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Barriers to Industry 4.0 Adoption in Pharmaceutical Manufacturing Companies: A Case Study

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Abstract:

Purpose: This study explores the barriers to adopting Industry 4.0 technologies within the pharmaceutical manufacturing sector. Despite the potential for transformative benefits, the sector has been slow in embracing these technologies due to unique regulatory and operational challenges. This paper seeks to understand these challenges in greater depth by analyzing key obstacles that pharmaceutical companies face during their digital transformation efforts.

Design/methodology/approach: A mixed-methods approach was employed, combining maturity assessments with insights from in-depth interviews with key stakeholders in the pharmaceutical industry. The study identifies and categorizes the main barriers to Industry 4.0 adoption, providing a sector-specific analysis.

Findings: The primary barriers to Industry 4.0 adoption in pharmaceutical manufacturing were found to be "prioritization and strategic alignment," "technological challenges," and "financial constraints." Contrary to common assumptions in the literature, "regulatory and compliance challenges" were perceived as less impactful by stakeholders, as these are often ingrained in routine operations.

Research limitations/implications: The research focuses on a single pharmaceutical manufacturing company, which may limit generalizability. However, as the company operates within the broader pharmaceutical industry as a contract development and manufacturing organization (CDMO), the findings could reflect broader industry dynamics.

Practical implications: Pharmaceutical companies should prioritize overcoming strategic and technological barriers to facilitate Industry 4.0 adoption. Clear leadership direction, strategic alignment, and addressing interoperability challenges are critical for successful digital transformation in the sector.

Originality/value: This study provides a novel contribution by offering a detailed analysis of barriers to Industry 4.0 adoption specific to the pharmaceutical manufacturing sector. It challenges the traditional view of regulatory hurdles as the primary obstacle, emphasizing the increasing integration of regulatory management into daily operations and shifting the focus toward overcoming technological and strategic challenges.

Keywords: industry 4.0, pharmaceutical manufacturing, digital transformation, technological barriers, regulatory compliance, strategic alignment

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1. Introduction

The rapid advancement of Industry 4.0 technologies has brought transformative potential across various sectors, with manufacturing industries being at the forefront of this digital revolution (Morrar, Arman & Mousa, 2017; De-Propris & Bailey, 2021; Capello & Lenzi, 2021). Industry 4.0 encompasses a range of technologies, including the Internet of Things (IoT), artificial intelligence (AI), robotics, and big data analytics, which collectively enable the creation of smart factories (Oztemel & Gursev, 2020; Santos & Martinho, 2020; Martinelli, Mina & Moggi, 2021; Mariappan, Veerabathiran, Paranitharan & Vimal, 2023). These technologies promise to enhance operational efficiency, improve product quality, and enable greater flexibility in production processes (Bai, Dallasega, Orzes & Sarkis, 2020; Dalenogare, Benitez & Ayala, 2018; Frank, Mendes, Ayala & Ghezzi, 2019); they will also offer tangible operational benefits in highly regulated sectors such as pharmaceuticals (Mariappan et al., 2023).

Industry 4.0 represents a paradigm shift, as discussed by Kagermann, Wahlster and Helbig (2013) and Lasi, Fettke, Kemper, Feld and Hoffmann (2014), who define it as the convergence of smart factories, cyber-physical systems (CPS), and the Internet of Things (IoT). In this vein, Lee, Bagheri and Kao (2015) have proposed a cyber-physical systems (CPS) architecture that transforms traditional manufacturing systems into adaptive and interconnected environments, which could be highly beneficial for pharmaceutical production by enabling real-time monitoring and self-optimization. Furthermore, Machado, Winroth, Silva and Ribeiro-da-Silva (2020) link this digital shift to sustainability, noting that Industry 4.0 technologies help optimize resource use and reduce waste, in alignment with pharmaceutical companies' efforts to meet both operational efficiency and regulatory standards. However, as noted by Breunig, Kelly, Mathis and Wee (2016), rather than implementing all Industry 4.0 technologies simultaneously, manufacturers should adopt an incremental approach, starting with areas such as supply chain monitoring and digital quality management, where immediate value can be realized. This strategy is particularly relevant for pharmaceutical firms, which must balance regulatory compliance with the gradual adoption of technologies.

In the pharmaceutical industry, the adoption of Industry 4.0 is particularly critical due to the sector's stringent regulatory requirements, the complexity of its production processes, and the need for continuous innovation (Marques, Moniz & de Sousa, 2020; Arief, Gustomo, Roestan & Putri, 2022). Despite the potential benefits, the implementation of Industry 4.0 in pharmaceutical manufacturing has been relatively slow compared to other sectors (Riedel, 2024; Silva, Resende, Amorim & Borges, 2020). This lag in adoption can be attributed to several barriers, including technological challenges, regulatory constraints, financial limitations, and organizational resistance (Kamble, Gunasekaran & Sharma, 2018). Zutin, Barbosa, de-Barros, Tiburtino, Kawano and Shiki (2022) highlight that while some technologies, such as simulation and systems integration, have reached higher maturity levels, others, such as IoT and augmented reality, are still in the early stages of deployment, reflecting the similar technological disparities found in pharmaceutical manufacturing. Jena and Patel (2022) emphasize the high initial costs and technological infrastructure gaps in industries such as pharmaceuticals, which operate under stringent compliance requirements. Alcácer, Rodrigues, Carvalho and Cruz-Machado (2022) emphasize that using readiness models, such as the IMPULS Industry 4.0 Readiness Model, helps companies assess the maturity of Industry 4.0 technologies, allowing them to map progress and tailor interventions to specific internal departments, which is crucial for overcoming adoption barriers. Ávila-Bohórquez and Gil-Herrera (2022) propose a comprehensive Industry 4.0 maturity model designed specifically for small and medium-sized enterprises (SMEs), which is particularly relevant to the pharmaceutical sector, where readiness for digital transformation is critical for regulatory compliance and competitiveness. Their model's emphasis on leadership and strategy, alongside cyber-physical integration, is pivotal to guiding pharmaceutical manufacturers in this transition (Ávila-Bohórquez & Gil-Herrera, 2022).

Arden, Fisher, Tyner and Lawrence (2021) argue that the pharmaceutical industry's slow adoption of Industry 4.0 technologies is partly an effect of perceived (as opposed to actual) barriers posed by regulatory frameworks. This strategic hesitancy often delays innovation as firms wait to observe how competitors navigate new technologies before committing. This view contrasts with Raj, Dwivedi, Sharma, Lopes-de-Sousa-Jabbour and Rajak (2020), who highlight regulatory frameworks in emerging economies as a genuine and critical barrier, exacerbated by a lack of standardization across regions. Similarly, Ogunye, Egwuatu, Anene, Azubuike, Asenuga, Sargwak et al. (2024) highlight infrastructural limitations and skill shortages as key barriers in regions such as Africa, further complicating the adoption process. These findings resonate with the broader challenges of integrating emerging technologies in pharmaceutical production environments.

Recent studies have identified various barriers to Industry 4.0 adoption, particularly in emerging economies and traditional manufacturing sectors (Sharma, Sehrawat & Giannakis, 2023). However, there is a growing recognition that these barriers are not uniform across industries, and the pharmaceutical sector, with its unique regulatory and operational demands, faces distinct challenges (Arden et al., 2021; Sharma, Sehrawat et al., 2023). Understanding these barriers in the context of pharmaceutical manufacturing is crucial for developing strategies that can accelerate the adoption of Industry 4.0 technologies (Javaid, Haleem, Singh & Suman, 2022). The insights gained from analyzing these barriers can guide companies in overcoming resistance and enhancing their digital maturity, ultimately leading to the more effective adoption of Industry 4.0 technologies (Senna, Lima, Gouvea-da-Costa & Pesqueira, 2022). However, despite extensive research on the barriers to Industry 4.0 adoption in various sectors, there is a notable gap in the literature specifically addressing the pharmaceutical industry (Sharma, Sehrawat et al., 2023). Alcácer, Rodrigues, Carvalho and Cruz-Machado (2021) found significant variation in readiness levels across industries, often due to a lack of alignment between business models and technological strategies. Breunig et al. (2016) highlight that only 16% of manufacturers have an overall Industry 4.0 strategy, mirroring the challenges in the pharmaceutical sector, where aligning business models with technological advancements remains an unresolved barrier (Raj et al., 2020). This underscores the need for sector-specific studies that consider the unique regulatory, operational, and financial challenges faced by pharmaceutical companies. Therefore, this study focuses on exploring and analyzing the barriers to Industry 4.0 adoption. A case study approach is utilized to obtain a deeper understanding of the particular challenges faced by pharmaceutical companies.

This study aims to address this gap by providing a detailed, sector-specific study of the barriers to Industry 4.0 adoption within pharmaceutical manufacturing companies. The study identifies the key factors that contribute to each of these barriers. The study thereby contributes to the broader literature on Industry 4.0 by offering a detailed account of the barriers to Industry 4.0 adoption in the pharmaceutical industry. By examining the factors that hinder digital transformation (Nimawat & Gidwani, 2023), this study provides contextually grounded insights that can inform how pharmaceutical companies strategically align their digital initiatives with overall business goals, thereby facilitating a smoother transition to Industry 4.0 and overcoming barriers to digital transformation.

The remainder of this paper is structured as follows: The next section provides a review of the relevant literature on Industry 4.0 adoption and its associated barriers. The subsequent section outlines the methodology used in this study; this is followed by the presentation of the results. The paper concludes with a discussion of the findings, their relevant implications for the pharmaceutical industry, and recommendations for future research.

2. Literature Review

This section first discusses the general literature barriers to Industry 4.0 adoption, after which the focus is shifted toward the specific challenges faced by pharmaceutical companies.

2.1. General Barriers to Industry 4.0 Adoption

Industry 4.0 generally refers to the integration of digital technologies such as the Internet of Things (IoT), artificial intelligence (AI), robotics, and advanced analytics into manufacturing systems (Lasi et al., 2014; Kagermann et al., 2013; Lee et al., 2015). While these technologies can improve product quality, operational efficiency, and production flexibility (Moeuf, Pellerin, Lamouri, Tamayo-Giraldo & Barbaray, 2018; Cohen, Faccio, Pilati & Yao, 2019), their implementation in practice has been slower than anticipated due to a range of barriers. These benefits are

particularly relevant in highly regulated environments such as pharmaceutical manufacturing, where data integrity and regulatory compliance are critical. For example, Mariappan et al. (2023) illustrate how intelligent value stream mapping (IVSM), based on real-time data collection, can be used to dynamically optimize production processes and reduce lead times and bottlenecks in regulated pharmaceutical settings.

As noted by O'Donovan, Leahy, Bruton and O'Sullivan (2015), the path toward the full-scale adoption of Industry 4.0 technologies is fraught with challenges, especially in highly regulated sectors such as pharmaceuticals, where stringent regulations and complex production processes contribute to the complexity of implementing these innovations. Raj et al. (2020) emphasize the so-called "productivity paradox," which raises questions about the clear economic benefits of Industry 4.0 technologies and contributes to delayed adoption. Moreover, as Geissbauer, Schrauf, Koch and Kuge (2014) highlight, high investment costs are a major hurdle, particularly for industries with complex production processes. Kagermann et al. (2013) classify these barriers into technological challenges, regulatory barriers, financial constraints, and organizational resistance, a finding echoed by Breunig et al. (2016), who found that only 16% of manufacturers have a clear Industry 4.0 strategy. Senna et al. (2022) identify standardization issues and a lack of off-the-shelf solutions as high-impact barriers, emphasizing that the integration of legacy systems complicates digital transformation efforts. Similarly, Sharma, Raut and Sehrawat (2023) highlight organizational resistance and workforce reskilling as high-dependency barriers that delay Industry 4.0 implementation. Schröder (2016) notes that in highly regulated sectors such as pharmaceuticals, regulatory barriers further complicate the adoption process, as regulators struggle to keep pace with rapidly evolving technologies.

Overall, the literature suggests that the main categories of challenges hindering the adoption of Industry 4.0 can be grouped into technological, financial, and organizational barriers, which are discussed in the following subsections.

