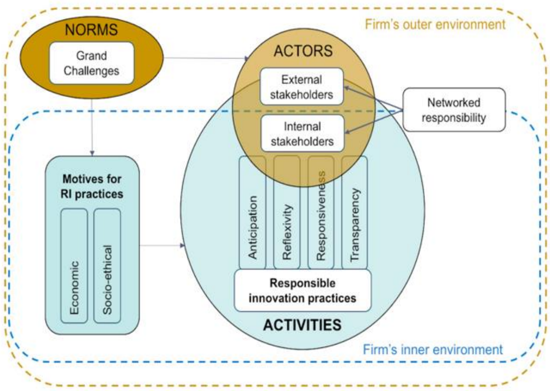


FIGURE 2: RESPONSIBLE INNOVATION AT THE FIRM LEVEL (CEICYTE & PETRAITE, 2018)

Central to a firm's internal environment are its RI practices or activities, which can be characterized using Stilgoe et al.'s (2013) aforementioned four dimensions: anticipation, reflexivity, inclusion, and responsiveness.

In the specific context of the industry, anticipation is necessary to mitigate the uncertainty surrounding innovation by attempting to forecast its potential negative consequences. Within the framework of the NRA, anticipation plays a crucial role as firms strive to shape and align external norms with their innovation objectives while also adapting their behavior and decision-making processes to accommodate other stakeholders and actors within the network (Ceicyte and Petraite, 2018). Reflexivity should be integrated from the outset of the innovation process and entails reflecting on innovation activities, adherence to standards, and other pertinent factors. This dimension can be reinforced through third-party assessments, fostering an informal self-assessment culture, or employing formal evaluations. Inclusion involves engaging diverse stakeholders throughout the innovation process, ensuring their participation and representation. Systematic inclusion integrates actors with different backgrounds, knowledge, and perspectives to seek consensus on innovations. In commercial contexts, inclusion is intertwined with anticipation, reflexivity, and responsiveness, as firms should involve stakeholders across these dimensions (Lubberink et al., 2017). Anticipation involves developing roadmaps for achieving desired impacts, while reflexivity entails reframing problems and encouraging stakeholders to challenge approaches. Responsiveness requires firms to collaborate with stakeholders to adapt innovations to their feedback. As a RI activity, responsiveness involves the capacity to alter innovation in response to stakeholder values and public feedback. It strengthens network ties and consolidates various dimensions of RI into a common effort. In this context, transparency can be seen as a prerequisite for responsiveness.

The motives for RI activities in the industry encompass both economic and socio-ethical considerations. Economic motives play a significant role in RI within the industry, yet they have often been overlooked by scholars (Stahl et al., 2017). Despite firms being primarily self-interested, they are driven by the need to stay updated with technological advancements and acquire external knowledge to enhance their internal innovation activities. Even as firms prioritize market success, instrumental economic motives, such as meeting consumer demand and managing reputation, can support the dissemination of responsible products. Thus, integrating economic motives into the conceptual framework of RI is essential for achieving responsible outcomes in a commercial setting (Garst et al., 2017).

On the other hand, socio-ethical motives are also integral to RI. These motives are often influenced by external factors such as legislation or market mechanisms, and they reflect evolving norms and values, including Grand Challenges. By scanning their environment, firms can recognize the importance of adhering to these changing norms and values to maintain a social license to operate and gain acceptance from society (Dreyer et al., 2017). Incorporating socio-ethical motives into RI is crucial as it extends existing corporate social responsibility policies and strengthens ties with stakeholders (Van De Poel et al., 2017).

Stahl (2022) uses the term ‘innovation ecosystem’ to apply the RRI and RI framework, which ‘provides a straightforward and widely accepted concept that can be applied to understand the dynamics of economic systems and mechanisms of innovation’ (Nylund et al., 2019). In the context of AI, Stahl (2022) uses the term ‘AI innovation ecosystem’ as AI is still lacking a clear definition and is therefore often described as ‘a family of overlapping aspects, technologies and techniques’. Over the past decade and a half, public interest surrounding the ethical dimensions of AI has surged, driven by significant advancements and enhancements such as machine learning (ML) algorithms and the widespread adoption of artificial neural networks. This heightened concern is further fueled by the growing demand for extensive computational resources and the ready availability of vast datasets. While a multitude of promising beneficial applications have emerged, AI also carries the potential to adversely affect stakeholders and societies (Stahl, 2022; Baum, 2017; Cave & Óhéigeartaigh, 2019). Therefore, establishing robust governance mechanisms within AI innovation ecosystems is essential.

An effective approach to addressing these concerns is through the implementation of regulatory frameworks. In March 2024, the European Union endorsed its first major regulatory act aimed at addressing AI-related risks: the 'Artificial Intelligence Act'. This legislation introduces clear requirements and obligations for AI developers and deployers, with the goal of reducing administrative and financial burdens for businesses. It is part of a broader initiative to support trustworthy AI, which includes the 'AI Innovation Package' and the 'Coordinated Plan on AI'. These measures are designed to ensure the safety and rights of individuals and businesses, as well as to foster AI uptake, investment, and innovation across the EU. Notably, the AI Act represents the world's first comprehensive legal framework on AI, aiming to promote trustworthy AI in Europe and beyond. Its objectives include ensuring respect for fundamental rights, safety, and ethical principles, while also addressing risks associated with powerful AI models (European Parliament, 2023).

In addition to large national and legislative frameworks, AI governance mechanisms can also be implemented at a local level, tailored to the specific innovation ecosystem. One such example is the creation of an 'AI Ethics Officer' position within an organization. This role would integrate technical and ethical expertise, serving as a gatekeeper for appropriate methodologies and facilitating discussions on potentially conflicting goals of AI development (Stahl, 2022). However, it's important to acknowledge the potential drawback of concentrating responsibility within this role rather than distributing it among all members of the organization.

DYNAMIC SUSTAINABILITY FRAMEWORK

Implementation science focuses on integrating research findings and evidence-based practices into routine practice across various sectors, including healthcare, education, and policy. Its goal is to bridge the gap between research and practice by identifying and addressing barriers to the adoption of proven interventions (Westerlund et al., 2019). One significant theoretical model in this field is the Dynamic Sustainability Framework (DSF). Developed to guide the implementation of evidence-based interventions, the DSF emphasizes the importance of context, complexity, and adaptation (Chambers et al., 2013).

The DSF recognizes that the effectiveness of an intervention is influenced by the surrounding environment, including social, political, economic, and cultural factors. It also acknowledges the inherent complexity of interventions, which consist of multiple interacting components. Moreover, the DSF promotes the adaptability of interventions to maintain their effectiveness over time, encouraging continuous learning and improvement. Sustainability, within the context of the DSF, refers to the ongoing ability of an intervention to maintain its effectiveness and relevance over time within a real-world setting. To achieve sustainability, interventions must continuously adapt to changing conditions and needs, as depicted in FIGURE 3.

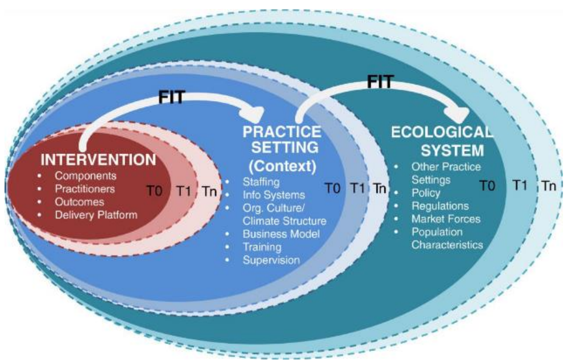


FIGURE 3: THE DYNAMIC SUSTAINABILITY FRAMEWORK (CHAMBERS ET AL., 2013)

To effectively implement an intervention using the DSF, it is crucial to consider the diverse environmental factors that influence its effectiveness. Additionally, a comprehensive understanding of the intervention and its potential impacts is necessary due to its inherent complexity. The DSF also emphasizes the importance of adaptability, enabling interventions to evolve and remain effective in response to changing needs and circumstances.

Overall, the DSF provides a flexible and dynamic approach to implementing interventions. It serves as a valuable tool in guiding the implementation process and maximizing its success.

For this study, the DSF offers a guide to instrumentalize the findings and inform the successful implementation of AI methods for sustainability in (bio)pharmaceutical manufacturing processes.

SYNERGY OF THEORIES

Integrating the three abovementioned theoretical perspectives provides a comprehensive approach to understanding and implementing AI for sustainability in (bio)pharmaceutical manufacturing processes. STT offers a lens to examine the dynamics of transitioning towards more sustainable practices, highlighting the importance of radical innovations and the multi-dimensional aspects of sustainability. RI complements this by emphasizing the ethical and societal aspects of these transitions, advocating for stakeholder engagement and anticipatory governance. It provides a normative approach to guide technological development in a socially acceptable and environmentally sustainable manner. On the other hand, DSF focuses on the practical implementation of these innovations, emphasizing the importance of context, complexity, and adaptation for long-term sustainability.

While each theory has its unique focus, they overlap in their emphasis on stakeholder engagement, anticipation of potential outcomes, and the need for continuous adaptation in response to changing circumstances. They differ in their level of focus, with STT concentrating on broader societal and industry-level changes, RI focusing on the ethical and societal aspects of individual innovations, and DSF centering on the practical implementation of these innovations. However, they complement each other by providing a holistic view of the transition towards sustainability, from the societal and industry-level changes required (STT), to the ethical considerations and stakeholder engagement needed (RI), and the practical aspects of implementing these changes (DSF).

Together, they provide a robust theoretical foundation for this study, guiding the exploration of key considerations for integrating AI methods for optimizing sustainability in (bio)pharmaceutical manufacturing processes.

METHODS

The following chapter provides a comprehensive overview of the research design employed in this study, detailing the processes of data collection and analysis. It also discusses the subsequent application of the collected and analyzed data. Furthermore, this chapter addresses the measures taken to ensure the reliability and validity of the research findings, as well as the ethical considerations adhered to throughout the study.

RESEARCH DESIGN

This study adopted a mixed methods research (MMR) approach, primarily focusing on qualitative research through a literature review and interviews, with a quantitative survey serving as a supplementary component. This approach allows to construct, confirm, and theorize based on the analysis and interpretation of mixed-method data. It also helps to explain contradictory outcomes from different methods, producing more credible findings by converging data from multiple sources. This convergence strengthens research conclusions and implications, as results from one method can inform or develop findings from another. Additionally, a mixed-method design enhances the complementarity of research by using separate yet dialectically related approaches, ultimately extending the breadth and range of inquiry (Dawadi et al., 2021; Bryman, 2006; Bryman 2016).

The literature review, interviews, and survey each play complementary roles in this study. The literature review primarily focuses on the technical aspects, aiming to identify potential AI methods that could be employed and the most feasible sustainability parameters to be improved. On the other hand, the interviews are designed to provide insights into the social and organizational aspects, such as potential barriers to implementation, existing knowledge gaps, and perspectives on AI and sustainability. Finally, the survey serves a dual purpose. It not only provides additional insights into the social and organizational aspects but also assesses the feasibility of improving specific sustainability parameters with AI.

LITERATURE REVIEW

The literature review aimed to identify the specific AI methods that have been used to improve sustainability in various manufacturing industries and the sustainability parameters they have impacted.

For this study, a semi-systematic review was chosen due to its practical advantages over a fully systematic review. The topic of AI utilization across various fields is researched by diverse groups, making the comprehensive review of every potential article an impractical endeavor (Wong et al., 2013). A semi-systematic approach therefore presents a pragmatic solution, recognizing the challenge of including every relevant article while still ensuring a thorough review process (Hall et al., 2016).

Zunder (2021, p.2) describes this method as "rigorous but flexible," and its application as increasingly prevalent in different contexts. Fisch and Block (2018, p.104) emphasize that a semi-systematic review aims to "summarize and categorize knowledge," thereby providing a thorough understanding of the subject matter. Furthermore, Wong et al. (2013) suggest that this approach enhances understanding by synthesizing relevant topics through meta-narratives, eliminating the need for quantitative measures such as effect sizes typically used in meta-analyses (Snyder, 2019).

In general, this semi-systematic literature review served as the foundational element for this study (Kraus et al., 2022), as it aimed to examine the application of AI in enhancing sustainability in various manufacturing sectors, with a specific focus on identifying the AI methods utilized and the sustainability parameters they have impacted. This approach involved reviewing relevant academic publications to distill insights into current practices and trends (Rudnicka & Owen, 2012).

The combination of keywords utilized in the search strategy encompassed the following terms:

- “artificial intelligence” AND
- “sustainability” AND
- “manufacturing”

The use of these keywords aimed to enhance the likelihood of capturing a diverse range of relevant literature. Furthermore, selection criteria were applied to filter the retrieved articles and reports. These criteria included:

1. **Publication Date:** To ensure the inclusion of recent advancements and developments, preference was given to articles published since 2014.
2. **Peer-Reviewed Status:** Priority was given to peer-reviewed articles to maintain a high standard of academic rigor and credibility.

3. **Open Access:** As a master student at Utrecht University, the researcher focused on articles and reports that are freely accessible to them and do not require a paid subscription.

4. **Relevance:** Articles and reports must directly address or provide substantial insights into the integration of AI technologies for sustainability of manufacturing processes.

OCLC's WorldCat.org was chosen as the singular database for this literature review due to its comprehensiveness and global reach. As one of the world's largest networks of library content, WorldCat provides access to a diverse collection of resources from thousands of libraries worldwide (Wakeling et al., 2017). This ensured a broad range of sources for the literature review, increasing the likelihood of capturing all relevant studies. Additionally, WorldCat's advanced search and discovery features facilitate efficient exploration of these resources.

The steps undertaken for this semi-systematic review are based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines, which aim to enhance transparency, credibility, and reproducibility (Page et al., 2021).

The process of identifying relevant literature for the final analysis in a literature review, as illustrated in FIGURE 4, involves several key stages. Initially, 106 records were identified through a database search using a previously defined combination of keywords, focusing on peer-reviewed articles within the timeframe of 2014 to 2024. After removing duplicates, non-English, and non-accessible records, 99 records remained. During the screening phase, abstracts were reviewed, and 7 non-applicable records were excluded due to their lack of coverage on AI and sustainability in the context of manufacturing. The remaining 69 records were then assessed for full-text reading. Of these, 30 records were excluded because they did not cover the use of AI to improve sustainability. Ultimately, 16 records were included in the final review.

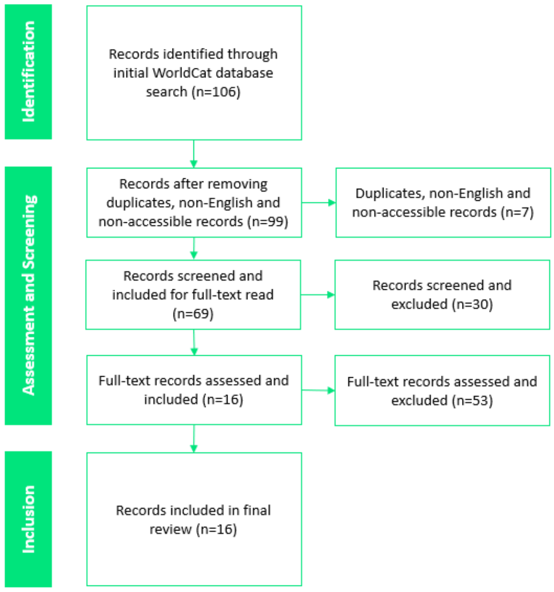


FIGURE 4: PROCESS OF IDENTIFYING RELEVANT LITERATURE

To ensure a systematic analysis of the relevant papers, the following guiding questions have been phrased:

- Which sustainability parameter was most frequently targeted for optimization using AI techniques in the relevant records?
- Which AI technique was most commonly employed or referenced for optimizing sustainability parameters?
- How was the AI technique applied to enhance the specific sustainability parameter?
- What were the outcomes of applying the AI technique to the specific sustainability parameter(s)?
- What challenges were encountered during the application process, and how were these addressed?

This approach provides a structured and consistent framework for evaluating each paper, ensuring a comprehensive and thorough review process. It also helps to focus the review on the specific research questions of the study, enabling a targeted and efficient exploration of the literature. Moreover, it facilitates the extraction of key insights and findings from each paper, which can be synthesized to answer the research questions.

