The impact of Smart Manufacturing on the Digital Maturity of Medical Device Industry

A thesis submitted in partial fulfilment of the requirements for MSc in Digital Transformation (Life Science)

Innopharma Labs Faculty of Science

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CANDIDATE DECLARATION

I hereby declare that the dissertation titled **" The impact of Smart Manufacturing on the Digital Maturity of Medical Device Industry"** submitted for the degree of MSc in Digital Transformation (Life Science) is my original work, under the supervision of Dr. Omar Mahfoud. I have acknowledged all sources used for this research study through accurate referencing. This work has not been submitted for any degree for this University or any other university.

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LIST OF ABBREVATIONS

MedDev	**Medical Device**
SM	**Smart Manufacturing**
NIST	**National Institute of Standard and Technology**
AI	**Artificial Intelligence**
ML	**Machine Learning**
IoT	**Internet of Things**
AR	**Augmented Reality**
VR	**Virtual Reality**
AM	**Additive Manufacturing**
DT	**Digital Transformation**
DMM	**Digital Maturity Model**

ABSTRACT

The study explores the impact of smart manufacturing on the digital maturity of the medical device industry. The research aims to assess smart manufacturing technologies contributions to digital maturity, focusing on technological advancements, connectivity features, and overall industry improvements.

The literature review highlights the importance of operational efficiency, quality improvement, product customization, and regulatory compliance as primary drivers for adopting digital technologies in the medical device industry. Additionally, the study emphasizes the significance of a robust data strategy, seamless digital integration, and smart manufacturing practices. The study adopts a mixed-methods approach, combining qualitative and quantitative data to understand the impact of smart manufacturing on digital maturity, involving a comprehensive literature review and a survey of industry professionals from India and Ireland. Findings suggest that digital maturity positively impacts operational efficiency and product quality, with potential benefits including enhanced quality, efficiency, and innovation through advanced technologies like AI, IoT, and big data analytics. However, challenges such as data security and system interoperability need to be addressed. The research recommends a supportive organizational culture, leadership commitment, and continuous employee training to drive digital maturity, ultimately fostering innovation and competitiveness.

Keywords: Smart Manufacturing, Medical Device Industry, Digital Maturity, Impact

CHAPTER 1 INTRODUCTION

1.1 Overview

The medical device (MedDev) industry has grown significantly over the last ten years, and it is now an essential partner in healthcare. These days, technology plays a key role in every aspect of our daily lives, and innovative developments in MedDev have become crucial for maintaining health. MedDev companies offer advanced medical devices and diagnostics used in the prevention, diagnosis and treatment of disease (Awasthi and Stanick, 2019). Smart manufacturing (SM) is considered as a new paradigm that makes work smarter and more connected, bringing speed and flexibility through the introduction of digital innovation (Cioffi *et al.*, 2020). According to the National Institute of Standards and Technology (NIST), smart manufacturing encompasses fully integrated, collaborative manufacturing systems that respond in real time to meet changing demands and conditions in the factory, in the supply network and in customer needs (Kusiak, 2023). The integration of smart manufacturing technologies such as the Internet of Things (IoT), artificial intelligence (AI), and data analytics into the manufacturing processes, has emerged as a transformative force across various industries. Medical device manufacturers are also embracing digitalization and smart manufacturing in their industries to maximize efficiency, reduce errors, and meet regulatory requirements. This cultural shift towards smart manufacturing is essential for remaining competitive in the marketplace, especially in the face of unprecedented challenges such as the global pandemic. The adoption of advanced manufacturing technologies, including smart manufacturing, is being accelerated to strengthen the nation's public health infrastructure. This shift towards smart manufacturing in the medical device industry is a critical aspect of its evolution in the age of digitalization which can define the digital maturity of the company. In order to achieve digital maturity, it is essential that an evolutionary transformation path is followed from an initial phase to a target phase (Lahrmann *et al.*, 2011). According to Bernard Marr, simple definition is that digital maturity is a measure of how well-positioned a business or organisation is to leverage technology to affect growth and positive change (Marr, 2023). Digital maturity is essential, as it enables the transition from manual processes to digital, automated processes, ultimately improving operational efficiency and minimizing risks, especially for medical device sector, particularly in highly regulated industries (Singh, n.d.).

The maturity model frameworks provide a valuable technique in order to assess processes or organization from different perspectives, which provides large scale knowledge of the current state of the company and the path to be taken to implement strategies of industry 4.0 (Akdil *et al.*, 2018). The maturity model provides guidance on how organizations approach their transformation or how incorporation of smart technologies are contributing to digital maturity of the organization. In general, digital maturity models consist of dimensions and criteria that explain actions or measures that indicate an evolution towards maturity of an organization (Haryanti *et al.*, 2023).

1.2 Research Purpose

Research topic 'The impact of Smart Manufacturing on the Digital Maturity of Medical Device Industry' is mainly linked to '**Advance Manufacturing in Smart Factory' and 'Business Strategy and Change Management'** modules in the course of digital transformation in life science industry as it discusses the effects of incorporating advanced manufacturing techniques which function as the essential basis for reaching a higher degree of digital maturity and how various business strategies act as a fundamental building block for the medical device industry towards a more competitive and future-oriented state. The integration of digitization and Industry 4.0 technologies has transformed manufacturing and business operations across various industries, including the medical device industry, making it essential for companies to adapt to these changes to remain effective in an ever-changing landscape. Overall, the integration of smart manufacturing in the medical device industry has the potential to revolutionize the production and delivery of medical devices, leading to improved patient care, better outcomes, and increased efficiency in the healthcare system.