2.1.1. Technological Barriers

Technological challenges to the adoption of Industry 4.0 technologies can partly be explained by the fact that Industry 4.0 often necessitates substantial upgrades to existing infrastructure, making it both costly and complex, particularly for small and medium-sized enterprises that lack the necessary funding for such advancements (Raj et al., 2020). Moreover, the issue of interoperability between new and legacy systems presents significant technical hurdles. As highlighted by Cohen et al. (2019) and Kiel, Arnold and Voigt (2017), the synchronization of diverse technologies, methods, and communication languages can lead to substantial challenges in creating seamless integration. Zutin et al. (2022) propose that applying the technology readiness level (TRL) scale is an effective means to evaluate the maturity of different technologies, such as IoT and simulation, which is relevant to pharmaceutical companies where certain technologies remain underdeveloped or at pre-production levels.

However, the adoption of Industry 4.0 is not purely a rational process driven by technological and financial incentives. Fogaça, Grijalvo and Sacomano-Neto (2022) argue that institutional isomorphism—the tendency of organizations to conform to external pressures—plays a crucial role in shaping Industry 4.0 adoption across industries. This institutional perspective is particularly relevant in sectors such as pharmaceuticals, where regulatory and compliance pressures often drive digital transformation (Fogaça et al., 2022). Data security also poses a critical barrier; Breunig et al. (2016) note that firms often lack the required expertise to address cybersecurity concerns effectively in an Industry 4.0 environment. Bagherian, Srivastav and Mukherjee (2024) emphasize that smart factory adoption faces non-regulatory barriers such as high technology costs, legacy system integration, and skill shortages —barriers that resonate with those faced by pharmaceutical manufacturers.

These insights can be contrasted with Arden et al. (2021), who suggest that the real issue may not lie solely in the regulatory environment but in the inadequate implementation of applicable technologies such as real-time analytics and cloud-based solutions. Alcácer et al. (2021) note that technological readiness varies widely across companies, with many lacking a clear strategic vision to implement the necessary infrastructure for full-scale adoption. In addition, Alcácer et al. (2022) found that different departments within an organization can have varying levels of Industry 4.0 readiness, highlighting the importance of strategic alignment and targeted interventions to address disparities across production lines and support services.

2.1.2. Financial Barriers

Financial constraints represent a significant barrier for many companies seeking to implement Industry 4.0 technologies. According to Raj et al. (2020), firms aiming to adopt Industry 4.0 may need to commit to increasing their annual capital investments by up to 50% for several years, thus necessitating a re-engineering of their strategies. This heavy financial burden, as Senna et al. (2022) emphasize, is particularly challenging for small and medium-sized enterprises (SMEs), which often lack the necessary financial resources to upgrade infrastructure and purchase new equipment. While SMEs face more direct financial challenges in adopting Industry 4.0 technologies (Mittal, Khan, Romero & Wuest, 2018), larger pharmaceutical companies are more likely to grapple with financial prioritization issues, balancing investments in new technologies with the high costs of compliance and operational demands (Türkeş, Oncioiu, Aslam, Marin-Pantelescu, Topor & Căpuşneanu, 2019). Moreover, the uncertainty around the return on investment (ROI), as noted by Kamble et al. (2018), further complicates decision-making, making it difficult for companies to justify these expenditures.

Graham (2024) notes that regulatory compliance in the pharmaceutical industry serves as both a driver and a barrier to Industry 4.0 adoption. While compliance pressures frequently motivate firms to adopt advanced technologies, the financial and validation costs associated with meeting regulatory standards make this process expensive, particularly for companies operating with thin margins, such as generic pharmaceutical manufacturers. Ogunye et al. (2024) further underscore the financial challenges in regions where infrastructure limitations are significant, noting that even in countries with emerging pharmaceutical sectors, the high costs of implementing new technologies and training personnel are major barriers to Industry 4.0 adoption.

2.1.3. Organizational Barriers

The organizational barriers to Industry 4.0 adoption are compounded by knowledge gaps and a lack of workforce readiness, particularly in highly regulated sectors such as pharmaceuticals. Reinhardt, Oliveira and Ring (2020) demonstrate that awareness of Industry 4.0 technologies is often concentrated at the senior management level, leaving a significant portion of the workforce uninformed about the benefits and requirements of digital transformation. This lack of knowledge exacerbates resistance to change; Reinhardt et al. (2020) note that awareness remains limited among non-management staff, with only 42% of respondents indicating knowledge of these technologies. Bagherian et al. (2024) identify technological complexity, skills shortages, and data management challenges as significant barriers to Industry 4.0 adoption in highly regulated sectors, echoing the difficulties faced by the pharmaceutical industry in integrating new technologies with existing legacy systems.

This lack of awareness is a major barrier, particularly at the operational level, where resistance to new technology can hinder digital transformation. Additionally, while regulatory compliance often serves as a motivator for adopting advanced technologies, it also acts as a barrier due to the high costs and complexity of integration (Graham, 2024). In addition, while extensive research has been conducted regarding the adoption of Industry 4.0 in various manufacturing sectors, there is a notable gap in the literature specifically addressing its implementation within the pharmaceutical industry.

Similarly, Nimawat and Gidwani (2023) emphasize that workforce readiness plays a critical role in successful Industry 4.0 adoption. Sharma, Kumar, Lai and Chen (2022) and Ávila-Bohórquez and Gil-Herrera (2022) note that overcoming cultural resistance is heavily reliant on top management support and strategic alignment, which can foster a culture of change and minimize resistance. Without adequate training and development programs, companies struggle to overcome the skills gap, which is essential for operating and maintaining new technologies effectively.

Finally, resistance to change is a well-documented barrier to the adoption of new technologies. Horváth and Szabó (2019) emphasize that adopting Industry 4.0 technologies requires a significant shift in mindset, both at operational and management levels. Without this cultural shift, resistance from the workforce, particularly due to a lack of skills, can become a major obstacle. According to Kiel, Müller, Arnold and Voigt (2017), fears of job losses due to automation exacerbate this resistance, especially among employees and middle managers, who have expressed concerns about how these changes will affect the social structure within the company. Kamble et al. (2018) further

highlight the importance of continuous workforce retraining and upskilling, stressing that companies must be willing to invest in the development of their employees to successfully implement Industry 4.0 technologies.

2.2. Barriers Specific to the Pharmaceutical Industry

2.2.1. Complexity-Related Challenges

While the barriers to Industry 4.0 adoption are relevant across various manufacturing sectors, the pharmaceutical industry faces unique challenges, primarily due to its stringent regulatory framework. Marques et al. (2020) emphasize that this framework makes technological innovation more time-consuming and costly, with regulatory requirements such as good manufacturing practices (GMP) significantly constraining the adoption of new technologies. Schröder (2016) similarly highlights how regulatory challenges compound the technical difficulties of integrating innovations in the pharmaceutical industry, requiring rapid adaptations from both firms and regulators. Additionally, the sense of urgency in adopting Industry 4.0 technologies can differ across organizational levels. Stark, Wan and Chin (2022) note that while strategic decision-making is often responsible for the initial adoption of Industry 4.0, tactical management drives technology selection and implementation.

Within the pharmaceutical sector, regulatory complexity adds another layer of difficulty to Industry 4.0 adoption. Arden et al. (2021) stress that regulatory concerns, such as the need for good practice (GxP) compliance and technology validation, remain key hurdles preventing the full-scale adoption of new technologies such as continuous manufacturing. This is also supported by Reinhardt et al. (2020), who found that regulatory compliance decelerates the adoption of digital technologies due to the need for re-validation processes.

In the Indian pharmaceutical sector, Sharma, Sehrawat et al. (2023) have observed that high implementation costs, data security concerns, and infrastructure limitations are critical impediments to Industry 4.0 adoption, reflecting similar challenges in other regions. Ogunye et al. (2024) further emphasize that infrastructural limitations, particularly in emerging markets, exacerbate the difficulty of adopting emerging technologies such as AI, IoT, and predictive analytics. Interestingly, Arief et al. (2022) have found that many pharmaceutical firms, particularly in developing countries such as Indonesia, are still in the early stages of digital integration (simplification and automation).

Graham (2024) highlights the paradox wherein regulatory compliance, while driving the adoption of advanced technologies to meet data integrity and supply chain visibility requirements, also creates significant barriers due to the costs of validation and re-validation processes. Ogunye et al. (2024) have similarly found that the complex production processes in pharmaceutical manufacturing, particularly in regions with infrastructural limitations, add financial and operational challenges to the adoption of Industry 4.0 technologies. Zutin et al. (2022) draw parallels between the high operational costs and technological integration challenges faced by aircraft and pharmaceutical industries, both of which operate under stringent regulatory constraints. Additionally, Alcácer et al. (2021) emphasize the variations in readiness levels across different pharmaceutical companies, pointing to the need for a more structured approach to digital transformation that aligns with regulatory standards and operational demands. More specifically, Alcácer et al. (2022) note that readiness models can be essential tools for pharmaceutical companies to assess their progress toward Industry 4.0 adoption, especially in areas where digital maturity is critical for regulatory compliance.

Moreover, the complexity of pharmaceutical production, particularly in biotechnological processes where product stability cannot always be guaranteed, further complicates the adoption of Industry 4.0 technologies (Silva et al., 2020). Arden et al. (2021) note that the lack of regulatory precedence often induces companies to maintain conventional processes rather than adopt new technologies, thus increasing the time and expenses associated with technological innovation. Bagherian et al. (2024) argue that partnerships with technology providers and fostering a culture of innovation can help pharmaceutical companies overcome technical and organizational barriers by incorporating external expertise and aligning internal capabilities with new technologies. Furthermore, the vast institutional and regulatory knowledge linked to existing technologies, as well as the need to ensure compliance with both existing and emerging regulations, adds financial and operational complexity (Arden et al., 2021; Lee et al., 2015).

2.2.2. Barriers in the Pharmaceutical Industry

According to the literature, the barriers that the pharmaceutical industry faces may be summarized as follows:

- Compliance with regulatory standards
- Complexity of production processes
- Financial and strategic alignment issues

One challenge of "compliance with regulatory standards" is that the pharmaceutical industry is particularly heavily regulated. On the other hand, it stands to benefit significantly from integrating Industry 4.0 technologies such as the Internet of Things (IoT) and artificial intelligence (AI) (Arden et al., 2021). These technologies promise to enhance the agility, efficiency, and quality of drug manufacturing processes. However, integrating IoT and AI into such a tightly controlled environment will involve challenges. As noted by Marques et al. (2020), the regulatory landscape for pharmaceuticals imposes stringent protocols, particularly regarding safety and efficacy evaluations, which adds complexity to any technological upgrades. Furthermore, Sharma, Sehrawat et al. (2023) highlight that the adoption of Industry 4.0 technologies in the pharmaceutical sector is often hindered by obstacles such as the lack of standardization across regulatory frameworks. Ensuring compliance with GxP standards during the integration of new technologies remains a key concern, requiring rigorous validation to align with the industry's strict guidelines, as Arief et al. (2022) emphasize.

Due to the "complexity of production processes," pharmaceutical manufacturing firms, as noted by Arden et al. (2021), involve complex, multi-stage processes that must adhere to precise specifications. The introduction of Industry 4.0 technologies, such as AI and robotics, into these processes requires careful consideration to avoid disruptions. Marques et al. (2020) emphasize that the transition to continuous manufacturing and other advanced systems can eliminate inefficiencies but also carries significant risks of operational disruptions if not properly managed. Additionally, Arden et al. (2021) note that the high cost of failure and regulatory uncertainties make pharmaceutical companies cautious about adopting new technologies, often preferring to observe how competitors handle these innovations before committing. Marques et al. (2020) further highlight that the intense cost pressures faced by the pharmaceutical industry exacerbate these challenges, as firms must carefully balance innovation with financial viability.