SEMI-STRUCTURED INTERVIEWS

The implementation of semi-structured interviews aimed to further enrich the data collected through the literature review, allowing for the exploration of nuanced perspectives from key stakeholders, including industry professionals, AI experts, and sustainability specialists, which were purposively selected to ensure a diverse range of insights.

The interviews provide qualitative data, offering in-depth insights into the experiences and perspectives of professionals in the field. A primary advantage of semi-structured interviews is their flexibility, which allows the researcher to explore new topics that arise during the conversation while maintaining comparability across interviews. This method provides rich, detailed data and helps build rapport, leading to more honest and insightful responses. Additionally, interviewers can clarify and probe deeper into responses, enhancing the quality of the data collected. However, potential limitations include interviewer bias, the time-consuming nature of conducting and analyzing interviews, and the challenge of ensuring consistency across different interviewers (Magaldi and Berler, 2020).

The interview questions were informed by the theoretical concepts of Sustainability Transitions Theory and Responsible Innovation, which provide a robust framework for understanding the dynamics of sustainable innovation and the role of AI in this process.

A total of seven interviews were conducted, with six interviewees employed at pharmaceutical companies and one interviewee working at a tech startup closely collaborating with pharmaceutical firms. The interviewees were selected to provide a representative insight into various fields, including sustainability and circular economy, artificial intelligence and data science, as well as engineering technologies. This diverse selection ensures a comprehensive understanding of the intersection between artificial intelligence and sustainability from multiple professional perspectives.

The researcher, who served as a thesis intern from February 2024 until the end of August 2024, shared a common employer with six of the seven interviewees. This unique position as an insider-researcher offered several advantages. Firstly, it allowed for enhanced access to the organization and its stakeholders, which facilitated richer data collection through informal conversations. Secondly, the pre-existing relationships within the company likely fostered a level of trust that led to more open and honest responses from the interviewees. Lastly, the researcher's familiarity with the company's culture and processes offered valuable context for interpreting the data (Unluer, 2015; Warner, 2024; McKenzie & Bartunek, 2023).

However, this insider-researcher role also introduced several limitations. The potential for a lack of objectivity was present, as personal experiences and biases could color the interpretation of data. The researcher might also face role conflict, having to balance responsibilities as an employee and a researcher. Over-familiarity with the research context could lead to assumptions or blind spots, and the challenge of establishing and maintaining professional boundaries when researching within one's own organization was a potential issue (Unluer, 2015; Warner, 2024; McKenzie & Bartunek, 2023).

Despite these limitations, the benefits of being an insider-researcher significantly compensated for the small sample size of the interviews. The multi-method nature of the study further mitigated these limitations. Objectivity was regained by not solely relying on insights from the interviews but also by combining, comparing, and enriching them with findings from the literature review and the survey. This approach ensured a comprehensive and balanced understanding of the research topic.

The semi-structured format of the interview guide (see Appendix) allowed for flexibility while maintaining consistency across participants. Additionally, it included questions tailored to the expertise of each interviewee. The duration of the interviews varied, reflecting the depth of responses provided by the participants. The shortest interview lasted about 35 minutes, while the longest extended to about 120 minutes.

To analyze the interview data, thematic analysis was selected due to its ability to identify, analyze, and report patterns within qualitative data (Braun and Clarke, 2006). It offers flexibility in coding and theme development, aligning with the semi-structured interviews and diverse expertise of the participants. Despite potential limitations such as time consumption, interpretative skill requirement, and possible researcher bias, it is deemed suitable for handling large volumes of qualitative data, like the extensive interview transcripts collected in this study (Naeem et al., 2023).

ONLINE SURVEY

Conducting a survey has been chosen for this study due to several key advantages. Surveys are cost-effective and time-efficient, allowing researchers to gather data from a larger number of respondents without significant financial or temporal investment. The ease of data collection is another benefit, as surveys can be distributed and completed online, reaching a wide audience quickly. This method is also convenient for respondents, who can complete the survey at their own pace and at a time that suits them, contributing to a quick turnaround in data collection (Bhattacherjee, 2019).

However, there are limitations to this approach, such as low response rates, which can impact the representativeness of the data. Additionally, respondents may misunderstand questions, leading to inaccurate responses. Finally, surveys typically provide limited depth of information, as they do not allow for the exploration of complex issues in the same way that qualitative methods, such as interviews, do (Brewer et al., 2015).

Despite these limitations, the advantages make surveys a suitable choice for this study. As part of a multi-methods research approach, combined with the literature review and interviews, the survey provides a valuable quantitative angle. This integration allows for a broader perspective and the possibility of statistical analysis, thereby enhancing the robustness and generalizability of the findings.

The conducted survey consisted of a series of questions designed to gather data on the perceptions, experiences, and practices of a larger sample of professionals working in or closely with the pharmaceutical industry. These questions were primarily closed-ended, combining single choice, multiple choice as well as ranking questions, and allowing for clear, concise responses that can be easily quantified. Moreover, some open-ended questions were included to capture additional qualitative insights (see Appendix).

The '2nd Sustainable Medicine and Environment' summit, held in Munich on 22nd and 23rd of May 2024, served as the initial platform for the online survey conducted via Microsoft Forms. The summit attendees, representing various stakeholders from the pharmaceutical industry with expertise in sustainability topics, provided an optimal environment for initiating the survey. Subsequently, the survey was disseminated to multiple departments within Boehringer Ingelheim, including Development Operations, Data Science, and Legal Affairs. This strategic selection of participants ensured a diverse range of perspectives and backgrounds, enriching the survey's results. The survey concluded on 8th of July 2024 with a total of 48 participants.

The majority of the participants (44) were employees of pharmaceutical companies, while the remaining 4 represented external stakeholders from academia and public affairs. Most participants were from Austria, and nearly half had been working in the pharmaceutical sector for over a decade. The participants represented a variety of roles within the pharmaceutical industry, with the majority (23 out of 48 participants) working in manufacturing and operations. Only 13% of the participants stated that their roles did not involve any sustainability-related activities. More than 75% of the participants were at least slightly familiar with AI technologies and their application in the pharmaceutical industry.

RELIABILITY, VALIDITY AND ETHICS

To enhance the reliability of the study, a meticulous and systematic research design has been adopted. This includes clearly defined operationalization of key concepts, rigorous criteria for data collection, and a detailed description of the research procedures. Furthermore, the triangulation of data from multiple sources, including the systematic literature review, interviews, and concluding case study, serves to cross-verify findings and enhance the overall reliability of the study.

Validity was maintained through careful consideration of the study's design, data collection methods, and the alignment of research instruments with the research question. The semi-systematic literature review was designed to encompass a broad range of relevant studies, ensuring that the findings are representative of the current landscape of AI implementation across different manufacturing industries. Moreover, the use of semi-structured interviews and a survey allowed for a nuanced exploration of diverse stakeholder perspectives, contributing to the internal validity of the findings.

The ethical dimensions of this study were underpinned by a firm commitment to safeguarding the rights and well-being of all involved stakeholders. The study was conducted in adherence to established ethical principles, and particular attention was given to the ethical challenges arising from the sensitive nature of the data. As this thesis was part of an internship at Boehringer Ingelheim RCV GmbH & Co KG, a Non-Disclosure Agreement (NDA) was signed to protect any confidential information the intern might access during the research project. It is important to note that the NDA did not compromise the independence or scientific integrity of the study, as no sensitive information was required to answer the research questions. The researcher, with support from the university's data privacy officer, ensured that appropriate measures were taken to prevent any information traceable to individual participants from being shared with the company. Additionally, any un-anonymized data was stored only on university servers and was deleted once the anonymization process was completed.

In the context of semi-structured interviews and the survey, explicit and informed consent was obtained from all participants. The consent form clearly outlined the purpose of the study, the nature of participation, and the use and protection of the collected data. Participants were assured of confidentiality, and their voluntary participation was emphasized. Only the researcher had access to the raw data, while all other parties only saw the edited data and analysis results, ensuring that participants' anonymity was maintained.

This study aligned with General Data Protection Regulation (GDPR) guidelines. Privacy and data protection were prioritized throughout the research process. Measures were in place to ensure the secure handling and storage of personal information, safeguarding the privacy rights of participants.

FINDINGS

This section consolidates the key findings from the literature review, in-depth interviews, and survey, providing a comprehensive understanding of the research topic and addressing the core research questions and objectives. The literature review offered insights into the technical aspects, identifying specific sustainability parameters for optimization with AI and the most suitable AI methods for this purpose. The interviews shed light on social and organizational dimensions, highlighting potential barriers to implementation, existing knowledge gaps, and perspectives on AI and sustainability. The survey further explored these social and organizational aspects, assessing the feasibility of enhancing specific sustainability parameters with AI.

SUSTAINABILITY PARAMETER

The findings from the literature review, interviews, and survey revealed a multifaceted perspective on the most feasible sustainability parameters in pharmaceutical manufacturing that could be optimized using AI techniques. However, it was important to note that the literature review findings were considered the most accurate due to their basis in comprehensive research and expert analysis, whereas the interview and survey inputs might have reflected personal opinions rather than established facts.

The literature review consistently identified energy efficiency as the primary sustainability parameter optimized through AI-based methods. This focus on energy efficiency was due to its significant impact on operational costs, resource utilization, and environmental sustainability (Arana-Landín et al., 2023; Asif et al., 2023; Azizi, 2020; Hsu et al., 2023; Othman & Yang, 2023; Tang et al., 2024a; Willenbacher et al., 2021). The emphasis on energy efficiency aligned with the survey results, where high energy consumption was highlighted as the most significant sustainability challenge by 40% of participants. Additionally, the majority of survey participants also believed that energy consumption was the most feasible parameter to improve with AI integration.

In contrast, the interview findings presented a more diverse set of opinions. Interviewees 1, 3, and 5, emphasized the importance of optimizing carbon emissions due to their substantial impact on climate change. They argued that reducing carbon emissions could lead to improvements in other areas, such as waste reduction and energy consumption. This perspective was partially supported by the survey, where GHG emissions were also considered a critical parameter by many participants.

Other interviewees highlighted different sustainability parameters. Interviewee 2 focused on water usage, stressing the need to minimize water waste and address environmental concerns related to pharmaceuticals in water supplies. Interviewee 6 emphasized the optimization of raw materials, noting that AI could significantly enhance sustainability in this area. Interviewee 7, aligning with the literature review and survey, underscored the importance of optimizing energy consumption, particularly in energy-intensive clean rooms.

The survey findings further supported the notion that process optimization was viewed as the most effective method for addressing sustainability challenges, with over half of the participants endorsing this approach. Additionally, the survey revealed that AI integration was perceived to offer several advantages, including improved efficiency, enhanced decision-making, and cost savings. These benefits were echoed by the interviewees, who highlighted the potential of AI in real-time monitoring and optimization of sustainability-relevant parameters.

In summary, while energy efficiency emerged as a common priority across the literature review, survey, and some interviews, the literature review findings were deemed the most accurate. This was because not all interviewees and survey participants possessed expert knowledge on the topic, and their inputs might have reflected personal opinions rather than established facts.

Consequently, the findings concluded that energy efficiency was the most feasible sustainability parameter to optimize with AI techniques. Carbon emissions, water usage, resource efficiency, and raw material optimization were also identified as essential areas for AI-driven sustainability improvements. This diversity of perspectives underscored the complexity of achieving sustainability in pharmaceutical manufacturing and the need for a multifaceted approach that leveraged AI to address various environmental and operational challenges. However, the literature review’s emphasis on energy efficiency should be considered the most reliable basis for future research and practical applications in this field.

AI TECHNIQUE

The findings from the literature review and interviews revealed a comprehensive understanding of the application of AI techniques to enhance process sustainability, with a particular emphasis on machine learning. The literature review identified ML as the most used AI technique, applied in various ways to optimize sustainability parameters in (bio)pharmaceutical manufacturing processes. Specifically, 9 out of the 16 relevant records covered its application (Abidi et al., 2022; Çınar et al., 2020; Cioffi et al., 2020; Hsu et al., 2023; Jung et al., 2021; Othman & Yang, 2023; Turner et al., 2022; Uwamungu et al., 2022; Willenbacher et al., 2021). This included improving energy efficiency through data analysis from sensors and smart meters, developing predictive maintenance models to forecast equipment failures, and enhancing product quality by predicting and controlling quality outcomes (Abidi et al., 2022; Çınar et al., 2020; Hsu et al., 2023; Jung et al., 2021).

The interviewees generally supported the findings from the literature, highlighting the flexibility and predictive capabilities of AI in optimizing resource consumption and process efficiency. For instance, Interviewee 1 emphasized AI's ability to model processes based on input and output data, which simplified the complex task of modeling sustainability parameters. This aligned with the literature's focus on ML's role in improving energy efficiency and predictive maintenance. Similarly, Interviewee 3 underscored the importance of AI techniques that handled large datasets and provided predictive analytics, resonating with the literature's emphasis on ML's application in process optimization and waste reduction.

Interviewee 4, on the other hand, presented a more cautious view, suggesting that AI should be part of a broader strategy that included scientific breakthroughs and efficient research processes. Interviewees 6 and 7 further diversified the discussion by emphasizing the importance of selecting AI techniques based on specific models and data as well as advocating for a combination of tools and methods depending on the use case.

In summary, the convergence of these findings underscored the potential of AI, particularly ML, in optimizing sustainability parameters, while also highlighting the need for a nuanced and flexible approach to AI implementation.

DATA MANAGEMENT

A predominant theme across all sources was the critical importance of high-quality data. Both the literature and interviewees emphasized that data integrity and completeness were essential for accurate predictions and optimal outcomes. Poor data quality could significantly hinder the effectiveness of AI algorithms, as noted by multiple studies (Çınar et al., 2020; Abidi et al., 2022) and interviewees. This sentiment was echoed in the survey, where participants identified data availability and quality as the most significant barriers to AI implementation.

Another common challenge highlighted was the complexity of integrating diverse data sources. The literature pointed out that data in manufacturing environments often came from various sensors, smart meters, and IoT devices, making integration into a cohesive dataset challenging but necessary for comprehensive analysis and optimization (Hsu et al., 2023; Arana-Landín et al., 2023). Interviewee 1 and

Interviewee 7 also stressed the importance of integrating data from various systems into a centralized data lake, noting that the challenge lay not in data availability but in effective access and curation.

The complexity of data analysis was another significant challenge identified in both the literature and interviews. The use of sophisticated algorithms and machine learning models required a deep understanding of data structures and effective data preprocessing, including tasks such as data cleaning, normalization, and feature selection (Asif et al., 2023; Jung et al., 2021). Interviewee 2 and Interviewee 6 further emphasized the need for comprehensive data collection, including both structured and unstructured data, to uncover hidden relationships and optimize processes effectively.

Furthermore, Interviewee 1 highlighted the need for data specific to individual processes within the manufacturing environment, such as measuring energy input and output for specific processes like fermentation. This level of detail was crucial for identifying specific energy consumption hotspots and accurately calculating the environmental impact of substances used in biopharmaceutical manufacturing. Additionally, they highlighted the importance of understanding the processes and reasons behind AI-driven optimizations to maintain and tweak them as needed over time.

Finally, both the literature and interviews highlighted the need for extensive historical data to train machine learning models effectively. Without sufficient historical data, models might not perform well, leading to less reliable predictions and outcomes (Çınar et al., 2020; Reuter, 2016). Interviewees 4 and 5 also stressed the importance of data accessibility and quality, advocating for better digitalization and data sharing practices to enhance data utilization.

In summary, the findings from the different data sources converged on the importance of high-quality data, the complexity of data integration and analysis, and the need for comprehensive and specific data collection. These insights underscored the necessity of robust data management strategies and interdisciplinary collaboration to successfully implement AI methods for sustainability enhancement in (bio)pharmaceutical manufacturing.

CAPABILITY BUILDING AND EXPERTISE

The findings from both the literature review and interviews converged on several key points regarding capability building and expertise. There was a consensus on the shortage of skilled personnel capable of managing and analyzing the complex data required for utilizing AI applications. This skill gap was highlighted in the literature (Azizi, 2020; Uwamungu et al., 2022) and echoed by several interviewees who emphasized the need for continuous learning and training to keep up with rapidly evolving AI technologies.