Finally, the "financial and strategic alignment issues" related to adopting Industry 4.0 technologies in the pharmaceutical sector are substantial, as Arden et al. (2021) explain, with initial investments in both capital and operational expenses required to update or build new facilities. However, these financial challenges are further compounded by the need for strategic alignment within global organizations. Raj et al. (2020) note that the absence of a cohesive digital strategy, combined with resource scarcity, exacerbates the difficulties faced by multinational firms. According to Marques et al. (2020), this misalignment between local and global priorities often results in delays and inefficiencies, thus complicating the implementation of Industry 4.0 initiatives. While Schröder (2016) highlights the regulatory complexity, Arden et al. (2021) argue that many barriers attributed to regulation may, in fact, stem from inadequate technological infrastructure, suggesting that more advanced technologies could ease compliance concerns.

2.3. Literature Discussion

To synthesize the most relevant contributions on Industry 4.0 adoption, digital transformation, and associated barriers in pharmaceutical and related manufacturing sectors, Table 1 summarizes selected studies, their sectoral focus, methodological approaches, and main insights regarding barriers and Industry 4.0 maturity. This overview also positions the present study within the existing body of research and highlights the research gaps it addresses.

As indicated by the previous sections, extensive research has been conducted regarding the barriers to Industry 4.0 adoption in manufacturing sectors, while studies that focus specifically on the pharmaceutical industry remain comparatively few. Much of the existing literature addresses traditional manufacturing sectors such as automotive or electronics (e.g., Raj et al., 2020; Javaid et al., 2022) or examines emerging economies where infrastructure and regulatory environments differ from those in highly regulated industries. In contrast, the pharmaceutical sector, with its stringent regulatory requirements, complex production processes, and unique operational demands, remains relatively underexplored in terms of how general Industry 4.0 barriers manifest in practice.

Study	Context and method	Main focus	Key findings on barriers / maturity	Gap relative to this study
Raj et al. (2020)	Expert-based empirical MCDM study using Grey-DEMATEL (cross-sector manufacturing)	Identification and causal analysis of Industry 4.0 barriers across economic contexts	Highlights lack of digital strategy, resource scarcity, and high investment costs as critical causal barriers	Cross-sectoral; does not include a maturity assessment or detailed intra-firm barrier ranking
Marques et al. (2020)	Conceptual model and case-informed analysis (pharmaceutical manufacturing)	Decision-support and operational challenges in chemical-pharmaceutical manufacturing	Emphasizes that GMP requirements, regulatory constraints, and process complexity hinder digitalization; identifies decision-support limitations related to data availability and integration	Does not systematically map or rank barriers; no maturity assessment; lacks plant-level empirical investigation
Reinhardt et al. (2020)	Survey (European pharmaceutical manufacturing; Ireland-focused sample)	Current Industry 4.0 adoption, awareness across roles/departments, and planned digital initiatives	Reveals major gaps in Industry 4.0 awareness between senior management and operational staff; documents uneven adoption across functions; identifies most commonly implemented and planned technologies	Does not analyze barriers or regulatory factors in depth; no maturity assessment; no structured barrier mapping or prioritization
Arden et al. (2021)	Conceptual / illustrative cases (pharmaceutical/biotech manufacturing)	Industry 4.0 vision for pharmaceutical manufacturing, including digital maturity, automation, AI, cyber-physical systems, and regulatory/technical challenges	Highlights regulatory uncertainty, lack of precedent, validation burdens, technical integration challenges (AI, PAT, Big Data), cybersecurity risks, and workforce skill gaps	Does not analyze barriers within a single organization or CDMO; no maturity assessment or barrier ranking
Sharma, Sehrawat, et al. (2023)	Expert interviews + MCDM (AHP–CODAS–DEMATEL) (Indian pharmaceutical sector)	Identification, ranking, and causal analysis of barriers and potential solutions for Industry 4.0 adoption (transition to I4.0+)	Finds costly venture, deficit of customer awareness, lack of senior management support, lack of supplier flexibility, and standardization/regulatory issues as the most critical barriers; no maturity assessment conducted	Focused on a specific national context; does not include plant-level analysis or a structured maturity assessment
Ogunye et al. (2024)	Literature review with secondary case illustrations (pharmaceutical manufacturing in Africa and emerging markets)	Impact of emerging technologies (AI, ML, IoT, Robotics) on process design and optimization in African pharmaceutical manufacturing	Identifies major adoption barriers including infrastructural limitations, financial constraints, regulatory challenges, skills shortages, and uneven technological readiness across countries; emphasizes that full digital maturity is still limited	Provides macro-level, regional insights but no plant-level analysis, no maturity assessment, and no structured prioritization of barriers within a single organization
Alcácer et al. (2021, 2022)	Case studies using IMPULS-based I4.0 maturity assessment (regulated manufacturing sectors; automotive value chain)	Assessment of I4.0 maturity levels across internal departments and value-chain elements; tracking differences and monitoring progress over time	Demonstrate significant variation in readiness/maturity levels across departments; highlight integration limitations, uneven adoption of enabling technologies, and gaps in internal value-chain alignment	Do not analyze barriers in a structured way or prioritize them; do not link maturity results to a barrier framework; do not focus on pharmaceutical or CDMO settings

Study	Context and method	Main focus	Key findings on barriers / maturity	Gap relative to this study
Argiyantari, Simatupang & Basri (2020)	Systematic literature review (global pharmaceutical supply chain)	Lean supply chain implementation in the pharmaceutical supply chain; classification of prior research and identification of underexplored areas (supplier management, downstream activities, logistics, IT integration)	Highlights significant research gaps in PSC lean implementation—limited attention to downstream logistics, supplier engagement, IT integration, and the lack of integrated upstream–downstream lean approaches; does not assess Industry 4.0 or digital maturity	Conceptual rather than empirical; does not address Industry 4.0 maturity, digital transformation, or barrier prioritization within a CDMO context

Table 1. Selected studies on Industry 4.0 adoption, barriers, and maturity

Furthermore, while the existing literature discusses various barriers to the adoption of Industry 4.0 in manufacturing industries broadly (Kagermann et al., 2013; Raj et al., 2020), there is limited specificity regarding how these barriers affect different types of pharmaceutical organizations and production settings. Highly regulated environments introduce additional layers of complexity, particularly around compliance with GxP standards, the validation of new technologies, and the financial and strategic alignment required to implement digital transformation initiatives at a global scale. Prior work also tends to analyze barriers at an aggregated sector or national level, whereas fewer studies combine a detailed, plant-level analysis with a systematic assessment of Industry 4.0 maturity.

In conclusion, the literature provides a wealth of knowledge concerning Industry 4.0 adoption across various industries, and it identifies a set of barriers that appear to be generalizable to the pharmaceutical sector. However, as also pointed out by Argiyantari et al. (2020), there is still a need for research that moves beyond conceptual and literature-based analyses toward empirical studies within specific pharmaceutical organizations and supply chains, examining how transformation initiatives are implemented in practice. In particular, there is a lack of studies that (i) integrate a structured maturity assessment with a qualitative identification of barriers and (ii) prioritize these barriers within a concrete organizational setting. To address these gaps, the present study undertakes an in-depth single case study of a pharmaceutical contract development and manufacturing organization (CDMO), combining an Industry 4.0 maturity assessment with qualitative data to identify and rank barriers. This design aims to provide rich, context-sensitive insights that complement existing survey-based and conceptual contributions by offering analytical generalization to the broader population of pharmaceutical manufacturers rather than statistical generalization.

3. Methodology

The purpose of the empirical research was to understand how barriers to Industry 4.0 adoption manifest within a pharmaceutical manufacturing organization and to uncover the contextual factors that shape these barriers. To do so, a single case study design was selected following established guidance for in-depth empirical investigation of complex organizational phenomena (Yin, 2017; Eisenhardt & Graebner, 2007; Voss, Tsikriktsis & Frohlich, 2002). This approach is particularly appropriate when the objective is to understand how Industry 4.0 barriers manifest within a specific organizational and regulatory context—insights that cannot be captured through high-level surveys or conceptual analyses alone. As highlighted in the literature review, prior research on Industry 4.0 in pharmaceuticals has predominantly provided sector-level or conceptual discussions, while studies combining an Industry 4.0 maturity assessment with a detailed, plant-level barrier analysis remain scarce.

The selected case, a large pharmaceutical CDMO operating in a highly regulated environment, offers an information-rich setting that enables analytical generalization rather than statistical generalization. By examining this case in depth, the study aims to generate nuanced, context-sensitive insights into the barriers to Industry 4.0 adoption that complement existing survey-based and cross-sector studies.

The study was designed to identify how barriers to Industry 4.0 adoption manifest within a pharmaceutical manufacturing context. To achieve this, the research followed a structured sequence of analytical steps:

1. Current State Maturity Assessment: A structured questionnaire survey was conducted with 20 stakeholders to assess the company's existing Industry 4.0 maturity level.
2. Desired State Maturity Assessment: A similar survey was conducted with the leadership team to gauge the desired future state of digital maturity. Hereafter, the differences between the current and desired states were analyzed to identify areas of improvement.
3. Barrier Identification and Classification: Barriers to Industry 4.0 adoption were identified from the surveys and organized using terminology identified from the literature.
4. Barrier Ranking: The barriers were ranked based on their significance through in-depth semi-structured interviews with the 20 stakeholders.
5. Understanding of Barriers: The in-depth semi-structured interviews were analyzed for a deeper understanding of the barriers.
6. Identification of Contributing Factors: The factors contributing to these barriers in the pharmaceutical industry were identified to contextualize the findings.

The steps outlined in this study are visually represented in Figure 1, which presents a diagram illustrating the correlation and integration of each stage. The diagram maps the entire research process, from data collection to analysis, culminating in the identification of the reasons behind the barriers and contributing factors. This figure emphasizes how each step is interconnected to provide a comprehensive understanding of the barriers hindering Industry 4.0 adoption.

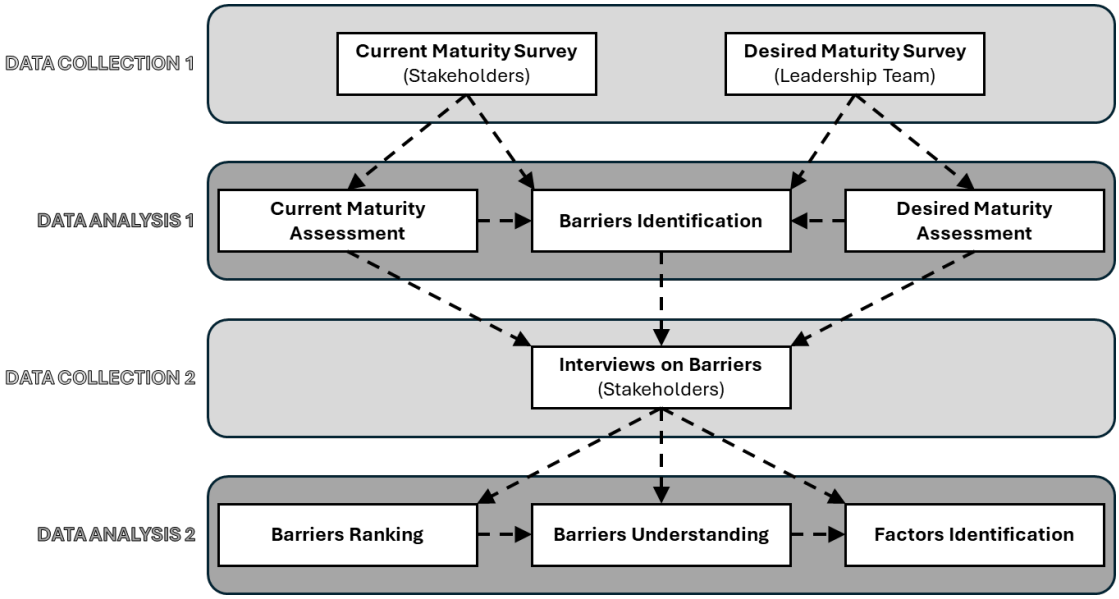

Figure 1. Research process overview

3.1. Case Context

The case company, a leading global player in the biopharmaceutical contract development and manufacturing organization (CDMO) sector, operates across 10 sites worldwide with over 4,200 employees. The company specializes in developing and manufacturing biologics, advanced therapies, and vaccines, and providing comprehensive services to pharmaceutical companies. Significant recent investments totaling 8.6 billion USD have expanded its global footprint, particularly in Europe and the United States.

The case company's manufacturing site in Denmark is one of the largest end-to-end cell culture production facilities in Europe. This facility employs more than 1,600 people and generates approximately 460 million euros in annual revenue. The site is crucial to the company's operations, offering both drug substance production and finished goods services. It plays a vital role in advancing the company's capabilities in manufacturing complex biologics such as monoclonal antibodies and other innovative therapies.

This study focuses on the Finished Goods department of the Danish facility, which operates within a highly regulated and technologically advanced environment. The site's adoption of Industry 4.0 technologies, combined with Denmark's strong position in biopharmaceutical development, makes it an ideal case study for examining the barriers and drivers of digital transformations in pharmaceutical manufacturing. By investigating this specific facility, the study provides valuable insights into the company's efforts to enhance digital maturity and operational efficiency.

3.2. Data Collection

This study employed a mixed-methods approach, integrating both quantitative (maturity assessment) and qualitative (stakeholder interviews) data to comprehensively assess the barriers to Industry 4.0 adoption within the case company. Data were collected in three main stages: a current state maturity assessment with 20 stakeholders, a desired state maturity assessment with the site leadership team, and in-depth semi-structured interviews with the same 20 stakeholders regarding barriers. The assessed component involved the analysis of data derived from the maturity model assessment, while the perceived component was based on insights gathered through the interviews. This combined approach allowed for a nuanced understanding of both the actual and perceived barriers to digital transformation.

Within the Current State Maturity Assessment, a structured questionnaire was distributed to 20 stakeholders from various functional areas of the company to evaluate the company's existing digital and technological capabilities, providing a quantitative foundation for the research.

In parallel, a Desired State Maturity Assessment was administered to the leadership team to determine their expectations regarding future digital maturity. The results from these assessments were then used to conduct a gap analysis to identify discrepancies between the current and desired states. This analysis served to highlight critical areas that needed to be addressed for successful digital transformation.

3.2.1. Current State Maturity Assessment

The first phase of the research involved conducting a maturity assessment of the company's current state with respect to Industry 4.0 adoption. The assessment was based on the Acatech Industry 4.0 Maturity Index (Schuh, Anderl, Dumitrescu, Krüger & ten-Hompel, 2020), which was selected for several key reasons:

- Comprehensive coverage: The Acatech model across critical dimensions such as Resources, Information Systems, Organizational Structure, and Culture makes it particularly suitable for the needs of the case company. This broad approach ensures that all relevant aspects of digital transformation are captured and evaluated.
- Flexibility and adaptability: The model allows for adjustments tailored to the specific context of a Contract Development and Manufacturing Organization (CDMO). This adaptability is essential for accurately reflecting the unique characteristics and requirements of the pharmaceutical manufacturing sector.
- Detailed descriptions: The model offers detailed descriptions of each dimension, sub-dimension, and capability, facilitating a deep understanding of what is required at each maturity level. This depth ensures an accurate assessment and helps identify specific areas for improvement.
- Strategic integration: The model incorporates strategic input from the company, aligning the assessment with the company's long-term goals and priorities. This makes the assessment more than a static snapshot —it becomes a forward-looking tool for guiding future improvements.

- Industry validation: The Acatech model has been validated through its adoption by various industries, including pharmaceuticals, as recognized by the International Society of Pharmaceutical Engineering (ISPE). This validation provides confidence in the model's applicability and reliability.

Overall, the Acatech Industry 4.0 Maturity Index was deemed the most suitable model for conducting a comprehensive and tailored assessment of the case company's digital capabilities and Industry 4.0 maturity.

This index categorizes digital maturity into six stages: computerization, connectivity, visibility, transparency, predictive capacity, and adaptability. The assessment was designed to evaluate the company's current level of maturity across these stages, with a particular focus on the pharmaceutical manufacturing case company.

Data for the maturity assessment were collected through a structured survey distributed to 20 key stakeholders selected via a purposive sampling strategy within the organization. The stakeholders were chosen based on their roles within the company, with the aim of capturing a diverse range of perspectives from different functional areas, including logistics, production, process development, production support activities (PSA), and marketing and sales. The selected stakeholders included senior leaders, managers, and employees who were directly involved in or affected by the company's digital transformation initiatives. Table 2 summarizes the distribution of stakeholders by department and job title.

Department	Number of Stakeholders	Job Titles
Logistics	5	Sr Support Analyst, Analyst (Purchasing), Logistics Specialist, Associate (Strategic Planning & Analytics), Sr Analyst (Supply Planning)
Marketing & Sales	3	Sr Director (Commercial), Manager, Associate Director (Program Manager)
Process Development	3	Sr Manufacturing Support Associate, Associate Director (Process Science), Associate Director (Process Technology)
Production	4	Associate Manager (x2), Sr Director, Team Lead
Production Support Activities	5	Sr Operational Engineer (Maintenance), Young Grad (Maintenance), Sr Associate (Quality Assurance) (x3)

Table 2. Distribution and roles of the selected group of stakeholders

The survey included multiple-choice and open-ended questions related to the company's existing technological infrastructure, digital capabilities, and organizational culture. The responses were scored on a scale from 1 to 6, with higher scores indicating a higher level of digital maturity.

3.2.2. Desired State Maturity Assessment

Following the initial assessment of the company's current digital maturity, the same structured survey was administered to the site leadership team, but this time with a forward-looking perspective. The leadership team was asked to evaluate where they believe the company should be in the future (desired state) to remain competitive in the pharmaceutical industry, particularly in the context of Industry 4.0 advancements.

The maturity assessment, which included both the current state evaluation and the desired future state as envisioned by the leadership team, provided valuable insights into the company's digital transformation journey. By comparing the current and desired maturity levels, we were able to identify key gaps and obstacles that hinder the company's progress toward Industry 4.0 adoption.

In this context, the difference between maturity and readiness should be emphasized. In line with the literature, the Acatech Industry 4.0 Maturity Index is used in this study to evaluate the company's current state of digital capabilities (i.e., maturity), rather than its short-term preparedness to undertake specific change initiatives (i.e., readiness). In our design, readiness is therefore not directly measured by the maturity index, but is instead inferred more indirectly from the gap between current and desired maturity levels and from the qualitative insights obtained in the stakeholder interviews.

3.2.3. Stakeholder Interviews

Following the completion of the maturity assessment, the same 20 stakeholders were contacted again for in-depth, semi-structured interviews. These interviews served multiple purposes, primarily to gain deeper insights into the identified barriers to Industry 4.0 adoption and to contextualize these barriers within the specific operational realities of the pharmaceutical industry. The interviews also aimed to validate and expand upon the findings from the quantitative data, ensuring that the perspectives of key stakeholders were captured comprehensively. The specific objectives of the interviews were as follows:

- Clarify the relevance of different barriers from their perspective: Stakeholders provided their views regarding which barriers they believed were most impactful in hindering Industry 4.0 adoption.
- Understand the reasons behind the barriers: The interviews explored the underlying causes of each barrier, particularly those specific to the pharmaceutical industry.
- Validate and cross-check findings from the maturity assessment: The qualitative insights gathered in the interviews helped to verify and enrich the results of the initial survey.
- Gather actionable recommendations for overcoming the barriers: Stakeholders were asked to suggest potential strategies or solutions for addressing the barriers they identified.
- Explore the perceived impact of future digital initiatives: In addition to barriers, stakeholders discussed the anticipated benefits of Industry 4.0 adoption and the role that external support and internal maturity awareness would play in their digital transformation efforts.

The interviews were semi-structured, allowing for both guided questioning and open-ended responses. Each interview began with a brief overview of the study's objectives, followed by questions related to the identified barriers to Industry 4.0 adoption. The barriers discussed included understanding and awareness, technological challenges, organizational and cultural resistance, regulatory and compliance challenges, lack of skilled workforce, financial constraints, and prioritization and strategic alignment. Stakeholders were asked to rate the significance of each barrier on a scale from 1 to 5 and to provide qualitative insights into how these barriers manifested in their specific functional areas. In addition to these structured questions, open-ended questions were used to gather qualitative insights, allowing stakeholders to share their experiences and perspectives more freely. Topics such as the anticipated benefits of Industry 4.0, the importance of external support, and the future trajectory of digital transformation within the pharmaceutical industry were also explored.

Qualitative data were collected through the stakeholder interviews, which were conducted over a period of four weeks. Each interview lasted approximately 30 minutes and was recorded with the consent of the participants. The interviews were transcribed verbatim to ensure accuracy in capturing the stakeholders' perspectives.

3.3. Data Analysis

The quantitative data from the maturity assessment were aggregated and analyzed using descriptive statistics to calculate the average scores for each stage of digital maturity. This analysis provided insights into the company's overall maturity level across different departments, identifying areas where the company was most advanced and those where significant improvements were needed. The results were used to highlight key areas where the company was lagging and to prioritize the focus areas for the subsequent study.

The survey with the site leadership team provided a high-level understanding of the strategic goals and specific leadership expectations for digital transformation. In particular, it highlighted areas where the organization's present capabilities fall short of its future aspirations in terms of digital integration and Industry 4.0 adoption.

Using the responses from both surveys, we identified a set of barriers to Industry 4.0 maturity. Open-ended questions allowed respondents to provide detailed feedback about specific capabilities assessed by the maturity model, highlighting areas of friction or limitation that could be interpreted as barriers to further progression. The terminology used to describe these barriers was aligned with concepts found in the existing literature on Industry 4.0 adoption challenges, allowing for a systematic organization of the barriers identified.

The interviews' quantitative data on barriers' rankings according to their relevance was analyzed through descriptive statistics. Meanwhile, the qualitative data from the interviews was transcribed and systematically analyzed using both deductive and inductive coding (Fereday & Muir-Cochrane, 2006) to identify recurring themes and patterns related to the barriers to Industry 4.0 adoption. Specifically, deductive coding was applied to organize the data under the seven predefined barriers identified in the previous step. Inductive coding was used to identify themes from the data (i.e., to identify key factors that contribute to these barriers).

4. Results

4.1. Current Maturity Level

The case company's maturity levels were assessed based on the eight capabilities of the Acatech Industry 4.0 Maturity Index, as shown in Table 3. The results reflect the company's overall digital maturity and areas where critical gaps remain. The results, presented in Table 3, indicate that the company's overall digital maturity stands at 2.84, corresponding to the second level (connectivity stage) of the Acatech Index.

Structural Areas	Resources		Information Systems		Organizational Structure		Culture	
Capabilities	Digital Capability	Structured Communication	Information Processing	Integration of IT Systems	Organic Internal Organisation	Dynamic Collaboration within Value Networks	Social Collaboration	Willingness to Change
Results Principles	2.78	2.91	2.36	2.57	3.00	1.79	3.65	3.67
Results Structural Areas	2.84		2.47		2.39		3.66	
Result Maturity Level	2.84							

Table 3. Current maturity level results across resources, information systems, organizational structure, and culture

The assessment across the four structural areas produced the following results:

- Resources: The average maturity score is 2.84, with notable capabilities such as Digital Capability (2.78) and Structured Communication (2.91). However, gaps remain in fully aligning the diverse machinery and systems used on site, which are often disconnected and fail to share data effectively across platforms.
- Information Systems: This area exhibited the most significant lag, scoring 2.47. While some systems are in place, they are poorly integrated, creating silos of data and delaying the potential to achieve live, real-time data processing.
- Organizational Structure: The company's Organic Internal Organization is relatively well-developed at 3.00, promoting interdisciplinary communication and agility in daily operations. However, the Dynamic Collaboration within the Value Network (1.79) was the lowest-scoring principle, reflecting difficulties in fostering partnerships and collaboration within and beyond the company.
- Culture: Cultural aspects scored the highest, particularly in Social Collaboration (3.65) and Willingness to Change (3.67), suggesting that there is a strong foundation for change acceptance, which can be leveraged in future digitalization efforts.