The importance of continuous learning and improvement was also noted. Interviewee 2 emphasized the need for continuous learning to ensure the long-term effectiveness and reliability of AI-driven sustainability initiatives. Hsu et al. (2023) and Othman and Yang (2023) discussed the need for ongoing education and training to keep the workforce updated with the latest developments in AI technologies. Interviewee 2 also stressed the importance of having a strong background in data science, programming, and quality management to effectively implement AI solutions.

Both sources underscored the importance of interdisciplinary collaboration. Çınar et al. (2020) argued that successful AI implementation required the integration of knowledge from data scientists, engineers, and manufacturing professionals. This view was supported by Interviewee 6, who pointed out the necessity of collaboration between data scientists and subject matter experts (SMEs) to bridge the gap between data gathering and interpretation.

However, there were notable differences. While some interviewees, such as Interviewee 4 and Interviewee 7, believed that there was sufficient expertise and skilled human capital available for implementing AI solutions, others, like Interviewee 3, identified a significant skill gap that needed to be addressed. This discrepancy highlighted the varying perceptions of the current state of expertise within the industry.

Additionally, the literature placed a strong emphasis on the need for investing in talent development and fostering a culture of innovation and continuous improvement (Willenbacher et al., 2021). This was somewhat less emphasized in the interviews, where the focus was more on immediate training and collaboration needs.

In summary, both the literature and interview findings highlighted the critical need for skilled personnel, interdisciplinary collaboration, and continuous learning to successfully implement AI technologies in manufacturing settings. However, there were differing views on the current state of expertise and the emphasis on long-term talent development versus immediate training needs.

CHANGE MANAGEMENT AND SUSTAINABILITY INTEGRATION

A recurring theme regarding change management and the mindset shift necessary for implementing AI to optimize sustainability parameters was the critical role of leadership commitment and stakeholder engagement. Interviewees consistently emphasized the necessity of securing support from leadership to drive the adoption of AI technologies. Interviewee 1 highlighted that commitment from leadership was essential to foster a shift in mindset towards embracing AI and sustainability. This sentiment was echoed by Interviewee 2, who stressed the importance of leadership support for AI initiatives. The survey findings also supported this view, with 35% of participants identifying strong leadership and commitment from industry stakeholders as key success factors for promoting the widespread adoption of AI technologies for sustainability.

Interviewees underscored the importance of breaking mental barriers and embracing a more comprehensive approach to data analysis. Interviewee 2 advocated for moving beyond traditional methods to include all potential data inputs, while Interviewee 3 emphasized the need for stakeholders to accept and adapt to new technologies and processes. Interviewee 5 pointed out that the pharmaceutical industry's historical focus on time to market had led to neglecting sustainable practices, advocating for embedding sustainability into day-to-day decision-making. This aligned with the survey findings, where participants highlighted the importance of demonstrated cost savings and operational efficiencies as key success factors for AI adoption.

Integrating sustainability into the long-term vision and strategy of organizations was another central theme. Interviewees consistently stressed the importance of embedding sustainability into the core operations and strategic planning of companies. Interviewee 1 highlighted the need for sustainability to be part of the organization's long-term vision, emphasizing continuous improvement and resource allocation for sustainability initiatives. Similarly, Interviewee 7 underscored the importance of considering sustainability from the outset of product development, advocating for closer collaboration between development and operations to ensure long-lasting impacts on sustainability.

Another key aspect discussed was the necessity of organizational commitment and leadership in driving sustainability initiatives. Interviewee 3 argued that leaders must be actively involved in the journey towards sustainability, setting ambitious goals and aligning resources to achieve them. This sentiment was echoed by Interviewee 5, who emphasized that sustainability should be embedded into all processes and decisions, requiring a systemic change in how the pharmaceutical industry operates. The need for a clear framework and long-term commitment to ensure sustained progress was also highlighted by Interviewee 3.

Interviewee 4 stressed the need for a long-term commitment to sustainability driven by regulatory frameworks that enforce the internalization of environmental and social costs. They believed that sustainable practices should be economically incentivized through proper cost accounting, ensuring that all harmful impacts are accounted for in production costs. This perspective introduced the idea of regulatory and economic incentives as drivers for sustainability, which was less emphasized by other interviewees who focused more on internal organizational commitment and leadership.

In summary, both the interview and survey findings highlighted the critical need for leadership commitment, stakeholder engagement, a significant mindset shift, and continuous learning to successfully implement AI technologies for optimizing sustainability parameters in the (bio)pharmaceutical industry. Integrating sustainability into the long-term vision and strategy of organizations, driven by strong leadership and organizational commitment, is essential. Continuous learning and improvement are necessary to maintain the effectiveness of AI-driven sustainability initiatives, with differing views on the role of regulatory frameworks and economic incentives in driving sustainability.

OPEN INNOVATION AND KNOWLEDGE SHARING

The interviewees consistently emphasized the benefits of collaborating with academic partners, industry players, and other stakeholders to drive faster progress and innovation. Interviewee 1 highlighted the value of sharing knowledge and best practices within the industry, while Interviewee 2 noted that collaboration and sharing of data and models could significantly accelerate innovation. This sentiment was echoed by Interviewee 3, who advocated for collaboration among stakeholders to achieve common sustainability goals. The survey findings supported this view, with 67% of participants believing that knowledge sharing and collaboration were very important for advancing AI-driven sustainability initiatives.

Interviewees believed that sharing data, models, and best practices could lead to significant advancements in sustainability. Interviewee 5 argued that sharing data and best practices could reduce redundancy and accelerate the adoption of sustainable practices. Interviewee 6 supported the idea of transparent sharing of AI techniques while protecting sensitive data and saw conferences as key platforms for knowledge sharing and collaboration. The survey findings also highlighted the benefits of open innovation, with 40% of participants believing that it improved problem-solving capabilities, 33% citing access to diverse ideas and perspectives, and 19% noting faster innovation.

Interviewee 7 acknowledged the challenges of knowledge sharing due to intellectual property concerns but believed that companies already shared what they could. This concern was reflected in the survey findings, where 44% of participants identified the risk of IP theft as the main challenge of embracing open innovation. Additionally, 25% of participants cited overcoming organizational resistance as a significant challenge.

The role of collaboration between different types of stakeholders was emphasized, with interviewees and survey participants highlighting the importance of cooperation between pharmaceutical companies, academia, and external AI technology providers. Interviewee 3 highlighted the need for collaboration between companies, academia, and other industries to drive innovation and achieve sustainability goals. The survey findings indicated that the majority of participants ranked collaboration between pharma companies and academia/research institutions or external AI technology providers as the most necessary for successful implementation of AI-driven sustainability initiatives.

In summary, both the interview and survey findings highlighted the critical need for open innovation and knowledge sharing practices to drive the implementation of AI for optimizing sustainability parameters in the (bio)pharmaceutical industry. While there were significant benefits to collaboration and sharing of knowledge and resources, challenges such as intellectual property concerns and organizational resistance had to be addressed.

RESPONSIBLE INNOVATION

Another notable theme was the importance of data security and privacy. The literature review highlighted the critical need for robust cybersecurity measures to protect sensitive operational data in manufacturing processes, ensuring the protection of intellectual property and maintaining stakeholder trust and regulatory compliance (Othman & Yang, 2023; Turner et al., 2022). This concern was echoed by Interviewee 7, who stressed the need for clear guidelines and discussions with stakeholders to address data security and privacy concerns, particularly when monitoring employees with AI technologies.

Ethical considerations in AI implementation were also emphasized. Interviewees consistently underscored the importance of prioritizing ethical considerations to ensure responsible AI use. Interviewee 1 emphasized the responsibility of companies to consider their impact on society and the environment. Interviewee 2 highlighted the need to understand potential biases in data and the implications of AI outputs, advocating for a cautious approach where AI-generated results were thoroughly evaluated and verified by humans before implementation. This aligned with the survey findings, where most participants identified accountability and transparency, as well as data privacy and security, as the most relevant ethical considerations for guiding AI development and deployment.

The need for a cautious and well-considered approach to AI implementation was another critical aspect. Interviewee 4 emphasized the importance of using AI and other technologies to genuinely improve sustainability without causing unintended harm. They advocated for aligning AI implementation with broader sustainability goals and ethical considerations. Interviewee 5 supported this view, suggesting that the pharmaceutical industry should consider the broader implications of their products, including potential adverse effects on the environment and public health, advocating for a more holistic approach to innovation.

However, there were notable differences in perspectives. While some interviewees, such as Interviewee 6, emphasized the importance of not replacing people with AI and ensuring that AI complemented human expertise, others, like Interviewee 3, focused more on the need to respect nature and comply with ethical guidelines and regulations. This introduced a broader view of responsible innovation that included both human and environmental considerations.

In summary, both the literature and interview findings highlighted the critical need for robust data security and privacy measures, prioritizing ethical considerations, and adopting a cautious and well-considered approach to AI implementation to ensure responsible innovation. However, there were differing views on the specific aspects of responsible innovation, with some emphasizing the protection of human expertise and job security, while others focused on broader environmental and regulatory considerations.

DISCUSSION

This master thesis extends current theoretical insights (Weaver et al., 2022) and contributes to the existing literature by exploring the necessary considerations for implementing AI methods for sustainability in the pharmaceutical industry at the firm level. It addresses the need for guidance in this implementation process (Patel & Rabizadegan, 2021; Arias et al., 2023) and offers practical recommendations to facilitate it.

The insights from this study greatly contribute to the Industry 4.0 transformation within the pharmaceutical industry by highlighting key aspects for integrating AI methods to enhance sustainability practices. This integration is pivotal as it aligns with the core principles of Industry 4.0, which emphasize the use of advanced technologies to create more efficient, flexible, and sustainable production processes (Sharma et al., 2023). By offering practical recommendations, this research not only bridges the gap between theoretical concepts and real-world applications but also empowers pharmaceutical firms to adopt AI-driven sustainability initiatives effectively.

Additionally, the study facilitates the initiation of this integration process for pharmaceutical companies by providing clear recommendations on the sustainability parameter to focus on—energy efficiency—and the AI methods to utilize for that purpose, specifically machine learning. This targeted guidance helps firms prioritize their efforts and resources, ensuring a more streamlined and effective implementation of AI-driven sustainability practices.

Furthermore, this study sheds light on the controversial topic of intellectual property rights (IPRs) and their role in potentially hindering knowledge exchange regarding sustainability practices in the pharmaceutical industry (Vimalnath et al., 2023). The research highlights how stringent IPR can create barriers to the open sharing of innovative sustainability solutions, which is crucial for collective progress. By addressing these challenges, the study advocates for a balanced approach to IPR that protects innovations while fostering an environment conducive to knowledge exchange and collaborative efforts towards sustainability.

To achieve both immediate impact and long-term adaptability in enhancing the sustainability of pharmaceutical processes, this thesis contextualizes its findings within the Dynamic Sustainability Framework:

1. **Intervention**

The intervention involves implementing process optimization software that leverages machine learning techniques to enhance energy efficiency or consumption as a process parameter. This requires comprehensive data on energy consumption and efficiency across entire manufacturing processes or specific manufacturing steps. The practitioners involved must be equipped with knowledge in data science, have a deep understanding of the processes targeted for optimization, and be literate in sustainability. The expected outcome is improved energy efficiency in manufacturing processes. This intervention is delivered within pharmaceutical companies and their locations, as well as through collaborations between different pharmaceutical companies.

2. **Practice Setting**

The successful implementation of the intervention requires a well-prepared practice setting. This includes adequate human and financial resources to support the intervention, involving the hiring of skilled practitioners with expertise in data science, process optimization, and sustainability, as well as allocating a budget for necessary tools and technologies. An efficient information system is essential to facilitate the sharing of learnings and achievements across the organization, enabling real-time data access and communication among team members to ensure that best practices and successful strategies are disseminated effectively. A comprehensive strategy for training and supervising staff is vital, including regular training sessions to keep the team updated on the latest techniques and technologies in process optimization and sustainability, and supervision to ensure that the intervention is implemented correctly and consistently. Effective data management is critical for the success of the intervention, involving the collection, storage, and analysis of data on energy consumption and efficiency. A robust data management strategy ensures data accuracy, security, and accessibility, enabling informed decision-making.

Additionally, the practice setting should foster a mindset change that views sustainability as a core business objective rather than a ‘nice-to-have.’ This involves promoting the importance of sustainability throughout the organization and encouraging employees to integrate sustainable practices into their daily operations. Strong commitment from leadership is necessary to drive the intervention forward, with leaders actively supporting sustainability initiatives, demonstrating their importance through actions and resource allocation. Highlighting the cost savings achieved through the intervention can reinforce its value, as demonstrating tangible financial benefits helps to secure ongoing support and investment in sustainability efforts.

3. Ecological System

Within the ecological system of the intervention, it is required to stay up to date of policies and regulations that may support or hinder the utilization of AI in this context.

The DSF emphasizes that change is a constant factor at these three levels, influencing each other. For an intervention to be successful and sustainable, it must fit well within the practice setting and the broader ecological system. This fit should be continuously monitored and adjusted using reliable and relevant measures. The DSF expects that interventions, practice settings, and the ecological system will evolve over time, especially when data indicates potential improvements to better serve its purpose, enhance skills, and utilize resources effectively (Chambers et al., 2013).

To build upon the findings, future research should investigate how the optimization of one sustainability parameter affects other parameters. For instance, optimizing energy consumption might have implications for resource input, greenhouse gas emissions, waste generation, and water consumption. Understanding these interdependencies is crucial for developing holistic and effective sustainability strategies. Additionally, exploring which machine learning technique—whether supervised learning, unsupervised learning, reinforcement learning, or others—is most suitable for optimizing process parameters such as energy consumption is a critical next step, as each technique has its respective strengths and weaknesses (Wang et al., 2020).

While this research offers valuable insights, several limitations must be acknowledged. Firstly, six of the seven interviewees were employed at the company where the researcher conducted the thesis internship, potentially introducing bias as participants' opinions could be influenced by their affiliation with the hosting organization. Additionally, it must be emphasized that the findings from the interviews and surveys reflect individual opinions and perspectives, which may be subjective and biased, impacting the collected data. Furthermore, the accuracy and honesty of respondents' answers heavily depend on their ability to provide accurate information.

The research may also be limited by the scope of the literature reviewed, focusing only on literature published since 2014 and using only one database. Additionally, the dynamic nature of AI technology and sustainability practices may lead to evolving challenges that were not fully addressed in the study.

To mitigate these limitations, the researcher deliberately employed a mixed methods research approach, incorporating a comprehensive literature review to add a third, more objective data source. This approach aimed to triangulate the findings, enhancing the overall validity and reliability of the results, thereby ensuring that the research still provides valuable and credible insights. To address the additional limitations, future research should consider expanding the scope of the literature review to include multiple databases and a broader range of publication years. Additionally, ongoing updates and reviews should be conducted to account for the rapidly evolving nature of AI technology and sustainability practices.

Based on the research findings, several recommendations can be made that have managerial and policy implications. Firstly, it is recommended that pharmaceutical companies develop a clear strategy for data collection, management, and utilization. This will ensure that the data collected can be effectively utilized for the implementation of AI techniques to optimize sustainability parameters. Secondly, ensuring sustainability literacy among experts involved in the implementation process of AI techniques for sustainability purposes is crucial. This includes data scientists, manufacturing and operation experts, and other relevant professionals. By equipping them with the necessary knowledge and skills, companies can optimize the integration of AI technologies in sustainable practices. Lastly, there is a need to restructure pharmaceutical intellectual property rights. Currently, IPRs often protect information that could and should be shared with other stakeholders, especially when it is not related to therapeutic composition or their specific manufacturing steps. By reevaluating and reforming IPRs, pharmaceutical companies can foster collaboration and knowledge sharing, ultimately contributing to more sustainable practices across the entire industry.

CONCLUSION

The primary research question that guided this study was: "*What are the key considerations for successfully integrating AI methods for optimizing sustainability in (bio)pharmaceutical manufacturing processes?*" Additionally, two sub-questions were explored:

a. *Which sustainability parameters in (bio)pharmaceutical manufacturing can feasibly be adjusted or optimized with the help of AI?*

b. *Which AI methods are most likely to optimize the identified sustainability parameters in (bio)pharmaceutical manufacturing processes?*

The study, which combined a literature review, interviews, and a survey, revealed that the most feasible parameter to optimize with the help of AI was found to be energy consumption. In general, AI was identified as a tool that can and should be used for optimization of process parameters, monitoring, adaptive decision-making, and predictive maintenance. The literature review suggests that machine learning is the most appropriate AI technique for these purposes, given its successful use in other industries. Open-innovation and knowledge sharing were recognized as valuable tools for the development and diffusion of innovative sustainability practices, but established IPRs within the pharma industry create difficulties to engage in these activities.