4.2. Desired Maturity Level

The results of the survey on desired maturity levels involving the site leadership team are presented in Table 4. The strategic input provided by the leadership team reflects their desired maturity level of 4.25, which corresponds to

the transparency stage. This state emphasizes the need for enhanced data integration, more advanced automation, and strengthened collaboration between internal departments and external partners.

Structural Areas	Resources		Information Systems		Organizational Structure		Culture	
Capabilities	Digital Capability	Structured Communication	Information Processing	Integration of IT Systems	Organic Internal Organisation	Dynamic Collaboration within Value Networks	Social Collaboration	Willingness to Change
Results Principles	3	5	4	5	4	4	5	4
Results Structural Areas	4		4.5		4		4.5	
Desired Maturity Level	4.25							

Table 4. Desired maturity level results based on leadership strategic input

This desired state emphasizes better data integration, improved automation, and enhanced collaboration both internally and with external partners. The leadership team expects Information Systems to play a pivotal role in this transformation, with a target score of 4.5 for Information Processing and Integration.

As depicted in Figure 2, the company has reached a maturity level of 2.84 in the Connectivity stage, indicating some level of digitalization but falling short of the desired Transparency stage (4.25). This gap underscores the need for significant improvements across different areas.

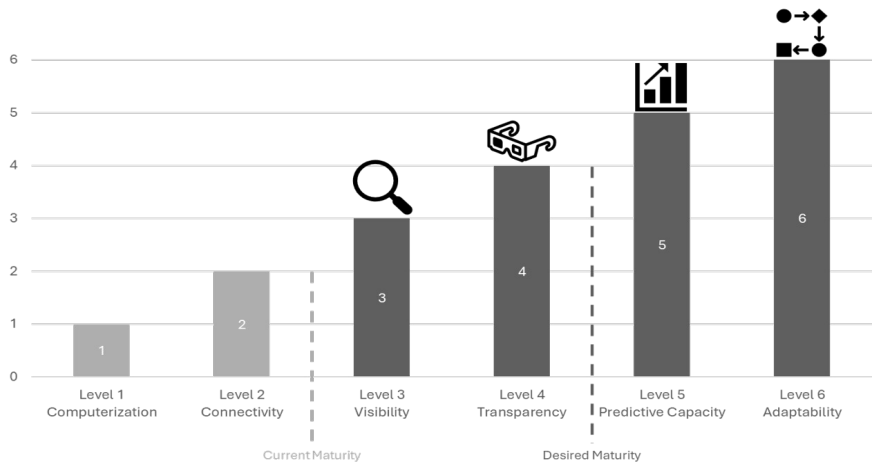

Figure 2. Overview of current and desired maturity levels according to the Acatech Maturity Model

To further illustrate the discrepancies between the current and desired states of digital maturity, a radar chart was used to compare maturity scores across key structural areas, as illustrated in Figure 3. The chart highlights where the most significant gaps exist, particularly in Information Systems and Organizational Structure.

Figure 3 shows the discrepancies between the current and desired maturity levels, particularly in Information Systems and Organizational Structure:

- Information Systems showed the largest deviation of -2.03, driven by insufficient real-time data processing and poor system integration. For instance, while enterprise resource planning (ERP) systems are in place, they are not fully leveraged to enable comprehensive data flow and visibility across the organization.

- Organizational Structure demonstrated a gap of -1.61, with Dynamic Collaboration requiring considerable attention. The low level of interdepartmental and external collaboration impedes the company's ability to respond flexibly to customer needs and market changes.
- Resources and Culture also exhibited moderate gaps of -1.16 and -0.84, respectively, reflecting the need for enhanced Structured Communication (currently 2.91) and a more uniform commitment to change across all levels of the organization.

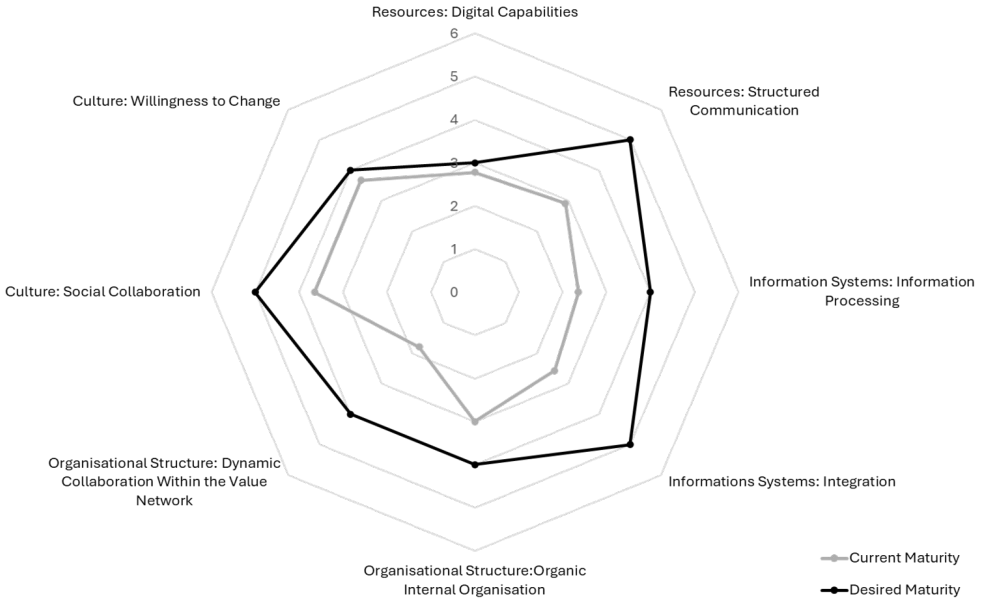

Figure 3. Radar chart of current and desired maturity levels across structural areas

In summary, the initial findings highlighted a significant gap, with the current maturity level at 2.84 and the desired level at 4.25, as depicted in Figures 2 and 3. This discrepancy underscored the need for substantial improvements across various domains. While the company exhibits strong cultural openness and willingness for digital transformation, the significant gaps in Information Systems and Organizational Structure suggest that technological infrastructure and collaboration mechanisms are critical bottlenecks that must be addressed to reach the leadership's desired state of digital maturity.

4.3. Identified Barriers

Building on the previously described gap analysis, barriers were identified from the maturity assessment surveys with the stakeholders and the site leadership team. In these surveys, respondents highlighted specific limitations and challenges to Industry 4.0 adoption. The identified barriers were initially broad and varied, encompassing technological, organizational, and strategic challenges. To refine our understanding and focus our analysis, these barriers were organized, merged, and categorized by leveraging both our empirical findings and the existing literature. This dual approach allowed us to distill the barriers into seven primary categories that are particularly pertinent to the pharmaceutical industry. The process of merging and prioritizing barriers involved a qualitative analysis, where the impact and frequency of each identified challenge were assessed. This assessment was based on the empirical data from the maturity assessments and the answers from the stakeholders in the questionnaire survey. Barriers that were frequently mentioned or those that had a significant impact on the company's digital transformation efforts were prioritized. Others, while noted, were considered to be either overly specific to certain departments or redundant within the context of broader, more impactful challenges. These seven barriers, structured to provide a foundation for further exploration in this study, include the following:

1. Prioritization and Strategic Alignment: A lack of clear strategic direction and leadership alignment with Industry 4.0 initiatives and the company's broader goals.

2. Technological Challenges: The complexity of integrating advanced Industry 4.0 technologies with legacy systems, which often lack full interconnectivity.
3. Financial Constraints: The limited financial resources available to fund expansive digital transformation efforts.
4. Regulatory and Compliance Challenges: Specific industry constraints that complicate the adoption of new technologies within the highly regulated pharmaceutical sector.
5. Lack of Skilled Workforce: A significant deficit in the workforce's technical expertise is necessary for implementing and managing advanced digital technologies.
6. Understanding and Awareness: Organizational knowledge gaps regarding the capabilities and benefits of Industry 4.0 technologies.
7. Organizational and Cultural Resistance: Internal resistance at various organizational levels, which impedes the adoption of new processes and technologies.

During the barrier identification process, several additional challenges were noted but were not distinctly categorized as primary barriers. These included issues such as "Lack of clear leadership," "Misalignment between global and local priorities," and "Complexity of GxP requirements." While significant, these challenges were found to be components of the broader barriers already identified. For instance, these include the following:

- A lack of clear leadership and a misalignment between global and local priorities were integrated into the Prioritization and Strategic Alignment barrier because these elements fundamentally influence the strategic direction and coherence in executing Industry 4.0 initiatives. Clear leadership is essential for establishing priorities that resonate across all levels of the organization, while the alignment of global and local priorities ensures that the strategic decisions support uniform advancement towards these goals, preventing fragmented efforts and conflicting objectives.
- High costs of implementation and competing financial priorities were subsumed under Financial Constraints because both directly impact the company's ability to invest in new technologies. High implementation costs often require substantial upfront investment, which can conflict with other financial obligations and priorities within the company. This category reflects the broader financial challenges of balancing the need for advanced technology with other fiscal responsibilities and resource allocations.
- The complexity of GxP requirements and the risk of non-compliance were included within Regulatory and Compliance Challenges, since both concern the legal and regulatory framework that governs the pharmaceutical industry. The complexity of GxP is directly linked to ensuring compliance with stringent standards, which is a prerequisite for legal and safe operations. Thus, both barriers are crucial considerations that affect every aspect of technology adoption, from system design to operation, ensuring that compliance is maintained.
- Lack of top-level awareness and uneven awareness across departments contributed to the formation of the Understanding and Awareness barrier because these issues indicate a significant disparity in the recognition of the benefits and requirements of Industry 4.0. This barrier captures the need for comprehensive education and communication strategies to ensure that all organizational levels and departments have a consistent understanding of what Industry 4.0 entails and how it can benefit the company.

This rigorous classification and merging process ensured that the final list of barriers not only reflects the most critical challenges the company faces but also aligns with the literature concerning Industry 4.0 adoption in the pharmaceutical sector. It provides a structured approach to addressing these barriers, facilitating targeted interventions and strategic planning.

Finally, by merging related challenges and focusing on the most impactful barriers, this categorization provides a clear framework for understanding the specific hurdles the company faces in its journey toward digital maturity. The next section will delve into the alignment of these assessed barriers with stakeholder perceptions, offering a nuanced comparison of internal and external views on Industry 4.0 adoption.

4.4. Stakeholders' Ranking of Barriers

The first part of the semi-structured interviews involved asking the interviewees to rank barriers identified in the previous step. Table 5 presents the average scores for each barrier, ranked from the most significant to the least significant according to the stakeholders' perceptions.

Stakeholders	Functional Area	Understanding and Awareness	Technological Challenges	Organizational and Cultural Resistance	Regulatory and Compliance Challenges	Lack of Skilled Workforce	Financial Constraints	Prioritization and Strategic Alignment
Sr Support Analyst (Supply Chain)	Logistics	3	2	1	4	2	3	3
Analyst (Purchasing)	Logistics	2	3	2	4	2	2	2
Logistics Specialist (Shipping & Cust. Serv.)	Logistics	1	3	2	1	1	2	2
Associate (Strategic Planning & Analytics)	Logistics	4	4	1	3	4	4	4
Sr Analyst (Supply Planning)	Logistics	2	4	3	4	3	3	3
Sr Director A (Commercial)	Mktg. & Sales	1	4	3	3	3	4	4
Manager (Program Manager)	Mktg. & Sales	2	2	1	1	4	1	1
Associate Director A (Program Manager)	Mktg. & Sales	4	2	2	4	2	4	4
Sr Mfg. Support Associate (Cont. Improv.)	Process Dev.	2	4	1	4	4	5	4
Associate Director B (Mfg. Sc. and Tech.)	Process Dev.	4	2	2	4	3	2	5
Associate Director C (Mfg. Sc. and Tech.)	Process Dev.	3	2	1	4	4	2	3
Associate Manager A (Inc. Mat. & Batch doc.)	Production	2	4	1	2	4	5	4
Associate Manager B (Management Mfg.)	Production	3	3	1	4	3	5	3
Sr Director B (Management Manufacturing)	Production	4	3	2	2	3	5	5
Team Lead (Manufacturing Associate)	Production	5	5	1	4	5	2	2
Sr Operational Engineer (Maintenance)	Prod. Support	2	3	1	2	4	4	5
Young Grad (Maintenance)	Prod. Support	3	4	3	4	4	3	4
Sr Associate A (Quality Assurance)	Prod. Support	3	4	1	4	3	3	3
Sr Associate B (Quality Assurance)	Prod. Support	2	5	1	2	2	4	5
Sr Associate C (Quality Assurance)	Prod. Support	1	3	1	1	2	3	3
	Avg.:	2.65	3.32	1.55	3.05	3.10	3.30	3.45
	Ranking:	6th	2nd	7th	5th	4th	3rd	1st

*Scale: 1 = very low significance, 2 = low significance, 3 = medium significance, 4 = high significance, 5 = very high significance. Rankings reflect stakeholders' assessment of the impact of each barrier on Industry 4.0 adoption.