Several obstacles to the successful utilization of AI methods for optimizing sustainability parameters were identified, including challenges with data quality and availability, integration into existing systems, skill gaps, organizational resistance, ethical and privacy concerns, economic and regulatory factors, and the need for a significant mindset shift towards embracing AI and sustainability.

Key considerations for successfully integrating AI methods for optimizing sustainability in (bio)pharmaceutical manufacturing processes were identified. These include:

- **Data Availability and Quality:** Ensuring access to high-quality data is crucial, as the effectiveness of AI models heavily relies on the data used for training and analysis. Organizations must focus on aggregating data into centralized systems, such as data lakes, to facilitate comprehensive analysis and model development.

- **Capability Building and Expertise:** There is a need for significant expertise and knowledge within organizations to effectively utilize AI technologies. This includes training personnel to understand AI applications and fostering a culture that embraces data science and AI-driven decision-making. Additionally, it needs to be ensured that these individuals also have sustainability literacy.

- **Change Management and Mindset Shift:** Organizations must be prepared for cultural shifts to overcome resistance to change. This involves building trust in data and AI outcomes, which is critical for successful implementation.

- **Sustainability Integration and Long-term Commitment:** Achieving sustainability goals, including net-zero emissions, is a long-term endeavor. Organizations must commit to persistent efforts and align their strategies with Sustainable Development Goals (SDGs). These goals should also be integrated into the organization's business model, ensuring that sustainability is a core component of their operations and decision-making processes.

- **Open Innovation and Knowledge Sharing:** Embracing open innovation approaches to accelerate AI-driven sustainability initiatives. Balancing intellectual property protection with collaborative innovation is crucial.

- **Responsible Innovation:** Addressing ethical implications of AI, such as potential job displacement and ensuring AI outputs are accurate and unbiased.

While there are challenges to integrating AI for sustainability in (bio)pharmaceutical manufacturing, they are not insurmountable. With careful consideration of the identified key factors and a commitment to innovative practices, AI can play a crucial role in optimizing sustainability in this sector.

APPENDIX

LITERATURE REVIEW OVERVIEW

Reference	Sustainability Parameters	AI methods	Application of AI	Outcomes	Challenges and Resolutions
Abidi, M. H., Mohammed, M. K., & Alkhalefah, H. (2022). Predictive maintenance planning for Industry 4.0 using machine learning for sustainable manufacturing. Sustainability, 14(6), 3387.	Operational efficiency and maintenance costs.	J-SLnO (Joint Stochastic Learning and Optimization) algorithm. This algorithm is specifically designed to improve predictive maintenance planning by leveraging machine learning capabilities.	The J-SLnO algorithm was applied in the context of improving the sustainability parameter of operational efficiency by predicting equipment failures before they occur. This proactive approach allows for timely maintenance actions, which can significantly reduce unplanned downtime and associated costs.	improved prediction accuracy for maintenance scheduling, leading to reduced maintenance costs and enhanced operational efficiency. This ultimately contributes to more sustainable manufacturing practices by minimizing resource waste and optimizing machine utilization.	Limitations of existing algorithms in handling diverse operational scenarios and the need for accurate data for effective predictions. To overcome these challenges, the paper suggests enhancing the J-SLnO algorithm's capabilities and integrating it with other advanced machine learning techniques to better address the complexities of predictive maintenance in various industrial contexts.
Arana-Landín, G., Uriarte-Gallastegi, N., Landeta-Manzano, B., & Laskurain-Iturbe, I. (2023). The contribution of Lean Management—Industry 4.0 technologies to improving energy efficiency. Energies, 16(5), 2124.	Energy efficiency.	Use of advanced analytics, particularly through the integration of big data and data analytics tools. These techniques were utilized to analyze the impact of various Industry 4.0 technologies on energy efficiency and quality management variables.	The application of data analytics involved conducting descriptive studies to calculate means and variances of quality management variables and energy efficiency. Additionally, correlation analyses were performed to explore the relationships between these variables, which provided insights into how quality management practices influence energy performance in industrial settings.	The outcomes of applying this AI technique for the specific sustainability parameter of energy efficiency included an observed improvement in energy performance, with findings suggesting that energy efficiency can improve by 15% to 25% when Industry 4.0 technologies are integrated into production processes. This demonstrates the significant potential of these technologies to enhance sustainability in industrial operations.	Difficulties in data collection and the need for a comprehensive understanding of the adoption process of Industry 4.0 technologies. To overcome these challenges, the article suggests that further research should focus on gathering more extensive data and exploring the experiences of companies with these technologies. Additionally, classifying analyses based on different applications across various sectors could provide more targeted insights, although this would require sufficient data and experience in those specific contexts.
Asif, M., Shen, H., Zhou, C., Guo, Y., Yuan, Y., Shao, P., Xie, L., & Bhutta, M. S. (2023). Recent Trends, Developments, and Emerging Technologies towards Sustainable Intelligent Machining: A Critical Review, Perspectives and Future Directions. Sustainability, 15(10), 8298.	Machining process efficiency (machining time, energy consumption, surface quality).	Back-propagation neural network (BPNN). This technique was specifically mentioned in the context of optimizing cutting parameters, demonstrating its relevance in enhancing machining processes.	BPNN was applied to develop a mathematical model that aimed to minimize machining time, energy consumption, and surface roughness. The model incorporated various cutting parameters, including spindle speed, path spacing, and depth of cut, to achieve optimized results.	BPNN application exhibited better performance compared to traditional approaches, leading to improved efficiency in the machining process and enhanced quality of the produced parts. The accuracy of the predictions made by the AI methodology was reported to be close to 98%, indicating a significant advancement in machining quality prediction.	Complexity of data mapping and the need for automatic feature selection. These challenges can be overcome by further refining the AI algorithms and integrating more robust data processing techniques, which would enhance the overall effectiveness of AI in optimizing sustainability parameters in machining processes.
Azizi, A. (2020). Applications of Artificial intelligence techniques to enhance Sustainability of Industry 4.0: Design of an artificial neural network model as dynamic behavior Optimizer of robotic arms. Complexity, 2020, 1–10.	Energy efficiency and waste generation.	Genetic Algorithm (GA); recognized as a well-known evolutionary optimization technique that was employed to find optimal parameters for the gimbal joints in robotic arms, which are essential for enhancing their performance.	The genetic algorithm was applied to optimize the highly nonlinear fitness function associated with the gimbal mechanisms of robotic arms. The GA was used to determine the optimal design parameters, such as truncation angles, which are crucial for achieving maximum force in the robotic arms. However, due to the time-consuming nature of the GA, an artificial neural network (ANN) was developed to model the behavior of the GA and act as a function optimizer, thereby streamlining the optimization process	The proposed ANN model demonstrated the ability to replace the complex and time-consuming GA in finding optimal parameters for the gimbal joints. The results indicated that increasing the number of neurons in the ANN led to a decrease in the number of iterations required to achieve a mean square error approaching zero, thereby enhancing the performance of the neural network and confirming its effectiveness as an optimizer for robotic applications.	Inherent time consumption associated with the genetic algorithm and the need for extensive training data for the ANN. To overcome these challenges, the research suggests utilizing other well-known optimization techniques, such as hybrid optimization methods, bee colony algorithms, and particle swarm optimization, as reference models to train the proposed neural networks. This approach could enhance the efficiency and effectiveness of the ANN in real-life industrial implementations.
Chatterjee, S., Chaudhuri, R., Kamble, S., Gupta, S., & Sivarajah, U. (2022). Adoption of Artificial Intelligence and Cutting-Edge Technologies for production system Sustainability: A Moderator-Mediation	Product system sustainability.	Big data analytics (BDA) was noted for its significant role in improving production system sustainability by enabling firms to analyze vast amounts of data, leading to better	AI techniques, particularly big data analytics, were applied to enhance operational performance sustainability. This application involved leveraging data-driven insights to optimize production processes,	Improved operational performance and enhanced firm performance. The study indicated that the adoption of AI and other cutting-edge technologies positively influenced production system	Technology turbulence, which could negatively impact the adoption and effectiveness of these technologies. To overcome these challenges, the study suggested that firms should focus on improving their dynamic capabilities and providing appropriate training

Analysis. Information Systems Frontiers, 25(5), 1779–1794.		decision-making and operational efficiencies.	reduce waste, and improve resource utilization, thereby contributing to overall sustainability goals.	sustainability, leading to measurable improvements in efficiency and effectiveness within firms.	to employees. Regular workshops and training sessions could help employees adapt to new technologies, thereby mitigating the adverse effects of technology turbulence and ensuring successful implementation of AI and other cutting-edge technologies.
Çınar, Z. M., Nuhu, A. A., Zeeshan, Q., Korhan, O., Asmael, M., & Safaei, B. (2020). Machine Learning in Predictive Maintenance towards Sustainable Smart Manufacturing in Industry 4.0. Sustainability, 12(19), 8211.	Manufacturing process efficiency.	Machine learning (ML) has been recognized as a powerful tool that can be applied to various applications, including predictive maintenance, to enhance the sustainability of manufacturing systems.	Machine learning was applied to enhance the efficiency of manufacturing processes. By leveraging data generated from industrial operations, ML algorithms can predict equipment failures and optimize maintenance schedules, thereby ensuring that machines operate at peak efficiency and reducing unnecessary downtime.	The outcomes of applying machine learning for improving efficiency in manufacturing processes were notable. The use of these AI techniques led to increased operational efficiency, reduced maintenance costs, and improved reliability of equipment. This, in turn, contributed to a more sustainable manufacturing environment by minimizing resource consumption and waste generation.	Issues related to data quality, the need for extensive historical data for effective algorithm training, and the integration of machine learning systems with existing manufacturing processes. To overcome these challenges, it is crucial to enhance data collection practices, ensure the accuracy and completeness of data, and promote collaboration between data scientists and manufacturing professionals to facilitate the successful implementation of AI technologies in manufacturing settings.
Cioffi, R., Travaglioni, M., Piscitelli, G., Petrillo, A., & De Felice, F. (2020). Artificial intelligence and Machine learning applications in smart Production: progress, trends, and directions. Sustainability, 12(2), 492.	Manufacturing process quality.	Machine learning (ML) was particularly noted for its ability to analyze large datasets and identify patterns that can lead to more efficient manufacturing processes.	Machine learning was applied to preprocess value series data, which in turn enhanced the quality of processes and products. This application allowed for better decision-making based on data-driven insights, ultimately contributing to more sustainable manufacturing practices.	Improved quality control and optimization of manufacturing systems. These advancements not only led to higher product quality but also promoted sustainable practices across various aspects of manufacturing, such as supply chain management and energy consumption.	Challenges in incorporating AI technologies into existing manufacturing systems. To overcome these challenges, the article suggests that a more conceptual and empirical investigation is necessary, along with a focus on developing frameworks that facilitate the adoption of these technologies in a sustainable manner.
Hsu, C., Jiang, B., & Lin, C. (2023). A survey on recent applications of artificial intelligence and optimization for smart grids in smart manufacturing. Energies, 16(22), 7660.	Energy efficiency.	The AI technique most commonly utilized or referenced for process and sustainability optimization was machine learning. This technique was frequently mentioned in the context of analyzing data and improving energy management within smart manufacturing systems, showcasing its relevance in enhancing operational efficiency.	In the context of improving energy efficiency, machine learning was applied to optimize load control and power scheduling. By analyzing data collected from smart meters and other IoT devices, machine learning algorithms were able to provide insights that led to more effective energy consumption strategies, thereby contributing to sustainability efforts.	The outcomes of applying machine learning for energy efficiency included significant improvements in energy savings and cost reductions. For instance, the article notes that efficient energy usage scheduling resulted in an energy efficiency increase of 129% and a 28% reduction in electricity costs. These results demonstrate the tangible benefits of integrating AI technologies into manufacturing processes.	Complexity of integrating diverse energy sources into the smart grid, as well as issues related to cybersecurity and the need for skilled personnel in AI technologies. To overcome these challenges, the article suggests enhancing cross-domain knowledge, investing in talent development, and implementing robust cybersecurity measures to protect the data and systems involved in smart manufacturing.
Jung, H., Jeon, J., Choi, D., & Park, J.-Y. (2021). Application of machine learning techniques in injection molding quality prediction: Implications on sustainable manufacturing industry. Sustainability, 13(8), 4120.	Product quality.	Machine learning (ML), specifically various algorithms such as tree-based algorithms, regression-based algorithms, and autoencoders. These techniques were employed to predict the quality of injection-molded products, demonstrating their relevance in addressing sustainability challenges within the manufacturing sector.	ML was applied to analyze and predict the factors influencing quality outcomes.	The study confirmed that machine learning models could capture complex relationships between input variables and product quality, with the autoencoder model showing superior performance in terms of accuracy, precision, recall, and F1-score. This application of AI techniques aimed to enhance the overall quality of products, thereby contributing to sustainable manufacturing practices.	Sensitivity of machine learning algorithms to the types and sizes of input data, which necessitated careful selection of appropriate algorithms for specific manufacturing contexts. To overcome these challenges, the article suggests the need for further research that focuses on developing explainable models and adapting the structure of deep learning techniques. This approach would enhance understanding of the factors influencing outcomes and improve the applicability of AI in the injection molding industry, ultimately supporting sustainable manufacturing goals.
Othman, U., & Yang, E. (2023). Human–robot collaborations in smart manufacturing environments: Review and outlook. Sensors, 23(12), 5663.	Energy consumption.	Machine Learning (ML), particularly valued for its ability to analyze large datasets and identify patterns that can lead to improved decision-making in manufacturing processes.	In the context of improving energy consumption, machine learning was applied to optimize manufacturing processes by predicting energy usage and identifying inefficiencies. This application allows manufacturers to adjust operations in real-time, leading to more sustainable	Significant reductions in energy usage and operational costs. By leveraging data analytics, manufacturers were able to tailor their processes to be more energy-efficient, resulting in enhanced sustainability and productivity.	Complexity of integrating AI systems into existing manufacturing frameworks and the need for comprehensive training programs for employees. To overcome these challenges, the article suggests that manufacturers should invest in ongoing training and development to ensure that operators are well-equipped to adapt to new technologies and that ethical considerations are

			practices and reduced energy waste.		addressed to safeguard data privacy and security.
Reuter, M. A. (2016). Digitalizing the circular economy. Metallurgical and Materials Transactions B, 47(6), 3194–3220.	Resource efficiency.	Big data analysis, particularly through the use of neural networks. These techniques have been applied since the early 1990s to model complex metallurgical processes and improve the understanding of thermodynamic relationships and kinetics within metallurgical reactors.	BDA was applied to optimize metallurgical processes by capturing real-time data and providing insights into the operational parameters of reactors. This optimization allowed for better decision-making regarding the use of materials and energy, ultimately leading to enhanced resource efficiency in the production and recycling of metals.	Improved process optimization and enhanced understanding of the metallurgical systems. This led to a more effective closure of material cycles and a reduction in environmental impacts associated with metal production and recycling, thereby contributing positively to sustainability goals.	Calibration of unit operation models from poorly defined data. To overcome these challenges, it is essential to develop robust analysis tools and sensors that can accurately measure and calibrate the necessary data from industrial materials, recyclates, and residues. By addressing these data variances and improving the quality of input data, the effectiveness of AI applications in optimizing sustainability parameters can be significantly enhanced.
Tang, J., Wang, T., Xia, H., & Cui, C. (2024a). An overview of artificial intelligence application for optimal control of municipal solid waste incineration process. Sustainability, 16(5), 2042.	GHG emissions, energy efficiency and operational performance..	Particle Swarm Optimization (PSO); this technique is noted for its effectiveness in optimizing manipulated and controlled variables within the MSWI process, thereby contributing to improved operational outcomes.	Particle Swarm Optimization was applied to enhance the control mechanisms of the MSWI process. It facilitated the optimization of various operational parameters, which in turn helped in achieving better combustion control and efficiency, ultimately leading to a more sustainable waste management process.	The outcomes of applying Particle Swarm Optimization in this context included improved energy efficiency and reduced emissions, which are critical for meeting sustainability goals. The application of this AI technique demonstrated significant potential in optimizing the operational aspects of the MSWI process, thereby contributing to enhanced environmental performance.	Challenges arose during the application process, particularly concerning the direct applicability of current AI algorithms due to the constraints of existing Distributed Control Systems (DCS) and safety requirements within MSWI enterprises. To overcome these challenges, the establishment of a hardware-in-loop simulation experimental platform is deemed necessary for testing and validating AI algorithms in industrial settings. This approach would facilitate a more robust integration of AI techniques into the operational framework of MSWI, enhancing their universality and applicability in real-world scenarios.
Tang, Q., Lee, Y., & Jung, H. (2024b). The industrial application of artificial intelligence-based optical character recognition in modern manufacturing innovations. Sustainability, 16(2), 2161.	Operational efficiency.	Deep learning, specifically through the implementation of a comprehensive OCR system. This system was designed to automate the registration of iron plates, addressing the unique challenges posed by industrial environments with limited data availability	Deep learning was applied through the development of a robust OCR pipeline that included data acquisition, a neural network model for text recognition, and a Graphical User Interface (GUI) for seamless integration into existing industrial processes. Additionally, synthetic image generation and strong data augmentation strategies were employed to enhance recognition accuracy and mitigate the challenges of insufficient training data	Significant improvements in the efficiency of iron plate registration processes, leading to substantial reductions in both time and labor costs for factories. The system's ability to accurately and rapidly process information also contributed to better resource allocation and waste reduction, which are crucial for sustainable industrial practices	Scarcity of training data, which is a common issue in industrial settings. This challenge was addressed through the innovative use of synthetic image generation and data augmentation techniques, which effectively enhanced the robustness and accuracy of the OCR system. By replicating real-world conditions and augmenting the training dataset, the study was able to overcome the limitations posed by insufficient data
Turner, C., Oyekan, J., Garn, W., Duggan, C., & Abdou, K. (2022). Industry 5.0 and the Circular Economy: Utilizing LCA with Intelligent Products. Sustainability, 14(22), 14847.	Carbon emissions.	Machine learning is applied in the context of improving sustainability parameters by enabling real-time monitoring of resource use and emissions through intelligent products. This application facilitates more sustainable manufacturing and maintenance practices.	AI methods are applied by enabling real-time monitoring of production processes, allowing for adaptive decision-making that incorporates human input; this approach supports product disassembly and maintenance processes, enhancing the sustainability of manufacturing operations.	The outcomes of applying machine learning for the reduction of carbon emissions include improved efficiency in resource utilization and enhanced product lifecycle management. This leads to a decrease in waste and supports sustainability goals in manufacturing.	Complexity of integrating AI systems with existing manufacturing processes and the necessity for high-quality data for effective machine learning model training. Overcoming these challenges involves investing in robust data collection systems and promoting collaboration between human workers and AI technologies.
Uwamungu, J. Y., Kumar, P., Alkhayyat, A., Younas, T., Capangpangan, R. Y., Alguno, A. C., & Ofori, I. (2022). Future of Water/Wastewater Treatment and Management by Industry 4.0 Integrated Nanocomposite Manufacturing. Journal of Nanomaterials, 2022, 1–11.	Water quality.	Artificial neural networks (ANN), due to their ability to represent complex processes and predict outcomes effectively in water treatment applications. Additionally, other machine learning techniques such as genetic algorithms and AdaBoost were also mentioned as part of the framework for enhancing the performance of water treatment processes.	ANNs were applied to predict the adsorption capacity of nanocomposite materials for removing various contaminants from water. The models utilized operational datasets to forecast the effectiveness of different adsorbents, thereby optimizing the pollutant removal processes.	Significant improvements in the accuracy of predictions regarding the effectiveness of various adsorbents. This led to enhanced decision-making in water treatment processes, resulting in cost savings and improved environmental protection through more efficient contaminant removal.	Need for high-quality operational datasets and the complexity of the data involved. To overcome these challenges, it is essential to develop robust data collection methods and improve the integration of AI models, such as ANNs and genetic algorithms, with existing water treatment systems, ensuring that these models can be effectively utilized in real-world applications.

Willenbacher, M., Scholten, J., & Wohlgemuth, V. (2021). Machine learning for optimization of energy and plastic consumption in the production of thermoplastic parts in SME. Sustainability, 13(12), 6800.	Energy consumption and material usage.	Machine learning (ML) methods to analyze data from manufacturing processes, aiming to optimize energy consumption and reduce waste in the production processes.	Machine learning was applied to train data sets that revealed optimization opportunities in energy and plastic consumption during the production of thermoplastic parts. The project aimed to leverage current information technologies to facilitate sustainable digitalization, thereby reducing the environmental impact of the industry.	Increased efficiency in production processes and a reduction in the environmental footprint associated with energy and material usage. The application of these AI techniques demonstrated the potential for significant improvements in sustainability metrics within the SMEs involved.	SMEs often perceived digitalization as complex and expensive, leading to hesitance in adopting AI technologies. Additionally, a lack of internal expertise and resources made implementation difficult. To overcome these challenges, it is essential to provide targeted support and training for SMEs, as well as to simplify the integration of AI technologies into existing processes, thereby fostering a more conducive environment for digital transformation.

INTERVIEW GUIDE

Introduction

Thank you for participating in this interview. Your expertise and perspective are valuable in addressing key research questions related to this topic. Please note that all questions in this interview are designed to gather your personal opinions and perspectives. There are no right or wrong answers – your individual insights are what matter most. All questions are specifically related to the field of (bio)pharmaceutical manufacturing processes (etc.)

Background Information

1. What is your primary role and responsibility within the pharmaceutical industry?
2. How many years of professional experience do you have in the pharmaceutical industry?

Sustainability Challenges

3. What does sustainability within the (bio)pharmaceutical industry mean to you?
4. From your viewpoint, what do you consider to be the most pressing sustainability issues that the (bio)pharmaceutical industry is currently facing?
5. Can you elaborate on the different approaches you are aware of that are being employed to address these sustainability issues?
6. What opportunities does sustainability within the (bio)pharmaceutical industry present to you, and which ones are crucial to pursue?

In-depth questions on sustainability for environmental/sustainability experts

7. Do you believe that current sustainability practices within (bio)pharmaceutical manufacturing are sufficiently addressing environmental concerns? Why or why not?
8. In your experience, what are the key obstacles or barriers preventing the adoption of sustainable practices in (bio)pharmaceutical manufacturing? How can these be overcome?
9. How would you assess the level of awareness and understanding of sustainability concepts among stakeholders within the (bio)pharmaceutical manufacturing sector?
10. Looking ahead, what future trends or developments do you foresee in terms of sustainable practices and technologies within the (bio)pharmaceutical manufacturing landscape?

Sustainability Parameters and AI Methods

11. What does the term 'sustainability parameter' mean to you?

In the context of this study, sustainability parameters refer to specific aspects or indicators within (bio)pharmaceutical manufacturing processes that can be measured, monitored, and optimized to enhance sustainability. These factors are related to the environmental impact of (bio)pharmaceutical manufacturing processes and encompass energy consumption, water usage, waste generation, GHG emissions and raw material efficiency.

12. In your opinion, what is the key sustainability parameter faced in (bio)pharmaceutical manufacturing that should be improved?
13. In your opinion, what are the key sustainability parameters faced in (bio)pharmaceutical manufacturing that could benefit from AI integration?

In the context of this study, AI technologies refer to a range of computational algorithms and machine learning approaches utilized for process optimization. These include methods such as machine learning, predictive maintenance, optimization algorithms, natural language processing (NLP), digital twins, etc.

14. Can you think of any advantages or additional benefits associated with implementing AI methods to optimize sustainability in (bio)pharmaceutical manufacturing processes?
15. Can you think of any challenges associated with implementing AI methods to optimize sustainability in (bio)pharmaceutical manufacturing processes? How would you suggest addressing them?
16. In your view, what role does organizational commitment and leadership play in driving the adoption of AI for sustainability goals in the (bio)pharmaceutical sector?

In-depth questions on AI methods for process engineers/manufacturing experts

17. What specific sustainability challenges do you encounter in (bio)pharmaceutical manufacturing that you believe AI technologies could effectively address?
18. What are the primary barriers or challenges you foresee in implementing AI-driven sustainability initiatives within (bio)pharmaceutical manufacturing processes?
19. From your perspective, what types of data and information are critical for training AI models to optimize sustainability parameters in (bio)pharmaceutical manufacturing processes? How accessible are these data sources?
20. Do you believe there are sufficient experts or personnel with necessary skills and knowledge to effectively implement AI technologies for sustainability within (bio)pharmaceutical manufacturing? If not, what strategies could be employed to bridge this gap?
21. How can process engineers/manufacturing specialists contribute to the development and implementation of AI-driven sustainability initiatives within their organization?

In-depth questions on AI methods for AI/ data science experts

22. As an AI/ data science expert, what specific sustainability challenges do you encounter in (bio)pharmaceutical manufacturing that you believe AI technologies could effectively address?

23. How would you assess the current readiness of AI technologies to address sustainability challenges in (bio)pharmaceutical manufacturing?
24. In your opinion, what are the most promising AI techniques or algorithms that could be leveraged to optimize sustainability parameters within (bio)pharmaceutical manufacturing processes?
25. What types of data would you consider essential for training AI models to optimize sustainability in (bio)pharmaceutical manufacturing?
26. In your opinion, how can AI-driven sustainability initiatives be effectively integrated with existing manufacturing systems and processes in (bio)pharmaceutical settings?
27. What do you believe is important to ensure the long-term effectiveness and reliability of AI-driven sustainability initiatives?
28. Do you believe there are currently sufficient expertise and skilled human capital available to implement AI solutions for sustainable manufacturing processes?
29. From your perspective, what are the most promising future trends or developments in AI that could significantly advance sustainability goals in the (bio)pharmaceutical industry?

Responsible Innovation

30. In your view, what are the key factors critical to ensuring the successful implementation of AI-driven sustainability initiatives within the pharmaceutical manufacturing sector?
31. How can organizations foster a culture of innovation and experimentation to drive proactive engagement with AI-driven sustainability initiatives?
32. What ethical considerations should be prioritized when applying AI methods to optimize sustainability in (bio)pharmaceutical manufacturing?
33. Can you reflect on past initiatives where technological innovation was used to enhance sustainability in pharmaceutical manufacturing? What were the outcomes and lessons learned?
34. How do regulatory requirements and standards influence the implementation of technological innovations such as AI for sustainable manufacturing in the (bio)pharmaceutical sector?

Knowledge-Sharing

35. What do you believe has the biggest influence on the development and diffusion of AI-related knowledge?
36. How do you view the importance of knowledge sharing and collaboration among stakeholders (in advancing AI-driven sustainability initiatives) within the (bio)pharmaceutical manufacturing sector?
37. In your opinion, which types of knowledge-sharing relationships (such as industry-industry or industry-academia) should be emphasized and why?
38. Can you share examples of successful knowledge-sharing initiatives that have promoted the integration of technological innovations such as AI (into sustainable practices) in (bio)pharmaceutical manufacturing?
39. What is your perspective on open innovation approaches in the pharma sector?
40. In your opinion, what are the benefits and challenges of embracing open innovation approaches to drive the utilization of AI for sustainability in the pharmaceutical industry?

41. From your experience, how can companies strike a balance between protecting their IP assets and fostering collaborative innovation in the context of AI-driven sustainability initiatives?

SURVEY LAYOUT

You are invited to take part in this study on the utilization of artificial intelligence (AI) in (bio)pharmaceutical manufacturing. The purpose of the study is to learn about the key considerations for integrating AI methods for improving sustainability in (bio)pharmaceutical manufacturing processes. The study is conducted by Sophia Ester Neudeck who is a student in the MSc program Sustainable Business and Innovation at the Department of Sustainable Development, Utrecht University and intern at Boehringer Ingelheim RCV GmbH & Co KG, Vienna. The study is supervised by Dr. Susan van Hees from Utrecht University and Natalie Egreteau from Boehringer Ingelheim.

Your participation in this survey is completely voluntary. You can quit at any time without providing any reason and without any penalty. Your contribution to the study is very valuable to us and we greatly appreciate your time taken to complete this survey. We estimate that it will take approximately 10-20 minutes to complete this survey. Some of the questions require little time to complete, while other questions might need more careful consideration. The data is processed confidentially and in accordance with data protection legislation (the General Data Protection Regulation and Dutch Personal Data Act). For more information on how Utrecht University handles privacy-related issues, you can visit the website *uu.nl/privacy*, and contact the Data Protection Officer with questions and complaints about privacy via *fg@uu.nl*.

Informed Consent

In this study we want to learn about the integration of AI methods for optimizing sustainability in (bio)pharmaceutical manufacturing processes. Participation in this survey is voluntary and you can quit the survey at any time without giving a reason and without penalty. We will process your personal data confidentially and in accordance with data protection legislation (the General Data Protection Regulation and Dutch Personal Data Act). People with access to the original data have signed a privacy agreement. Boehringer Ingelheim will only have access to the anonymized survey answers and the results of their analysis. Please respond to the questions honestly. Everything you say will be confidential and anonymous. This means that we do not collect any personal information that could be used to identify you.

I confirm that:

- I am satisfied with the received information about the research;
- I have no further questions about the research at this moment;
- I had the opportunity to think carefully about participating in the study;
- I will give an honest answer to the questions asked.

I agree that:

- the data to be collected will be obtained and stored securely for scientific purposes;
- the collected, completely anonymous, research data can be shared and re-used by scientists to answer other research questions;

1. the anonymized research data can be accessed and re-used by Boehringer Ingelheim for scientific purposes.Do you agree to participate?

- Yes
- No

Introduction

Thank you for participating in this survey. Your expertise and perspective are valuable in addressing key research questions related to this topic. Please note that all questions in this survey are designed to gather your personal opinions and perspectives. There are no right or wrong answers – your individual insights are what matter most. All questions are specifically related to the field of (bio)pharmaceutical manufacturing processes.

2. Please indicate your role within the pharmaceutical industry.

   - Research and Development (R&D)
   - Manufacturing and Operations
   - Legal/ Regulatory Affairs
   - Sustainability/ Corporate Responsibility
   - Quality Assurance/ Control
   - Academic Professional

3. How many year of experience do you have working in/with the (bio)pharmaceutical sector?

   - Less than 1 year
   - 1-5 years
   - 6-10 years
   - More than 10 years

4. In which country are you currently employed?

   ----

5. Which stakeholder group do you primarily represent?

   - Academic institutions
   - Pharmaceutical companies
   - Government agencies/ regulatory bodies
   - Non-governmental organizations (NGOs)
   - Industry associations
   - Other:

6. To what extent does your current role involve activities related to sustainability initiatives?

   - Extensively involved
   - Moderately involved
   - Slightly involved
   - Not involved at all

Artificial Intelligence (AI) Technologies and Sustainability

In the context of this study, AI technologies refer to a range of computational algorithms and machine learning approaches utilized for process optimization. These include methods such as machine learning, predictive maintenance, optimization algorithms, natural language processing (NLP), digital twins, and more.

The concept of sustainability, in this study, primarily pertains to its environmental dimension. In this context, sustainability refers to the long-term preservation and protection of the natural environment. It involves various aspects, such as reducing carbon emissions, conserving resources, promoting eco-friendly practices, and mitigating the impact of human activities on the planet. While sustainability also encompasses social and economic factors, it's important to note that this study will primarily focus on the environmental perspective of sustainability.

7. How familiar are you with artificial intelligence (AI) technologies and their application in the (bio)pharmaceutical industry?

    - Very familiar
    - Moderately familiar
    - Slightly familiar
    - Not familiar at all

8. What does environmental sustainability within the (bio)pharmaceutical industry primarily mean to you?

    - Minimizing environmental impact
    - Efficient use of resources
    - Minimizing waste
    - Compliance with environmental regulations
    - Other:

9. Please rank the significance of the following (environmental) sustainability challenges currently faced by the (bio)pharmaceutical industry (1=most significant).

    - High energy consumption
    - Excessive waste generation
    - Greenhouse gas (GHG) emissions
    - Wastewater/ water contamination

10. Is there any other* sustainability challenge that you perceive as significant? *That has not been mentioned as an option previously.

    ____

11. Which of the following methods are you aware of for addressing sustainability challenges in the (bio)pharmaceutical industry?