Table 5. Stakeholders' Ranking of Barriers to Industry 4.0 Adoption

The results suggest that Prioritization and Strategic Alignment is perceived as the most significant barrier, with an average score of 3.45. This indicates that stakeholders believe there is a critical need for clearer strategic direction and alignment within the company. Technological Challenges follow closely, with an average score of 3.32, reflecting the complexities involved in integrating new technologies into existing systems, particularly in the highly regulated pharmaceutical environment.

Financial Constraints also rank highly, with a score of 3.30, underscoring the financial challenges the company faces in implementing Industry 4.0 technologies. These top three barriers highlight the need for a strategic approach that aligns technological initiatives with the company's overall financial planning and strategic goals.

Interestingly, Organizational and Cultural Resistance has the lowest score, at 1.55, suggesting that cultural resistance to change is not viewed as a major barrier within the organization. This may indicate a generally positive attitude toward digital transformation among employees, though other structural and procedural challenges may still need to be addressed.

In summary, the quantitative analysis underscores the importance of strategic alignment, technological capabilities, and financial planning as critical factors in overcoming the barriers to Industry 4.0 adoption within the company.

As presented in Table 5, the ranking of the overall barriers yielded the following insights:

- Prioritization and Strategic Alignment has the highest average score of 3.45, indicating that it is perceived as the most significant barrier.
- Technological Challenges follows closely, with an average score of 3.32.
- Financial Constraints ranks third, with a score of 3.30.
- Regulatory and Compliance Challenges and Lack of Skilled Workforce are also significant but slightly less so, with scores of 3.10 and 3.05, respectively.
- Understanding and Awareness have a lower average score of 2.65, indicating that it might be less of a barrier.
- Organizational and Cultural Resistance has the lowest score of 1.55, suggesting that it is perceived as the least challenging barrier.

In addition, some further insights can be gleaned from the results. In relation to the "Functional Area Analysis," it should be noted that Logistics and Production seem to have lower scores across most barriers, indicating that these areas might perceive the barriers as less significant compared to other departments. Also worth noting is that "Production Support Activities (PSA) and Process Development" have higher scores, particularly in the areas of "Financial Constraints and Technological Challenges," indicating a stronger perception of these barriers.

Different stakeholders perceive barriers differently based on their roles within the company. For instance, stakeholders working in Quality Assurance (QA) and Process Development tend to rate "Technological Challenges" and "Financial Constraints" higher, which can be attributed to the direct impact these barriers have on their daily operations. It is likely that these stakeholders experience the complexities of integrating new technologies and the limitations imposed by financial constraints more acutely than other departments.

The results also provide important implications for the company's digital transformation strategy. First, "Prioritization and Strategic Alignment" being identified as the top barrier highlights a critical need for clearer strategic direction and alignment within the organization. This suggests that while there is awareness of the necessity to adopt Industry 4.0 technologies, there remains a gap in how these initiatives are prioritized and integrated into the company's broader strategy.

Another notable finding is that "Regulatory and Compliance Challenges" were ranked only as the fifth most impactful barrier, which is surprising when viewed from an external perspective. Regulatory requirements are typically considered a significant hurdle in highly regulated sectors such as pharmaceuticals. However, pharmaceutical stakeholders within the company seem to perceive these challenges as less impactful, perhaps due to their familiarity with regulatory processes and the normalization of compliance within routine operations.

Moreover, the high ranking of "Technological Challenges" underscores the complexities associated with integrating new technologies into existing systems, especially in a highly regulated environment such as the pharmaceutical industry. These challenges include both technological incompatibilities and the stringent validation processes required to maintain regulatory compliance.

The relatively low ranking of "Organizational and Cultural Resistance" is another interesting observation. This might suggest that the company culture is relatively adaptable and open to change, which bodes well for future

digitalization efforts. It indicates that the organization is ready to embrace new technologies, as long as the technical and strategic challenges are addressed effectively.

Finally, the dispersion of scores across different functional areas implies that certain barriers are more pertinent to specific departments. This highlights the importance of a targeted approach, where the company addresses the most relevant barriers for each department rather than applying a one-size-fits-all strategy. Tailoring the digital transformation plan to specific departmental needs could enhance the effectiveness of the company's Industry 4.0 adoption efforts.

4.5. Reasons Behind Barriers

After the ranking of barriers, the interviews with the 20 stakeholders explored their perceptions of the barriers to Industry 4.0 adoption, as described in the following subsections.

4.5.1. Understanding and Awareness

The interviews revealed a diverse range of perceptions regarding the company's understanding and awareness of Industry 4.0 technologies. Notably, only the Team Lead evaluated this aspect as "very high," while the Logistics Specialist, Sr Director A, and Sr Associate C assessed it as "very low." Despite this, key decision-makers such as Sr Director A, the Manager, and the Analyst perceived a relatively low barrier to understanding, suggesting that those in leadership positions have a solid grasp of Industry 4.0. Conversely, Associate Director A and the Sr Manufacturing Support Associate noted a significant variance in awareness across the organization, particularly among employees in non-technical roles who exhibit a substantial gap in their understanding of Industry 4.0 technologies.

Sr Director B and Sr Associate A further emphasized that awareness is particularly low at the top management level, which impacts strategic planning and investment. This lack of awareness among leadership can hinder the development of a cohesive strategy for digital transformation. In contrast, stakeholders in Quality Assurance (QA) roles, such as Sr Associate C and Sr Associate B, viewed awareness as less of a barrier, indicating that their departments are already actively exploring and understanding relevant technologies.

The mixed perceptions across different levels and functional areas suggest that while some parts of the organization are well-prepared for Industry 4.0, there are significant gaps in awareness that must be addressed to ensure a unified approach to digital transformation.

4.5.2. Technological Challenges

Technological challenges emerged as a significant barrier across most interviews. It is noteworthy that the Team Lead and Sr Associate B evaluated this as "very high," while the Sr Support Analyst, Manager, and Associate Directors A, B, and C rated it as "low." This variation in perception can be explained by the different degrees of interaction with and reliance on advanced technology within their respective roles. Stakeholders deeply involved in daily operations or in areas with aging infrastructure, such as Sr Director A, the Associate, and the Sr Manufacturing Support Associate, specifically highlighted the complexities and risks associated with adopting new technologies. The age of existing equipment and the difficulty of integrating new systems with legacy technologies were recurring themes, especially in production areas, reflecting greater concerns among those who directly manage or interact with the production processes.

Associate Manager B and the Sr Manufacturing Support Associate indicated that these technological challenges are often linked to financial constraints, as the cost of implementing new technologies can be prohibitive. Sr Director B noted that while new technologies are on the horizon, the company is still in the early stages of fully embracing Industry 4.0, indicating a gradual progression rather than a rapid transformation.

In addition to these overarching technological challenges, stakeholders identified the Change Management Request (CMR) process as a critical factor complicating technological adoption. At the case company, any new technological implementation or update to existing systems requires the initiation of a CMR, which involves several layers of review and approval across multiple departments, including Quality Assurance (QA), Compliance, and

Manufacturing Science and Technology (MSAT). Each step in the CMR process, from the creation of the request to final validation, is designed to ensure compliance with regulatory standards, but also introduces significant delays and resource demands. For instance, stakeholders reported that preparing the CMR documentation alone can take up to 60 hours, excluding the additional time needed for action items such as equipment validation, procedure updates, and operational qualifications (OQ). Figure 4 delineates the key steps in the CMR process, highlighting the extensive coordination required for even minor technological changes.

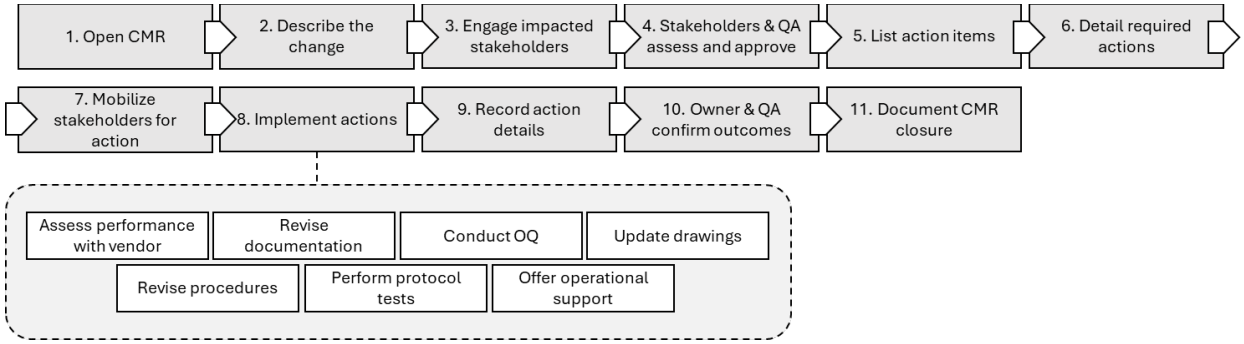

Figure 4. Change management request (CMR) process in the pharmaceutical industry

Finally, Sr Associate A expressed that the global nature of the company complicates technological upgrades, as aligning changes across different sites worldwide adds another layer of complexity. This barrier underscores the need for a comprehensive and well-coordinated technology strategy that considers both local and global requirements.

4.5.3. Organizational and Cultural Resistance

Cultural resistance to new technologies was generally perceived as low across the organization, underscoring a broad acceptance and adaptability to digital transformation efforts. Notably, only the Sr Analyst, Sr Director A, and the Young Grad evaluated this barrier as having "medium significance." The remaining stakeholders ranked this barrier as either "low" or "very low," indicating a widespread cultural openness within the organization to embrace technological advancements.

Stakeholders such as Sr Director B, Sr Associate C, and the Young Grad expressed that employees are open to changes that can improve efficiency and simplify their work. Sr Associate A also rated this barrier as low, reflecting a general willingness to adopt new technologies if they offer clear benefits.

However, Sr Director A and the Associate identified organizational resistance as a more significant barrier, particularly due to concerns about time constraints and risk aversion in the pharmaceutical industry. Associate Director A suggested that some of the perceived resistance might be attributed to citing regulatory and compliance challenges as excuses rather than genuine reluctance to change.

Despite the overall low cultural resistance, the Young Grad and Sr Director B noted that the decision-making processes within the organization are complex, which can decelerate the adoption of new technologies. This complexity may not stem from cultural resistance per se but rather from structural and procedural inefficiencies.

4.5.4. Regulatory and Compliance Challenges

Regulatory and compliance challenges were consistently identified as a moderate barrier, despite placing fifth in the rankings. No stakeholder evaluated it as "very high," and only the Logistics Specialist, Manager, and Sr Associate C assessed it as "very low." This low variation may be explained by the level of direct regulatory engagement within the pharmaceutical industries. Stakeholders who deal more directly with regulatory submissions, audits, and compliance enforcement typically might not perceive these challenges as acutely, viewing them as more manageable or routine.

The Analyst, Sr Director A, Associate Manager B, and the Sr Manufacturing Support Associate emphasized the complexity of GxP requirements and the cautious approach required in this industry. These challenges increase both the cost and complexity of implementing new technologies, making them a combined financial and regulatory issue.