    - Process optimization
    - Use of renewable resources
    - Use of renewable energy sources
    - Waste reduction
    - Recycling and reuse of materials
    - None of the above
    - Other:

12. Which of the following methods do you believe is most effective for addressing sustainability challenges in the (bio)pharmaceutical industry?

    - Process optimization
    - Use of renewable resources
    - Use of renewable energy sources
    - Waste reduction
    - Recycling and reuse of materials

Sustainability Parameters

In the context of this study, sustainability parameters refer to specific aspects or indicators within (bio)pharmaceutical manufacturing processes that can be measured, monitored, and optimized to enhance sustainability. These factors are related to the environmental impact of (bio)pharmaceutical manufacturing processes and encompass energy consumption, water usage, waste generation, greenhouse gas emissions and raw material efficiency.

13. Which sustainability parameter do you believe is most feasible* to be improved in (bio)pharmaceutical manufacturing? Please rank the following options (1=most feasible).

    **In this context, feasibility means determining wether it is realistically achievable or viable to optimize a sustainability parameter in pharmaceutical manufacturing. It involves assessing factors such as technical capabilities, available resources, cost-effectiveness, and potential impact on the overall manufacturing process.*

    - Energy consumption
    - Water usage
    - Waste generation
    - Greenhouse gas (GHG) emissions
    - Raw material efficiency

14. Is there any other* sustainability parameter you consider feasible to be improved in (bio)pharmaceutical manufacturing? *That has not been mentioned as an option previously.

    ----

15. Which sustainability parameter do you believe could benefit from AI integration the most?

    - Energy consumption
    - Water usage
    - Waste generation
    - Greenhouse gas (GHG) emissions
    - Raw material efficiency
    - I prefer not to answer due to insufficient knowledge.
    - Other.

16. From your professional perspective, what do you believe is the main advantage of implementing AI methods to optimize sustainability in (bio)pharmaceutical manufacturing?

    - Improved efficiency
    - Cost savings
    - Enhanced decision making

- Increased product quality
- Other:

17. Are there any other* advantages of implementing AI technologies for sustainability within (bio)pharmaceutical manufacturing? *That have not been mentioned as an option previously.

    ----

18. Please rank the following challenges/barriers foreseen in implementing AI technologies for sustainability within (bio)pharmaceutical manufacturing (1=most challenging).

    - Data availability and quality
    - Data privacy and security
    - Cost of technology adoption
    - Regulatory constraints
    - Resistance to change within the organization
    - Lack of skilled personnel
    - Ethical considerations
    - Lack of technological infrastructure

19. Are there any other* challenges/barriers you foresee in implementing Ai technologies for sustainability within (bio)pharmaceutical manufacturing? *That have not been mentioned as an option previously.

    ----

20. What additional resources or support do you believe is necessary to accelerate the adoption of AI technologies for sustainability in (bio)pharmaceutical manufacturing? Please rank the following options (1=most necessary).

    - Increased funding for R&D
    - Enhanced collaboration among industry stakeholders
    - Regulatory incentives or guidance
    - Training programs for AI implementation
    - Improved technological infrastructure

21. Are there any other* additional resources which you believe are necessary to accelerate the adoption of AI technologies for sustainability in (bio)pharmaceutical manufacturing? *That have not been mentioned as an option previously.

Open Innovation and Ethics

22. In your opinion, how important is knowledge sharing and collaboration among stakeholders in advancing AI-driven sustainability initiatives within the (bio)pharmaceutical manufacturing sector?

    - Very important
    - Moderately important
    - Slightly important
    - Not important at all

23. What kind of collaboration or partnerships do you believe is necessary to successfully implement AI-driven sustainability initiatives in (bio)pharmaceutical manufacturing? Please rank the following options (1=most necessary).

    - Collaboration among pharmaceutical companies
    - Collaboration between pharmaceutical companies and academia/research institutions
    - Partnerships among pharmaceutical companies and government agencies/regulatory bodies
    - Collaboration between pharmaceutical companies and external AI technology providers
    - Partnerships among pharmaceutical companies and NGOs/community organizations

24. Is there any other* kind of collaboration or partnership you believe is necessary to successfully implement AI-driven sustainability initiatives in (bio)pharmaceutical manufacturing? *That has not been mentioned as an option previously.

    ----

25. What do you believe is the main benefit of embracing open innovation approaches to drive sustainability through AI technology implementation in the (bio)pharmaceutical industry?

    - Increased collaboration between stakeholders
    - Faster innovation
    - Access to diverse ideas and perspectives
    - Improved problem-solving capabilities

26. What do you believe is the main challenge of embracing open innovation approaches to drive sustainability through AI technology implementation in the (bio)pharmaceutical industry?

    - Risk of intellectual property (IP) theft
    - Managing collaboration and communication among diverse stakeholders
    - Ensuring quality and relevance of contributions
    - Overcoming organizational resistance
    - Other:

27. What do you believe has the biggest influence on the development and diffusion of AI-related knowledge?

    - Academic research
    - Industry collaboration (between pharmaceutical companies)
    - Government initiatives
    - Technological advancements
    - Other:

28. In your opinion, what are relevant ethical considerations that should guide the development and deployment of AI technologies for sustainability in (bio)pharmaceutical manufacturing? Please rank the following options (1=most relevant).

    - Fairness and bias mitigation
    - Data privacy and security
    - Accountability and transparency
    - Inclusivity and stakeholder engagement

29. Are there any other* relevant key ethical consideration that should guide the development and deployment of AI technologies for sustainability in (bio)pharmaceutical manufacturing? *That have not been mentioned as an option previously.

   ----

30. In your opinion, what is the key success factor for promoting widespread adoption of AI technologies for sustainability across the (bio)pharmaceutical industry?

   - Strong leadership and commitment from industry stakeholders
   - Collaboration with regulatory agencies to streamline approval processes
   - Demonstrated cost savings and operational efficiencies
   - Public awareness and support for sustainable practices
   - Other:

Final Remarks

31. Is there anything else you would like to share or any additional remarks you would like to make?

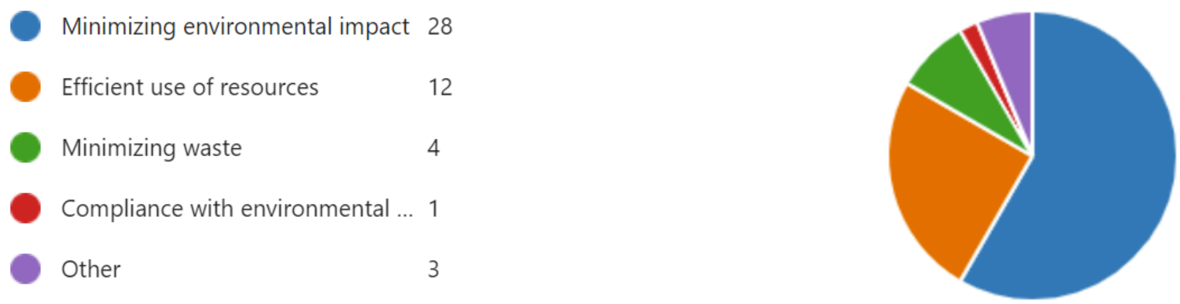
Thank you for taking the time to complete our survey. By sharing your insights and experiences, you are contributing to the advancement of AI technology in the (bio)pharmaceutical industry.

Please feel free to share the survey-link with anyone, who might be interested in contributing their insights. If you have any questions or need further information, please don't hesitate to reach out to us via s.e.neudeck@students.uu.nl.

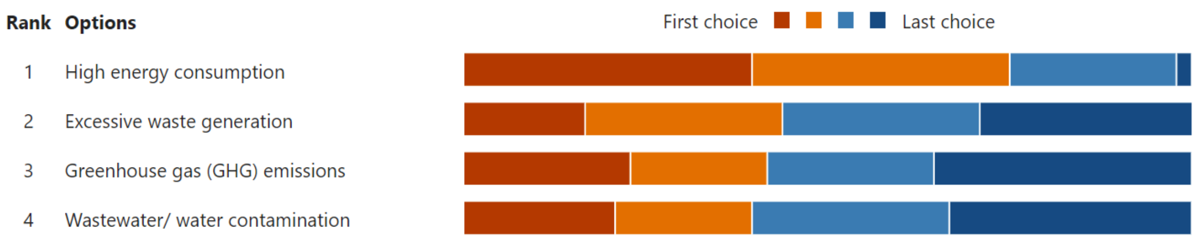
SURVEY RESULTS

Sustainability in the Pharmaceutical Industry

When asked about their understanding of environmental sustainability within the (bio)pharmaceutical industry, 58% of the participants primarily associated it with minimizing environmental impact, while 25% associated it with efficient resource use.



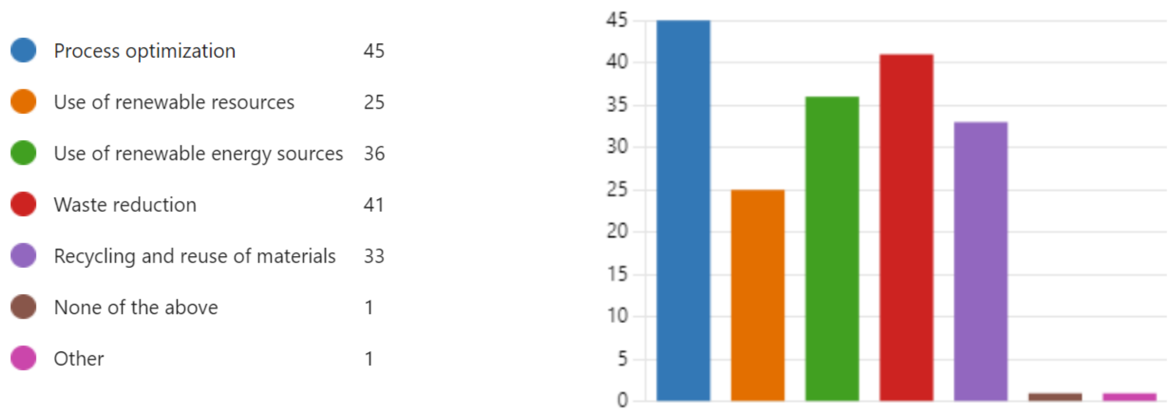
The industry's high energy consumption was ranked as the most significant sustainability challenge by 40% of the participants, surpassing concerns about GHG emissions, waste generation, and water contamination/wastewater.



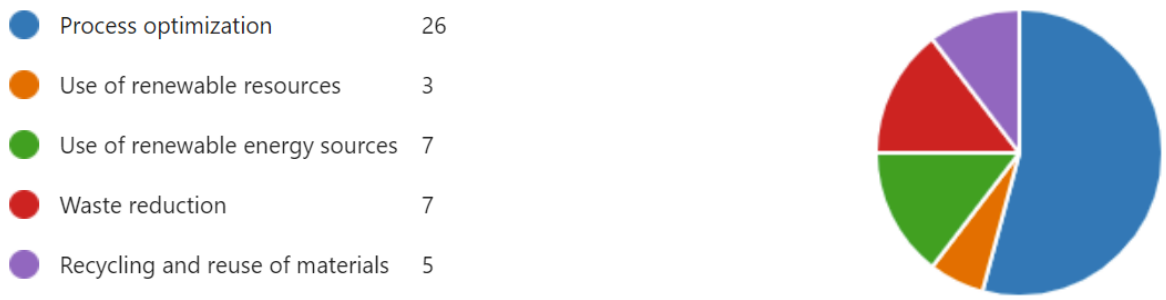
Other significant sustainability challenges mentioned by the participants included excessive water use, mindset changes, supply chain sustainability, adherence to emerging technical regulations/reporting and LCA requirements, and the use of substances of concern.

Approaches to Address Sustainability Challenges

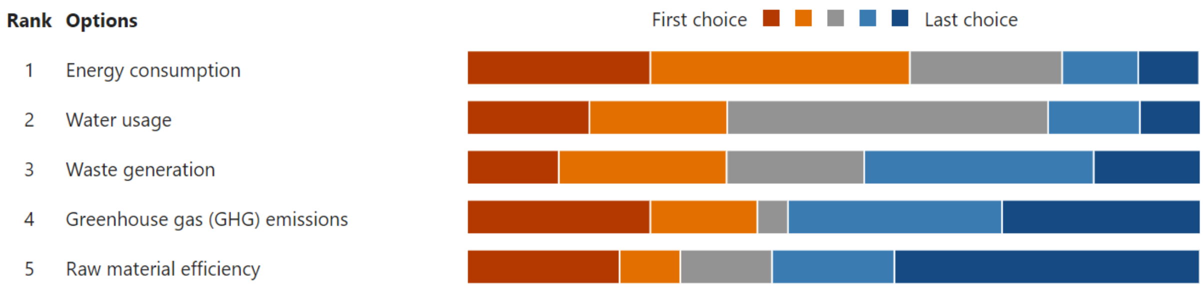
All but one participant were aware of various approaches to address sustainability challenges, with process optimization, waste reduction, use of renewable energy sources, recycling and reuse of materials, and use of renewable resources being the most commonly recognized methods.



Over half (54%) of the participants believed that process optimization was the most effective method for addressing sustainability challenges in the (bio)pharmaceutical industry.



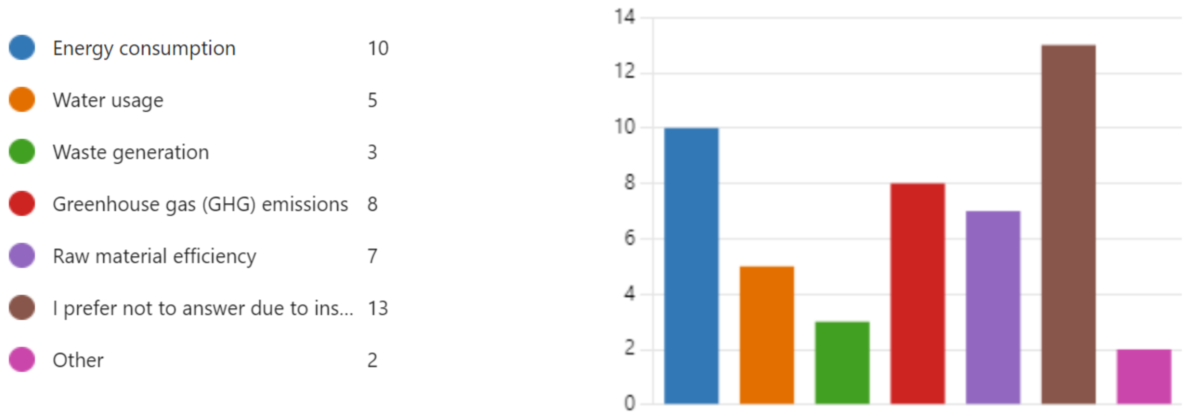
When asked about the most feasible sustainability parameter to improve, the majority of participants ranked either energy consumption or GHG emissions highest, while raw material efficiency was ranked as the least feasible by most participants.



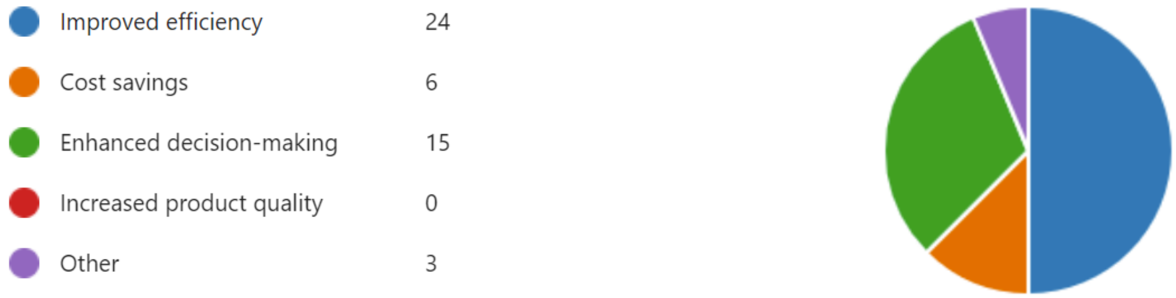
Other feasible sustainability parameters mentioned by the participants included recycling rates, use of substances of concern, and biodiversity impact.