Sr Associate B and Sr Associate C from QA provided contrasting perspectives, viewing regulatory challenges as manageable and not as a significant barrier, given their departments' focus on compliance. However, Sr Associate A and Sr Director B highlighted that the speed of technological advancement often outpaces the development of regulatory frameworks, particularly in global operations. This variation in perceptions suggests that while regulatory challenges are universally recognized, their impact may differ depending on the functional area and the specific technologies being considered for adoption.

In addition, an essential component of addressing regulatory and compliance challenges during technological adoption is the CMR process. The CMR process ensures that all technological changes comply with the pharmaceutical industry's stringent regulatory standards, such as GxP requirements. Each change undergoes a multi-step validation process that includes risk assessments, compliance checks, and operational qualifications (OQ). Stakeholders have noted that while this process helps mitigate regulatory risks, it also adds complexity and time to the implementation of new technologies. As indicated in Figure 4, the CMR process is structured to include these multiple layers of validation and regulatory checks, which align with the stringent requirements of GxP standards. The detailed stages of the CMR, such as risk assessments and compliance approvals, illustrate the complexity that stakeholders described when discussing the impact of regulatory challenges on the adoption of new technologies. This procedural rigor, while necessary for maintaining compliance, was also cited as one of the main reasons why regulatory challenges are often perceived as normal operational hurdles rather than the most critical barriers.

4.5.5. Lack of Skilled Workforce

The lack of a skilled workforce was identified as a moderate to high barrier by several stakeholders. Notably, only the Team Lead evaluated this as "very high," while only the Logistics Specialist assessed it as "very low." This variation may be explained by the differing demands of their functional roles within the company. Those in roles requiring specialized technical knowledge or those who face direct challenges in integrating new technologies perceive a greater barrier due to skill shortages. Conversely, stakeholders in areas less directly affected by these requirements, such as logistics, may not perceive this as a significant challenge.

Sr Director A, the Manager, Associate Director C, and the Sr Manufacturing Support Associate identified the challenges of finding and developing a skilled workforce, particularly in the country's competitive job market. Sr Associate C emphasized that this challenge is exacerbated by the global competition for talent, especially in the technology sector.

Despite these challenges, there was a consensus that existing employees could be trained to fill these gaps, although this would require significant investment in training and development programs. Associate Director A and Associate Director C suggested that hiring recent graduates with up-to-date knowledge of Industry 4.0 could help bridge this gap, while the Young Grad noted that the company could potentially train existing employees to meet the demands imposed by new technologies.

4.5.6. Financial Constraints

Financial constraints were consistently mentioned as a significant barrier to Industry 4.0 adoption. Notably, the Sr Mfg. Support Associate, Associate Manager A and B, and Sr Director B evaluated this as "very high," while only the Manager rated it as "very low." This divergence in perceptions may be explained by the varying impact of budget limitations on different departments and roles within the company. Those in higher-cost areas, such as production and manufacturing, where upgrading or replacing aging equipment is often necessary, tend to view financial constraints more critically. Conversely, roles less directly tied to capital expenditures, such as logistics and program management, may not perceive financial limitations as acutely.

Sr Director A, the Associate, the Sr Manufacturing Support Associate, Associate Manager B, and Associate Director A highlighted that financial resources are often directed toward immediate operational needs rather than long-term technological investments. This issue is closely tied to prioritization and strategic alignment, as financial decisions are often influenced by broader strategic priorities established by top management.

Sr Director B and Sr Associate A further noted that as the company becomes more global, financial decisions are increasingly influenced by global priorities, which may not always align with local needs. This misalignment can lead

to delays in securing funding for local initiatives, which hampers the company's ability to implement new technologies in a timely manner.

4.5.7. Prioritization and Strategic Alignment

The lack of prioritization and strategic alignment was identified as the most critical barrier to Industry 4.0 adoption. It is noteworthy that, again, four stakeholders evaluated this as "very high," while only the Manager assessed it as "very low."

Stakeholders such as Sr Director A, Associate, Sr Director B, and Sr Associate A emphasized the importance of having clear strategic directives from top management to drive these initiatives. Without this alignment, even well-understood and necessary technologies can struggle to gain traction within the organization.

Sr Associate C expressed that the lack of alignment between local and global priorities can create strategic gaps that hinder the adoption of new technologies. Associate Director A and the Sr Manufacturing Support Associate also noted that Industry 4.0 initiatives often struggle to gain traction because they are not aligned with the company's immediate strategic priorities.

This barrier highlights the need for stronger leadership and clearer strategic direction to ensure that Industry 4.0 initiatives are prioritized and integrated into the company's overall strategy.

4.6. Identification of Factors Contributing to Barriers

Finally, the qualitative analysis distilled the provided explanations of reasons for barriers into a set of factors contributing to these barriers. Table 6 summarizes and elucidates the key factors contributing to each barrier.

Barrier	Factor contributing to barrier	Explanation of factor
Prioritization and Strategic Alignment (1st)	Lack of clear leadership	Without strategic direction from leadership, digital initiatives struggle to gain the necessary traction and resources.
	Misalignment between global and local priorities	Global strategic goals often do not align with local needs, creating delays in decision-making and implementation.
	Varying risk appetites	Diverse risk tolerances among stakeholders can create conflicts and delay Industry 4.0 initiatives.
	Inconsistent communication of strategic vision	Unclear communication from top management can lead to misalignment and the under-prioritization of Industry 4.0.
	Short-term performance metrics	Emphasis on short-term results can detract from investments in long-term digital transformations.
	Legacy company culture	An entrenched culture favoring traditional methods may resist new digital strategies.
	Fragmented decision-making authority	Decentralized decision-making can cause strategic misalignment and resource allocation inefficiencies.
Technological Challenges (2nd)	Legacy infrastructure	Existing, outdated equipment makes integrating new technologies complex and expensive.
	High costs of implementation	Financial constraints limit the company's ability to invest in required technological upgrades.
	Integration complexity	The difficulty in achieving seamless integration between new and existing systems often requires substantial custom solutions, which can escalate costs and complexity.
	Data security concerns	Increased connectivity and the integration of cloud-based solutions raise concerns about data security and vulnerability to cyber-attacks, potentially slowing tech adoption.

Barrier	Factor contributing to barrier	Explanation of factor
Financial Constraints (3rd)	Competing financial priorities	Limited financial resources are directed toward immediate operational needs, delaying long-term technological investments.
	Delayed ROI	The return on investment from Industry 4.0 initiatives is not always immediate, making it harder to justify large upfront costs.
	Resource allocation for compliance	Significant portions of budgets are allocated to ensure compliance with existing regulations, leaving less available for new investments.
	Economic uncertainty	Fluctuations in the economic landscape can cause shifts in budget allocation, prioritizing short-term survival over long-term investments in technology.
Lack of Skilled Workforce (4th)	Competition for skilled talent	The competitive job market in the technology sector makes it difficult to attract and retain talent with Industry 4.0 expertise.
	Need for internal training	Existing employees lack the skills required for Industry 4.0 implementation, necessitating costly and time-intensive training programs.
	Rapid technological change	The pace of technological advancements can outstrip the current workforce's ability to adapt, requiring more frequent and comprehensive training.
	Brain drain	Attraction of skilled workers to more technologically advanced sectors or geographic regions, leaving gaps in the local talent pool.
Regulatory and Compliance Challenges (5th)	Complexity of GxP requirements	Strict regulatory requirements in the pharmaceutical industry add significant time and costs to the adoption of any given technology.
	Risk of non-compliance	The risk of failing to meet regulatory standards leads to a cautious approach to adopting new technologies.
	Evolving standards	Ongoing changes in regulatory standards require continuous updates to systems, which can be a moving target that complicates compliance efforts.
	International regulatory variability	Differences in regulatory requirements across countries can complicate global deployments of Industry 4.0 technologies.
Understanding and Awareness (6th)	Lack of top-level awareness	Limited awareness of Industry 4.0 technologies at the leadership level hampers strategic planning and investment.
	Uneven awareness across departments	Different departments have varying levels of understanding of Industry 4.0, leading to inconsistent adoption efforts.
	Interdepartmental communication gaps	Poor communication between departments can lead to silos of knowledge and misinformation about the benefits and capabilities of new technologies.
	Visibility of benefits	If the benefits of Industry 4.0 technologies are not clearly demonstrated and communicated, skepticism and resistance can persist.
Organizational and Cultural Resistance (7th)	Complexity in decision-making processes	While overall cultural resistance is low, organizational complexity slows down decision-making for technological initiatives.
	Mismatched incentive structures	If rewards and recognition are not aligned with the adoption of new technologies, employees may not have sufficient motivation to change behaviors and practices.
	Change fatigue	Previous continuous change initiatives may lead to weariness among staff members, making them less receptive to new transformations.

Table 6. Factors contributing to barriers to Industry 4.0 adoption

As indicated in Table 6, there was a complex and interconnected set of barriers to Industry 4.0 adoption within the company. While organizational and cultural resistance was generally low, significant challenges remain in the areas of technological integration, regulatory compliance, workforce skills, financial constraints, and strategic alignment. The factors contributing to the barriers were identified in both the quantitative and qualitative assessments. These factors, spanning technological, organizational, financial, and regulatory challenges, often compound each other,

creating significant obstacles to Industry 4.0 adoption in the pharmaceutical industry. This outlines the complex interplay of factors contributing to the barriers to Industry 4.0 adoption within the company. While financial and technological barriers are critical, factors such as leadership alignment, regulatory constraints, and workforce skills also play a significant role. Addressing these barriers will require a multifaceted approach, including improving strategic alignment, investing in technological upgrades, and enhancing workforce training.

In conclusion, while the company exhibits a general openness to digital transformation, significant barriers such as strategic alignment, technological challenges, and financial constraints must be addressed to facilitate the effective adoption of Industry 4.0 technologies. These barriers will need to be tackled through coordinated efforts across all functional areas, with a strong emphasis on leadership direction and resource allocation.

5. Discussion

The findings of this study highlight several key barriers to the adoption of Industry 4.0 technologies in the pharmaceutical manufacturing sector, aligning with and extending the existing literature. In both of the case study analyses, Prioritization and Strategic Alignment, Technological Challenges, and Financial Constraints emerged as the most critical barriers, while Organizational and Cultural Resistance was perceived as the least significant. These results not only reflect the unique challenges of implementing Industry 4.0 technologies in a highly regulated and complex environment such as pharmaceuticals but also provide practical insights for overcoming these barriers.

5.1. Alignment with the Literature

The findings align with prior studies that emphasize the significance of strategic alignment and prioritization in the successful adoption of Industry 4.0 technologies. For example, Ciravegna-Martins-da-Fonseca, Pereira, Oliveira, Ferreira and Busu (2024), Marques et al. (2020), and Kamble et al. (2018) similarly identified strategic alignment as a critical factor, particularly in sectors where digital transformation requires significant organizational shifts. In this study, the highest-ranked barrier, Prioritization and Strategic Alignment, underscores the need for clear leadership direction and alignment of Industry 4.0 initiatives with the company's broader business goals. Without this strategic alignment, even well-understood and potentially beneficial technologies may fail to gain traction.

Moreover, Technological Challenges emerged as the second most critical barrier, consistent with the findings of Haryanti, Rakhmawati and Subriadi (2023), Schröder (2016), and Breunig et al. (2016), who emphasize the complexity of integrating new technologies with legacy systems, particularly in highly regulated industries such as pharmaceuticals. The challenges of interoperability, data security, and system integration were recurrent themes in both the stakeholder interviews and the literature, highlighting the importance of addressing these technological hurdles to ensure seamless digital transformation.

5.2. The Unique Nature of the Pharmaceutical Context

While the barriers identified in this study from an overall perspective resemble those found in other manufacturing sectors, this research contributes a sector-specific understanding of the challenges faced by pharmaceutical companies. In this context, Regulatory and Compliance Challenges were ranked fifth in the quantitative analysis, while they were expected to emerge as a more significant barrier based on the existing literature (Marques et al., 2020; Silva et al., 2020). Studies often emphasize that compliance with stringent regulatory requirements, such as GxP, adds layers of complexity to any technological adoption. Given the high impact of regulatory constraints in the pharmaceutical industry, it was anticipated that this barrier would rank among the most significant.