AI Integration and Sustainability

When asked about the sustainability parameter that could benefit most from AI integration, 13 out of 48 participants declined to answer due to insufficient knowledge. Of the remaining participants, the majority (10/48) believed that energy consumption could benefit most, followed by GHG emissions (8/48) and raw material efficiency (7/48).

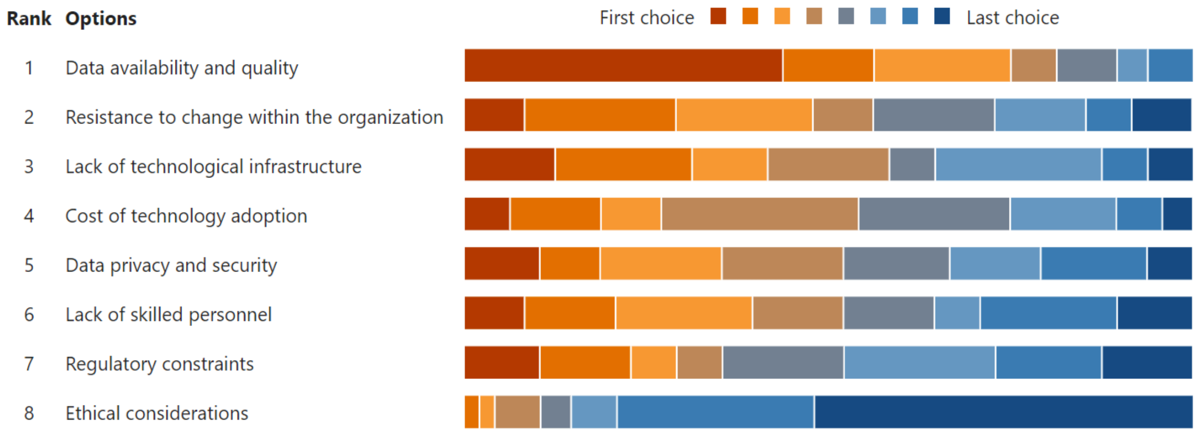


Half of the participants believed that the main advantage of implementing AI methods to improve sustainability was improved efficiency, while 31% believed it was enhanced decision making, and 13% believed it was cost savings. Other advantages mentioned included better data management, improved transparency, time savings, and better predictions/suggestions for improvement.



Challenges and Opportunities in Implementing AI Technologies

The majority of the participants identified data availability and quality as the most significant challenge/barrier foreseen in implementing AI technologies for sustainability within (bio)pharmaceutical manufacturing. Resistance to change within the organization and a lack of technological infrastructure were also ranked as significant challenges.



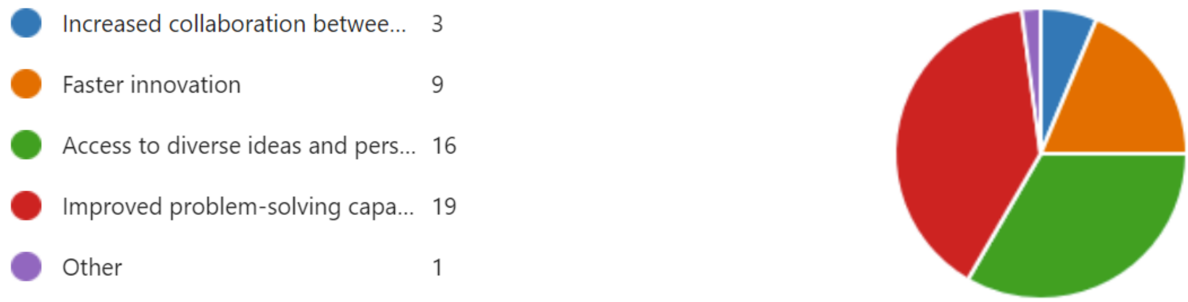
Other challenges mentioned included data storage time, definition of key parameters and data collection, differences in processes/methods/organisms, long-term maintenance, and staff training.

In terms of accelerating the adoption of AI technologies for improving sustainability in (bio)pharmaceutical manufacturing, enhanced collaboration among industry stakeholders, training programs for AI implementation, improved technological infrastructure, and regulatory incentives/guidance were all ranked as necessary by the participants. In comparison, increased funding for R&D was ranked as less necessary.

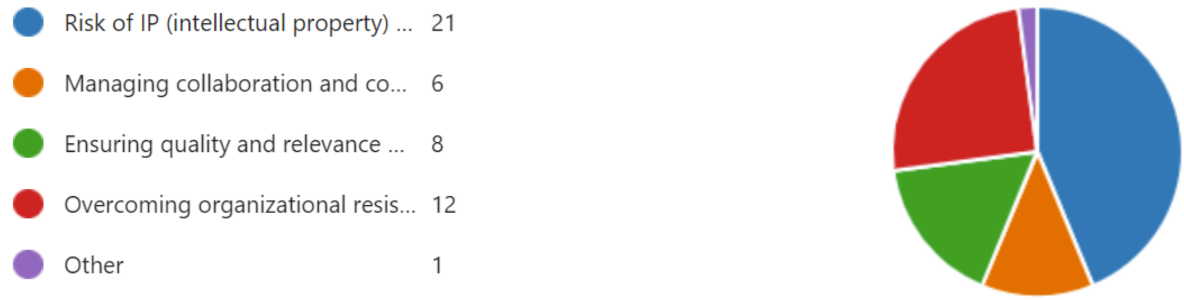
Collaboration and Open Innovation

All participants believed that knowledge sharing and collaboration among stakeholders were at least moderately important in advancing AI-driven sustainability initiatives, with 67% believing it was very important. When asked about the type of collaboration or partnerships necessary for successful implementation of AI-driven sustainability initiatives, the majority ranked either collaboration between pharma companies and academia/research institutions or collaboration between pharma companies and external AI technology providers highest.

When asked about the main benefit of embracing open innovation approaches to drive sustainability through AI technology implementation, 40% believed it was improved problem-solving capabilities, 33% believed it was access to diverse ideas and perspectives, and 19% believed it was faster innovation.



The main challenge of embracing open innovation, according to 44% of the participants, was the risk of IP theft, while 25% believed it was overcoming organizational resistance.

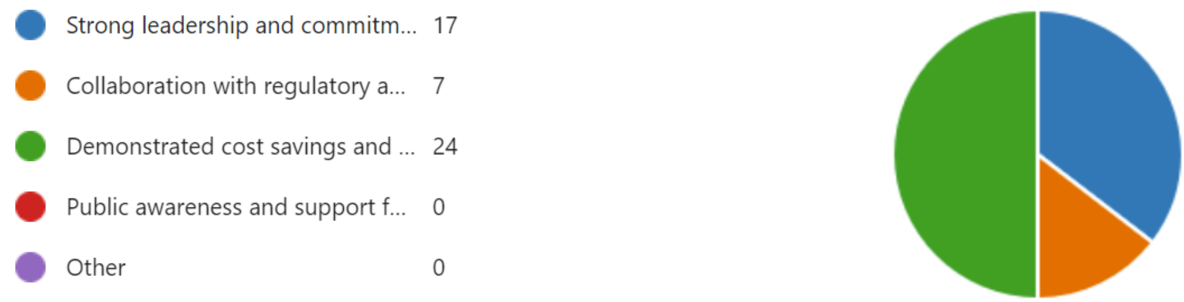


According to the survey, 44% of participants believe that collaboration between pharmaceutical companies has the greatest impact on the development and diffusion of AI-related knowledge, while 33% attribute the most influence on technological advancements.

Ethical Considerations and Success Factors

Most participants believed that accountability and transparency, as well as data privacy and security, were the more relevant ethical considerations to guide the development and deployment of AI technologies for sustainability, compared to fairness and bias mitigation and inclusivity and stakeholder engagement.

Half of the participants believed that demonstrated cost savings and operational efficiencies were the key success factors for promoting the widespread adoption of AI technologies for sustainability across the (bio)pharmaceutical industry. Strong leadership and commitment from industry stakeholders (35%) and collaboration with regulatory agencies to streamline approval processes (15%) were also considered key success factors.



In their final remarks, participants emphasized the importance of transparency in decision-making, the potential of AI to improve internal processes and contribute to sustainability, and the need for careful consideration of the energy load of AI technologies. They also highlighted the potential of recycling in the (bio)pharmaceutical industry and the need for a human in charge of AI-driven processes.

REFERENCES

Abidi, M. H., Mohammed, M. K., & Alkhalefah, H. (2022). Predictive Maintenance Planning for Industry 4.0 using machine learning for sustainable manufacturing. Sustainability, 14(6), 3387. https://doi.org/10.3390/su14063387

Abubakr, M., Abbas, A. T., Tomaz, I., Soliman, M. S., Luqman, M., & Hegab, H. (2020). Sustainable and Smart Manufacturing: an Integrated approach. Sustainability, 12(6), 2280. https://doi.org/10.3390/su12062280

Ahmad, S., Wong, K. Y., Tseng, M. L., & Wong, W. P. (2018). Sustainable product design and development: A review of tools, applications and research prospects. Resources, Conservation & Recycling, 132, 49–61. https://doi.org/10.1016/j.resconrec.2018.01.020

Ang, K. L., Saw, E. T., He, W., Xin, D., & Ramakrishna, S. (2021). Sustainability framework for pharmaceutical manufacturing (PM): A review of research landscape and implementation barriers for circular economy transition. Journal of Cleaner Production, 280(124264). https://doi.org/10.1016/j.jclepro.2020.124264

Arana-Landín, G., Uriarte-Gallastegi, N., Landeta-Manzano, B., & Laskurain-Iturbe, I. (2023). The contribution of Lean Management—Industry 4.0 technologies to improving energy efficiency. Energies, 16(5), 2124. https://doi.org/10.3390/en16052124

Arias, A., Feijoó, G., & Moreira, M. T. (2023). How could Artificial Intelligence be used to increase the potential of biorefineries in the near future? A review. Environmental Technology & Innovation, 32, 103277. https://doi.org/10.1016/j.eti.2023.103277

Asif, M., Shen, H., Zhou, C., Guo, Y., Yuan, Y., Shao, P., Xie, L., & Bhutta, M. S. (2023). Recent Trends, Developments, and Emerging Technologies towards Sustainable Intelligent Machining: A Critical Review, Perspectives and Future Directions. Sustainability, 15(10), 8298. https://doi.org/10.3390/su15108298

Azapagic, A., Millington, A., & Collett, A. (2006). A Methodology for Integrating Sustainability Considerations into Process Design. Process Safety and Environmental Protection, 84(6), 439–452. https://doi.org/10.1205/cherd05007

Azizi, A. (2020). Applications of Artificial intelligence techniques to enhance Sustainability of Industry 4.0: Design of an artificial neural network model as dynamic behavior Optimizer of robotic arms. Complexity, 2020, 1–10. https://doi.org/10.1155/2020/8564140

Bade, C., Olsacher, A., Boehme, P., Truebel, H., Bürger, L., & Fehring, L. (2023). Sustainability in the pharmaceutical industry—An assessment of sustainability maturity and effects of sustainability measure implementation on supply chain security. Corporate Social Responsibility and Environmental Management, 2023. https://doi.org/10.1002/csr.2564

Bhattacherjee, A. (2019). Survey research. In: Social Science Research: Principles, Methods and Practices (Revised edition). University of Southern Queensland. https://doi.org/10.26192/q7w89

Bhattamisra, S.K., Banerjee, P., Gupta, P., Mayuren, J., Patra, S. & Candasamy, M. (2023) Artificial Intelligence in Pharmaceutical and Healthcare Research. Big Data Cogn. Comput, 7(10). https://doi.org/ 10.3390/bdcc7010010

Belkhir, L., & Elmeligi, A. (2018). Carbon footprint of the global pharmaceutical industry and relative impact of its major players. Journal of Cleaner Production, 214(2019), 185-194. https://doi.org/10.1016/j.jclepro.201 8.11.204

Berlec, A., & Štrukelj, B. (2013). Current state and recent advances in biopharmaceutical production in Escherichia coli, yeasts and mammalian cells. Journal of Industrial Microbiology & Biotechnology, 40(3–4), 257–274. https://doi.org/10.1007/s10295-013-1235-0

Bioméruiex (n.d.). Eco-design. Retrieved February 12, 2024 from https://www.biomerieux.

com/us/en/our-responsibility/planet/eco-design.html

Boehringer Ingelheim (n.d.). Making our medicines greener through eco-design. Retrieved February 12, 2024, from https://www.boehringer-ingelheim.com/science-innovation/human-health-innovation/science-stories/greener-medicines-through-eco-design

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology, 3(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Brewer, E. W., Torrisi-Steele, G., & Wang, V. (2015). Survey Research: Methods, Issues and the Future. International Journal of Adult Vocational Education and Technology, 6(4), 46–64. https://doi.org/10.4018/ijavet.2015100106

Bryman, A. (2006). Integrating quantitative and qualitative research: how is it done? Qualitative Research, 6(1), 97–113. https://doi.org/10.1177/1468794106058877

Bryman, A. (2016). Social Research Methods (5th ed.). Oxford University Press.

Bünder, T. (2022). The Pharmaceutical Industry and Access to Health Products: Interrogating the Role of Multinational Companies in Tackling Global Development Challenges [Doctoral dissertation, Hertie School].

Chambers, D. A., Glasgow, R. E., & Stange, K. C. (2013). The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. Implementation Science, 8(1). https://doi.org/10.1186/1748-5908-8-117

Chatterjee, S., Chaudhuri, R., Kamble, S., Gupta, S., & Sivarajah, U. (2022). Adoption of Artificial Intelligence and Cutting-Edge Technologies for production system Sustainability: A Moderator-Mediation Analysis. Information Systems Frontiers, 25(5), 1779–1794. https://doi.org/10.1007/s10796-022-10317-x

Cioffi, R., Travaglioni, M., Piscitelli, G., Petrillo, A., & De Felice, F. (2020). Artificial intelligence and Machine learning applications in smart Production: progress, trends, and directions. Sustainability, 12(2), 492. https://doi.org/10.3390/su12020492

Çınar, Z. M., Nuhu, A. A., Zeeshan, Q., Korhan, O., Asmael, M., & Safaei, B. (2020). Machine Learning in Predictive Maintenance towards Sustainable Smart Manufacturing in Industry 4.0. Sustainability, 12(19), 8211. https://doi.org/10.3390/su12198211

Dawadi, S., Shrestha, S., & Giri, R. A. (2021). Mixed-Methods Research: A Discussion on its Types, Challenges, and Criticisms. Journal of Practical Studies in Education, 2(2), 25–36. https://doi.org/10.46809/jpse.v2i2.20

eDebnath B, Shakur MS, Bari ABMM, Saha J, Porna WA, Mishu MJ, et al. (2023.) Assessing the critical success factors for implementing industry 4.0 in the pharmaceutical industry: Implications for supply chain sustainability in emerging economies. PLOS ONE, 18(6). https://doi.org/10.1371/journal.pone.0287149

EFPIA - European Federation of Pharmaceutical Industries and Associations (2023). EFPIA Proactively managing the environmental risks associated with the patient use of human medicinal products: An extended Environmental Risk Assessment (eERA) proposal by the European pharmaceutical industry associations EFPIA, AESGP, and Medicines for Europe. Retrieved January 12, 2024, from https://www.efpia.eu/media/677261/interassociation-paper-on-extended-environmental-risk-assessment.pdf

Etit, D., Meramo, S., Ögmundarson, Ó., Jensen, M. K., & Sukumara, S. (2024). Can biotechnology lead the way toward a sustainable pharmaceutical industry? Current Opinion in Biotechnology, 87, 103100. https://doi.org/10.1016/j.copbio.2024.103100

European Commission (2020). Pharmaceutical Strategy for Europe. COM (2020) 761 final. 25.11.2020, Brussels. Retrieved February 12, 2024, from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761

European Commission (2023). Commission welcomes provisional agreement for more sustainable, repairable and circular products [Press release]. 5.12.2023, Brussels. Retrieved February 12, 2024, from https://ec.europa.eu/commission/presscorner/detail/en/ip_23_6257

European Parliament (2022). Sustainable economy: Parliament adopts new reporting rules for multinationals [Press release]. Retrieved August 21, 2024, from https://www.europarl.europa.eu/pdfs/news/expert/2022/11/press_release/20221107IPR49611/20221107IPR49611_en.pdf

European Parliament (2023). EU AI Act: first regulation on artificial intelligence. Retrieved March 13, 2024, from https://www.europarl.europa.eu/pdfs/news/expert/2023/6/story/20230601STO93804/20230601STO93804_en.pdf

Fisch, C., & Block, J. (2018). Six tips for your (systematic) literature review in business and management research. Management Review Quarterly, 68(2), 103–106. https://doi.org/10.1007/s11301-018-0142-x

Glavič, P., & Lukman, R. (2007). Review of sustainability terms and their definitions. Journal of Cleaner Production, 15(18), 1875–1885. https://doi.org/10.1016/j.jclepro.2006.12.006

González Peña,O.I., López Zavala, M.Á., Cabral Ruelas, H. (2021). Pharmaceuticals Market, Consumption Trends and Disease Incidence Are Not Driving the Pharmaceutical Research on Water and Wastewater. International Journal of Environmental Research and Public Health, 18 (2532). https://doi.org/10.3390/ijerph18052532

Hall, C., Dayal, N., Majstorović, D., Mills, H., Paul-Andrews, L., Wallace, C., & Truong, V. (2016). Accommodation Consumers and Providers' Attitudes, Behaviours and Practices for Sustainability: A Systematic review. Sustainability, 8(7), 625. https://doi.org/10.3390/su8070625

Hörisch, J. (2015). The Role of Sustainable Entrepreneurship in Sustainability Transitions: A Conceptual Synthesis against the Background of the Multi-Level Perspective. Administrative Sciences, 5(4), 286–300. https://doi.org/10.3390/admsci5040286

Hsu, C., Jiang, B., & Lin, C. (2023). A survey on recent applications of artificial intelligence and optimization for smart grids in smart manufacturing. Energies, 16(22), 7660. https://doi.org/10.3390/en16227660

Jung, H., Jeon, J., Choi, D., & Park, J. (2021). Application of Machine learning techniques in injection molding Quality Prediction: Implications on Sustainable Manufacturing industry. Sustainability, 13(8), 4120. https://doi.org/10.3390/su13084120

Kaplan, A., & Haenlein, M. (2019). Siri, Siri, in my hand: Who's the fairest in the land? On the interpretations, illustrations, and implications of artificial intelligence. Business Horizons, 62(1), 15–25. https://doi.org/10.1016/j.bushor.2018.08.004

Kraus, S., Breier, M., Lim, W. M., Dabić, M., Kumar, S., Kanbach, D. K., Mukherjee, D., Corvello, V., Chousa, J. P., Liguori, E. W., Marqués, D. P., Schiavone, F., Ferraris, A., Fernandes, C., & Ferreira, J. (2022). Literature reviews as independent studies: guidelines for academic practice. Review of Managerial Science, 16(8), 2577–2595. https://doi.org/ 10.1007/s11846-022-00588-8

Kulkov, I. (2021). The role of artificial intelligence in business transformation: A case of pharmaceutical companies. Technology in Society, 66 (101629). https://doi.org/10.1016/j.techsoc.2021.101629

Lalor, F., Fitzpatrick, J., Sage, C., & Byrne, E. (n.d.). Sustainability in the biopharmaceutical industry: Seeking a holistic perspective. Biotechnology Advances, 37(5), 698–707. https://doi.org/10.1016/j.biotechadv.2019.03.015

Latonen, S. H., Suominen, R. M., Juppo, A. M., Airaksinen, M., & Seeck, H. (2023). Organisation of cross-sector collaboration and its influence on crisis management effectiveness among pharmaceutical supply chain stakeholders during the COVID-19 pandemic. Public Health, 222, 196–204. https://doi.org/10.1016/j.puhe.2023.06 .042

Larsson, D. G. J. (2014). Pollution from drug manufacturing: review and perspectives. Philosophical Transactions: Biological Sciences, 369 (1656), 1–7. http://www.jstor.org/stable/24501903

Lilly. (2024). 2023 Sustainability Report. Retrieved April 21, 2024, from https://downloads.ctfassets.net/1o78rkhl3da6/6BZg6vj489Ga1HVyx28uNn/7e84c33147fbdfacc82bc6107e184ff0/2023_Sustainability_Report_Final.pdf

Magaldi, D. & Berler, M. (2020). Semi-structured Interviews. In: Zeigler-Hill, V., Shackelford, T.K. (eds) Encyclopedia of Personality and Individual Differences. Springer, Cham. https://doi.org/10.1007/978-3-319-24612-3_857

Malshe, H., Nagarajan, H., Pan, Y., & Haapala, K. (2015). Profile of sustainability in additive manufacturing and environmental assessment of a novel stereolithography process. In: Volume 2: Materials; Biomanufacturing; Properties, Applications and Systems; Sustainable Manufacturing. https://doi.org/10.1115/msec2015-9371

Mariani, M. M., Machado, I., Magrelli, V., & Dwivedi, Y. K. (2023). Artificial intelligence in innovation research: A systematic review, conceptual framework, and future research directions. Technovation, (122) 102623. https://doi.org/10.1016/j.technovation.2022.102623

McKenzie, J., & Bartunek, J. (2023). Mirror, mirror outside my wall: Reflexive Impacts of Insider/Outsider Collaborative Inquiry on the Insider Researcher. The Journal of Applied Behavioral Science, 59(4), 714–739. https://doi.org/10.1177/00218863231177486

Milanesi, M., Runfola, A., & Guercini, S. (2016). Pharmaceutical industry riding the wave of sustainability: Review and opportunities for future research. Journal of Cleaner Production, 261 (121204). https://doi.org/10.1016/j.jclepro.2020.121204

Naeem, M., Ozuem, W., Howell, K., & Ranfagni, S. (2023). A Step-by-Step process of thematic analysis to develop a conceptual model in qualitative research. International Journal of Qualitative Methods, 22. https://doi.org/10.1177/16094069231205789

Nishant, R., Kennedy, M., & Corbett, J. (2020). Artificial intelligence for sustainability: challenges, opportunities, and a research agenda. International Journal of Information Management, 53. https://doi.org/10.1016/j.ijinfomgt.2020.102104

Okeke, E. S., Ezeorba, T. P. C., Okoye, C. O., Chen, Y., Mao, G., Feng, W., & Wu, X. (2022). Environmental and health impact of unrecovered API from pharmaceutical manufacturing wastes: a review of contemporary treatment, recycling and management strategies. Sustainable Chemistry and Pharmacy, 30. https://doi.org/10.1016/j.scp.2022.100865

Othman, U., & Yang, E. (2023). Human–Robot Collaborations in smart Manufacturing Environments: Review and outlook. Sensors, 23(12), 5663. https://doi.org/10.3390/s23125663

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., Brennan, S. E., Chou, R., Glanville, J., Grimshaw, J. M., Hróbjartsson, A., Lalu, M. M., Li, T., Loder, E. W., Mayo-Wilson, E., McDonald, S., . . . Moher, D. (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. Journal of Clinical Epidemiology, 134, 178–189. https://doi.org/10.1016/j.jclinepi.2021.03.001

Panagiotopoulou, V. C., Stavropoulos, P., & Chryssolouris, G. (2021). A critical review on the environmental impact of manufacturing: a holistic perspective. The International Journal of Advanced Manufacturing Technology, 118(1–2), 603–625. https://doi.org/10.1007/s00170-021-07980-w

Patel, S., & Rabizadegan, M. (2021). Moving toward green production systems in the pharmaceutical industry: Implementing artificial intelligence to increase environmental efforts in SMEs [MSc Thesis, School of Industrial Engineering and Management]. http://kth.diva-portal.org/smash/record.jsf?pid=diva2:1587762

Paulick, K., Seidel, S., Lange, C., Kemmer, A., Cruz-Bournazou, M.N., Baier,A. & Haehn, D. (2022) Promoting Sustainability through Next-Generation Biologics Drug Development. Sustainability, 14 (4401). https://doi.org/ 10.3390/su140 84401

Reuter, M. A. (2016). Digitalizing the circular economy. Metallurgical and Materials Transactions B, 47(6), 3194–3220. https://doi.org/10.1007/s11663-016-0735-5

Rissman, J., Bataille, C., Masanet, E., Aden, N., Morrow, W. R., Zhou, N., Elliott, N., Dell, R., Heeren, N., Huckestein, B., Cresko, J., Miller, S. A., Roy, J., Fennell, P., Cremmins, B., Blank, T. K., Hone, D., Williams, E. D., De La Rue Du Can, S., . . . Helseth, J. (2020). Technologies and policies to decarbonize global industry: Review and assessment of mitigation drivers through 2070. Applied Energy, 266, 114848. https://doi.org/10.1016/j.apenergy.2020.114848

Richie, C. (2022). Environmental sustainability and the carbon emissions of pharmaceuticals. Journal of Medical Ethics, 48 (5), 334–337. https://doi.org/10.1136/medethics-2020-106842

Rosen, M. A., & Kishawy, H. A. (2012). Sustainable Manufacturing and Design: Concepts, practices and needs. Sustainability, 4(2), 154–174. doi.org/10.3390/su4020154

Rudnicka, A. R., & Owen, C. G. (2012). An introduction to systematic reviews and meta-analyses in health care. Ophthalmic and Physiological Optics, 32 (3), 174–183. https://doi.org/10.1111/j.1475-1313.2012.00901.x

Sanofi (2023). Eco-Design Factsheet. Retrieved February 12, 2024, from https://www.sanofi.com/assets/dotcom/content-app/documents/eco-design.pdf

Sarkar, C., Das, B., Rawat, V.S., Wahlang, J.B., Nongpiur, A., Tiewsoh, I., Lyngdoh, N.M., Das, D., Bidarolli, M., Sony, H.T. (2023). Artificial Intelligence and Machine Learning Technology Driven Modern Drug Discovery and Development. International Journal of Molecular Science, 24 (2026). https://doi.org/10.3390/ijms24032026

Sarkis, J. (2001). Manufacturing's role in corporate environmental sustainability: concerns for the new millennium. International Journal of Operations and Production Management, 21, 666–686.

Sarkis, M., Bernardi, A., Shah, N., & Papathanasiou, M. M. (2021). Emerging challenges and opportunities in pharmaceutical manufacturing and distribution. Processes, 9 (3), 457. https://doi.org/10.3390/pr9030457

Schneider, J.L., Wilson, A., Rosenbeck, J.M. (2010). Pharmaceutical companies and sustainability: an analysis of corporate reporting. Benchmark: An International Journal, 17 (3). https://doi.org/10.1108/14635771011049371

Schneider, P., Walters, W. P., Plowright, A. T., Sieroka, N., Listgarten, J., Goodnow, R. A., Fisher, J., Jansen, J. M., Duca José S, Rush, T. S., Zentgraf, M., Hill, J. E., Krutoholow, E., Kohler, M., Blaney, J., Funatsu, K., Luebkemann, C., & Schneider, G. (2019). Rethinking drug design in the artificial intelligence era. Nature Reviews Drug Discovery, 19 (5), 353–364. https://doi.org/10.1038/s41573-019-0050-3

Sharma, D., Patel, P., & Shah, M. (2023). A comprehensive study on Industry 4.0 in the pharmaceutical industry for sustainable development. Environmental Science and Pollution Research, 30(39), 90088–90098. https://doi.org/10.1007/s11356-023-26856-y

Shashi, M. (2022). The Sustainability Strategies in the Pharmaceutical Supply Chain: A Qualitative Research. International Journal of Engineering and Advanced Technology (IJEAT), 11 (6). https://doi.org/10.35940/ijeat.F3734.0811622

Shiammala, P. N., Duraimutharasan, N. K. B., Vaseeharan, B., Alothaim, A. S., Al-Malki, E. S., Snekaa, B., Safi, S. Z., Singh, S. K., Velmurugan, D., & Selvaraj, C. (2023). Exploring the artificial intelligence and machine learning models in the context of drug design difficulties and future potential for the pharmaceutical sectors. Methods, 219, 82–94. https://doi.org/10.1016/j.ymeth.2023.09.010

Snyder, H. (2019). Literature review as a research methodology: An overview and guidelines. Journal of Business Research, 104, 333–339. https://doi.org/10.1016/j.jbusres.2019.07.039

Tang, J., Wang, T., Xia, H., & Cui, C. (2024a). An overview of artificial intelligence application for optimal control of municipal solid waste incineration process. Sustainability, 16(5), 2042. https://doi.org/10.3390/su16052042

Tang, Q., Lee, Y., & Jung, H. (2024b). The industrial application of Artificial Intelligence-Based Optical Character recognition in modern manufacturing innovations. Sustainability, 16(5), 2161. https://doi.org/10.3390/su16052161

Turner, C., Oyekan, J., Garn, W., Duggan, C., & Abdou, K. (2022). Industry 5.0 and the Circular Economy: Utilizing LCA with Intelligent Products. Sustainability, 14(22), 14847. https://doi.org/10.3390/su142214847

United Nations (2023). What is sustainable development? Retrieved August 21, 2024, from https://www.un.org/sustainabledevelopment/wp-content/uploads/2023/08/SustDev_Explainer.pdf

Unluer, S. (2015). Being an insider researcher while conducting case study research. The Qualitative Report. https://doi.org/10.46743/2160-3715/2012.1752

Uwamungu, J. Y., Kumar, P., Alkhayyat, A., Younas, T., Capangpangan, R. Y., Alguno, A. C., & Ofori, I. (2022). Future of Water/Wastewater Treatment and Management by Industry 4.0 Integrated Nanocomposite Manufacturing. Journal of Nanomaterials, 2022, 1–11. https://doi.org/10.1155/2022/5316228

Vimalnath, P., Tietze, F., Eppinger, E., Jain, A., Gurtoo, A., & Elsen, M. (2023). Responsible intellectual property strategy for sustainability transition - An exploratory study. World Patent Information, 73, 102195. https://doi.org/10.1016/j.wpi.2023.102195

Wakeling, S., Clough, P., Connaway, L. S., Sen, B., & Tomás, D. (2017). Users and uses of a global union catalog: A mixed-methods study of WorldCat.org. Journal of the Association for Information Science and Technology, 68(9), 2166–2181. https://doi.org/10.1002/asi.23708

Walsh, G. (1999). Biopharmaceuticals, an overview. In: Walsh, G., Murphy, B. (Eds.) Biopharmaceuticals, an Industrial Perspective. Springer, Dordrecht. https://doi.org/10.1007/978-94-017-0926-2_1

Waltersmann, L., Kiemel, S., Stuhlsatz, J., Sauer, A., & Miehe, R. (2021). Artificial Intelligence Applications for Increasing Resource Efficiency in Manufacturing Companies—A Comprehensive Review. Sustainability (Basel), 13(12), 6689. https://doi.org/10.3390/su13126689

Wang, C., Tan, X., Tor, S., & Lim, C. (2020). Machine learning in additive manufacturing: State-of-the-art and perspectives. Additive Manufacturing, 36, 101538. https://doi.org/10.1016/j.addma.2020.101538

Warner, B. E. (2024). Clinical Colleague and Clinical Academic: A physician's autoethnographical reflexive account of opportunities and challenges as an 'Insider' researcher. International Journal of Qualitative Methods, 23. https://doi.org/10.1177/16094069241256278

Weaver, E., O'Hagan, C., & Lamprou, D. A. (2022). The sustainability of emerging technologies for use in pharmaceutical manufacturing. Expert Opinion on Drug Delivery, 19 (7), 861–872. https://doi.org/10.1080/17425247.2022.2093857

Westerlund, A., Nilsen, P., & Sundberg, L. (2019). Implementation of Implementation Science Knowledge: The Research-Practice Gap Paradox. Worldviews on Evidence-Based Nursing, 16(5), 332–334. https://doi.org/10.1111/wvn.12403

Willenbacher, M., Scholten, J., & Wohlgemuth, V. (2021). Machine learning for optimization of energy and plastic consumption in the production of thermoplastic parts in SME. Sustainability, 13(12), 6800. https://doi.org/10.3390/su13126800

Wong, G., Greenhalgh, T., Westhorp, G., Buckingham, J., & Pawson, R. (2013). RAMESES publication standards: meta-narrative reviews. BMC Medicine, 11(1). https://doi.org/10.1186/1741-7015-11-20

Zunder, T. H. (2021). A semi-systematic literature review, identifying research opportunities for more sustainable, receiver-led inbound urban logistics flows to large higher education institutions. European Transport Research Review, 13(1). https://doi.org/10.1186/s12544-021-00487-1