However, in this study, Technological Challenges were ranked as more difficult, with Regulatory and Compliance Challenges occupying a lower position. This discrepancy between the literature and our findings suggests that the perception of barriers within pharmaceutical companies may differ from the broader academic and industry perspectives. One possible explanation for this difference is the deeply ingrained nature of regulatory management in daily pharmaceutical operations. For companies operating in this highly regulated environment, managing compliance and regulatory processes is a routine part of operations, and while it remains a constant challenge, it may not be perceived as the most significant barrier to growth and innovation.

In contrast, Technological Challenges present a more complex issue. The process of adopting new technologies in the pharmaceutical industry is not only costly but also involves a lengthy and multi-step validation process to ensure compliance with regulatory standards (see Figure 4). For every new technology or process change, companies must navigate a rigorous approval process, including risk assessments, adherence to GxP standards, and comprehensive validation protocols. This complexity can make technological changes disproportionately challenging compared to other sectors, where regulatory oversight is less stringent. The slow adaptation to digital transformation in industries can significantly hinder sustainability (Haryanti et al., 2023). A delayed adoption, as stated by Haryanti et al. (2023), poses risks to the survival and competitiveness of companies, particularly in the pharmaceutical industry, where the inability to swiftly integrate digital innovations could lead to operational inefficiencies and regulatory non-compliance, ultimately threatening the sector's sustainability.

Moreover, although large pharmaceutical companies may have the financial resources to invest in Industry 4.0 technologies, the primary concern lies in the time, effort, and risk involved in implementing these technologies. The need to ensure that new systems do not compromise product safety or quality, combined with the extensive documentation and validation required, makes technological challenges a more immediate and pressing concern for stakeholders.

Thus, while regulatory compliance remains a significant operational hurdle, it is regarded as a manageable part of daily business, whereas the adoption of new technologies introduces new layers of complexity that stakeholders perceive as more challenging to overcome. This finding highlights the need for further research into how pharmaceutical companies perceive and prioritize barriers to digital transformation, particularly in relation to the specific operational and regulatory context of the industry.

The integration of both quantitative and qualitative findings underscores the interconnected nature of the barriers to Industry 4.0 adoption within the company. The consistent emphasis on strategic alignment, technological challenges, and financial constraints across both analyses suggests that addressing these barriers should be a priority for the company's digital transformation efforts. Moreover, the qualitative data provides a nuanced understanding of these barriers, revealing the importance of targeted interventions to bridge awareness gaps and leverage the company's openness to cultural change.

From a pharmaceutical industry perspective, the Technological Challenges barrier scored high among perceived barriers because implementing new technology is significantly more complex than in other sectors. While large pharmaceutical companies may have substantial financial resources, the challenges do not merely concern money. Any technological upgrade or change faces extensive regulatory scrutiny and a multi-step validation process that ensures product safety and compliance with GxP standards. This complexity means that, despite available financial resources, the time, effort, and risk involved in implementing new technologies make technological challenges a significant barrier. This contrasts with existing research, such as that conducted by Raj et al. (2020) and Ogunye et al. (2024), suggesting that regulatory frameworks significantly hinder technology adoption; in contrast, this study reveals that while regulatory compliance remains a barrier, it is increasingly managed as part of routine operations, and the real challenge lies in integrating new technologies and achieving strategic alignment.

Overall, the present study advances existing research on Industry 4.0 in the pharmaceutical sector (Arden et al., 2021; Arief et al., 2022; Graham, 2024; Marques et al., 2020; Sharma, Sehrawat et al., 2023; Silva et al., 2020) by providing insights into the relative salience of different barrier categories and the factors that give rise to them in a pharmaceutical CDMO setting. The barrier categories themselves, as well as many of the contributing factors, are consistent with prior studies on Industry 4.0 in pharmaceuticals and other regulated manufacturing sectors, suggesting that they are not unique to the focal site. At the same time, the relative importance assigned to each barrier is shaped by specific contextual features of the case company, including (i) its role as a large, end-to-end biopharmaceutical CDMO, (ii) its location in a highly regulated, high-cost European setting, (iii) substantial financial capacity combined with legacy production and IT systems, and (iv) the need to align local digital initiatives with global corporate strategies and multi-client requirements. The resulting barrier ranking should therefore be interpreted as a context-sensitive benchmark that is most likely to resemble the pattern found in organizations with similar characteristics. In this sense, the case offers a basis for analytical generalization to comparable contexts,

while recognizing that the exact ordering of barriers may differ in firms with other sizes, business models, or regulatory and market environments.

5.3. Implications for Practice

The findings of this study have important implications for pharmaceutical companies seeking to adopt Industry 4.0 technologies. First and foremost, the study suggests that companies must prioritize strategic alignment at both the local and global levels. This includes ensuring that Industry 4.0 initiatives are clearly aligned with the company's overall strategic goals, as highlighted by the high ranking of Prioritization and Strategic Alignment as a barrier. Leadership teams must provide clear directives and ensure that resources are allocated to support these initiatives.

Secondly, addressing Technological Challenges requires a comprehensive approach that not only considers the integration of new technologies but also the necessary upgrades to legacy systems. As the pharmaceutical industry is highly regulated, companies must also ensure that their technological innovations comply with evolving regulatory standards. This will require a proactive approach to regulatory compliance, including the development of frameworks that allow for the validation and continuous monitoring of new technologies.

Thirdly, the financial implications of Industry 4.0 adoption cannot be overlooked. While companies must be prepared to make significant capital investments in new technologies, they should also consider strategies for mitigating the risks associated with these investments. This includes conducting thorough cost-benefit analyses and ensuring that financial resources are aligned with long-term technological goals, as recommended by Senna et al. (2022).

6. Conclusion

The results of this study underscore the critical barriers faced by pharmaceutical companies in adopting Industry 4.0 technologies. Through a combination of quantitative and qualitative analysis, this research has provided a comprehensive understanding of these barriers, which include Prioritization and Strategic Alignment, Technological Challenges, and Financial Constraints, identified as the most significant obstacles. This study also sheds light on unique industry-specific challenges, such as Regulatory and Compliance Barriers, which, contrary to expectations, were ranked lower by stakeholders, suggesting that regulatory hurdles, while significant, are viewed as part of the industry's routine operations.

The Technological Challenges barrier was identified as particularly impactful due to the stringent regulatory scrutiny and validation processes involved in adopting new technologies in the pharmaceutical sector. The study revealed that while financial resources may be available, the complexities and time required to implement new technologies, ensure compliance, and maintain product safety significantly intensify the perceived difficulty of technological adoption.

Prioritization and Strategic Alignment emerged as the highest-ranking barrier, reflecting the need for pharmaceutical companies to align their Industry 4.0 initiatives with broader strategic goals, both at the local and global levels. Without clear leadership direction and the alignment of priorities, digital transformation efforts may struggle to gain traction, even when the necessary technologies and financial resources are available.

Financial Constraints, though not the most critical barrier, remain a significant challenge for companies. The heavy upfront investment required for Industry 4.0 technologies, combined with the uncertainty of return on investment, can hinder the pace of digital transformation. Companies need to strategically allocate financial resources while ensuring that investments align with long-term digital and operational goals.

The findings of this study have important implications for both academia and industry. From an academic perspective, this research contributes to the growing body of literature on Industry 4.0 adoption by providing a sector-specific analysis focused on the pharmaceutical industry. It highlights the need for further research into the perceived barriers within highly regulated industries and how these barriers can be effectively addressed through strategic and operational interventions. For industry practitioners, this study offers practical insights for overcoming barriers to Industry 4.0 adoption. To achieve successful digital transformation, pharmaceutical companies must prioritize strategic alignment, invest in technological infrastructure, and ensure that both financial and human resources are in place. Additionally, addressing the complexities of regulatory compliance and fostering a culture of openness to technological change will be essential in accelerating Industry 4.0 adoption within the pharmaceutical sector.

6.1. Limitations and Future Research

As described in the previous two subsections, the findings both confirm results from general studies of I4.0 barriers and include insights that appear particularly salient for pharmaceutical companies operating under similar regulatory and operational conditions. In this context, the study being conducted within a single pharmaceutical manufacturing company does not allow for statistical generalization. However, as previously noted, the case company operates within the broader pharmaceutical industry, serves multiple international clients, is part of a large multi-site CDMO group, and adheres to widely adopted industry and regulatory standards, which suggests that it may be treated as a typical case of a digitally transforming pharmaceutical manufacturer rather than an outlier (Yin, 2017). Thus, from an analytical generalization perspective (Yin, 2017), the findings are likely to apply to organizations with similar characteristics. Nevertheless, building on the foundation provided by the present study, future research should further explore this through survey-based studies.

Furthermore, the barriers identified in this study, such as strategic alignment, technological challenges, and regulatory compliance, are not unique but are commonly faced by pharmaceutical companies globally (Arden et al., 2021). Specifically, technological challenges such as interoperability and integration complexities with existing systems, as highlighted by Raj et al. (2020), along with the need to upgrade old systems and manage high costs, as emphasized by Breunig et al. (2016), present significant hurdles. Furthermore, the importance of strategic alignment in overcoming barriers to technology adoption has been noted by Kamble et al. (2018), and the lack of a clear strategy has been discussed as a major barrier by Senna et al. (2022), which resonates with our findings. Additionally, regulatory barriers, as underscored by Schröder (2016) and Graham (2024), corroborate our observations that regulatory compliance issues are a significant challenge in the pharmaceutical industry.

As indicated above, the analytical generalization (Yin, 2017) of these findings is supported by the alignment with existing theories and literature on Industry 4.0 adoption barriers, suggesting that these barriers could similarly impact other companies within the sector. Furthermore, the use of a maturity model assessment and stakeholder interviews provides a structured approach to identifying and understanding these barriers, reinforcing the relevance of the findings across similar organizational contexts.

Another limitation of the study is that the quantitative data used to derive the barrier ranking were collected through a maturity model assessment and stakeholder interviews, which inevitably involve subjective judgments. As a result, the ranking reflects the perceptions and experiences of stakeholders within this particular organization and should not be interpreted as statistically generalizable to all pharmaceutical companies. However, the exploration of the reasons behind the rankings through qualitative interviews helped to mitigate this limitation by providing a deeper understanding of why certain barriers are perceived as more critical in this specific context.

Although more studies are needed to clarify the general nature of the identified barriers and subfactors in pharmaceutical companies, this study provides a valuable starting point for understanding this matter. It advances existing knowledge on I4.0 adoption by supporting the critical need for continuous innovation and identifying specific challenges in pharmaceutical manufacturing due to regulatory requirements, as discussed by Marques et al. (2020) and Arief et al. (2022). Furthermore, Zutin et al. (2022) have identified the uneven maturity levels of technologies such as IoT and augmented reality in pharmaceutical settings, which aligns with the technological disparities found in this study.

Given the findings of this study, there are several avenues for future research. First, future studies could investigate the role of leadership and strategic alignment in greater detail, particularly how pharmaceutical companies can better align global and local priorities to support digital transformation. Additionally, research could explore the development of regulatory frameworks that facilitate the adoption of Industry 4.0 technologies while ensuring compliance with evolving standards.

Another area for future research involves the exploration of workforce development strategies to address the Lack of Skilled Workforce barrier. As identified in this study, the lack of technical expertise is a significant challenge for pharmaceutical companies. Future research could examine the effectiveness of different training and development programs aimed at enhancing employees' skills and knowledge of Industry 4.0 technologies.

Moreover, understanding the variability of barriers across diverse contexts presents another critical area for future inquiry. Future research could explore how the barriers identified in this study—strategic alignment, technological challenges, and regulatory compliance—manifest in other pharmaceutical companies or across different regions and regulatory environments. This investigation could provide a deeper understanding of the influence of cultural, economic, and regulatory differences on Industry 4.0 adoption. Investigating these variations can help in tailoring more effective industry-specific guidelines and global strategies that address both common and region-specific barriers, potentially accelerating Industry 4.0 integration across the pharmaceutical sector.

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