Studying the impact of smart manufacturing on the digital maturity of the medical device industry will be beneficial in assessing how much MedDev industry has evolved, transitioning from manual processes to digital, automated ones through Industry 4.0 maturity index model analysis. Therefore, the purpose of this research is to assess medical device industry's digital maturity level to understanding its readiness to adopt Industry 4.0 i.e., smart manufacturing technologies. Further by identifying and analyzing the potential opportunities, challenges and future prospects associated with the adoption and implementation of digital technologies, this research strives to provide general recommendations for medical device companies to enhance their digital maturity.

1.3 Research Aim and Questions

1.3(A) Aim

To assess the extent to which smart manufacturing contributes to the digital maturity of medical device industry, focusing on the technological advancements, connectivity features, and overall improvement in the lifecycle of this industry.

1.3(B) Research Questions

1. What are the key factors that contribute to the digital maturity of medical device industry in the terms of smart manufacturing?
2. What are the potential benefits, outcomes and challenges of increasing digital maturity in the medical device industry, including improvements in quality, efficiency, and innovation?
3. What steps can be taken to enhance the digital maturity of medical device companies in terms of their adoption of smart manufacturing technologies?

1.4 Research Objectives

1. To conduct a comprehensive literature review on smart manufacturing and digital maturity in the medical device industry.
2. To identify and analyze the main drivers for digital maturity in medical devices in the context of smart manufacturing.
3. To analyze the potentials, results, and challenges likely to emerge from the deepening of digital maturity in the medical device sector with the goal of improving quality and efficiency, including innovations.
4. To provide general recommendations for medical device companies to enhance their digital maturity through the adoption of smart manufacturing technologies and best practices.

1.5 Significance of the research

In today's evolving manufacturing landscape of medical device industry, studying the impact of smart manufacturing on the digital maturity level plays a significant role. Smart manufacturing is deeply rooted in data-centricity, technology adoption, and digital capabilities, which represents a pivotal shift towards full digitization within Industry 4.0. Digitally mature industries are positioned to reap substantial benefits, including increased revenue growth, net profit margins, process optimization, cost-efficiencies, and continuous improvement. Therefore, assessing the current level of digital maturity across key area like digital transformation is crucial for industries to navigate their digital transformation effectively and unlock the benefits of Industry 4.0 technologies.

1.6 Scope of the research

The scope of this research is to assess how smart manufacturing affects medical device industry's digital maturity level by understanding the evolution of manufacturing towards full digitization, the benefits gained from implementing digital technologies, and the characteristics of digitally mature organizations.

Key points for the scope this study include:

- To evaluate the existing level of digitalization within the industry, understanding its technological capabilities, and identifying areas where digital transformation has been successfully implemented or where improvements are needed.
- To identify areas within the industry where there are deficiencies or shortcomings in the adoption and integration of digital technologies.
- To identify gaps in digital maturity and transformation and to provide general recommendations to address those gaps in order to achieve higher levels of digital maturity.

1.7 Justification of the research

Justification for this research comes from its ability to provide insight on the gaps regarding the strategic integration of technologies for digital maturity and the specific dimensions defining digital maturity in the medical device industry. Further, by addressing the research objectives and looking at the opportunities, challenges, and future prospects associated with the adoption and implementation of digital technologies, this study can help the medical device industry to become more effective, and sustainable.

1.8 Overall layout of dissertation

Table 1: Overview of structure

	Title	Overview
CHAPTER 1	Introduction	It includes overview about the background of the study, outlines the purpose, aim, significance of the research. Highlights objectives, questions, justification and scope of the study.
CHAPTER 2	Literature Review	Firstly, summarize existing research relevant to the study of adoption and implementation of smart manufacturing in medical device industry in Ireland, its impact on maturity level of the companies and discussing theories, concepts and highlight key studies. Core literature on digital maturity model index and its strategies. Further, identify gaps in the literature to focus on narrowing down the research study.
CHAPTER 3	Research Methodology	Includes approach to research design of the study, including research philosophies and conceptual framework. Explaining the sampling technique, sample size and detail regarding data collection methods.
CHAPTER 4	Findings and Analysis	Present the collected data in a clear and organized manner (tables, graphs, charts). Analyze the data to answer the research questions and interpret the findings.
CHAPTER 5	Conclusions and Recommendations	Summarize the findings of the study. Providing general recommendations and emphasizing the importance of following the recommendation.

CHAPTER 2 LITERATURE REVIEW

2.1 Overview

In today's rapidly evolving technological landscape, the integration of smart manufacturing practices has emerged as a disruptive force across various industries including medical device industry. The combination of digital technologies with advanced manufacturing processes, has reshaped traditional paradigms of industries, offering unprecedented opportunities for efficiency, innovation, and competitiveness. Fundamental to this shift is the idea of "digital maturity", which summarizes an organization's capacity to use digital technology wisely in order to accomplish its strategic objectives and maintain an advantage in a competitive market. This chapter would summarize a critical review on existing literature following keywords around the research title. This literature review provides an insight on the integration of different advanced technologies into the manufacturing processes of medical device companies. Further review highlights the potential benefits and challenges of increasing digital maturity and its implication on implementation of these technologies. Finally, this chapter goal is to explore the impact of smart manufacturing on the digital maturity of the medical device industry, examining the current state of research, identifying key trends, and indicating gaps for further study.

2.2 Smart Manufacturing

Industries play a significant role in driving the economy and prosperity of a nation, and improved performance and high efficiency are associated with greater economic growth. In recent years, various industries have undergone a significant transformation driven by advancements in technology and changing market demands. SM is seen as a new paradigm that makes work smarter and more connected, bringing speed and flexibility through the introduction of digital innovation. With the integration of cutting-edge technologies and data-driven approaches, smart manufacturing, also known as Industry 4.0, represents the culmination of these changes, which promises to transform traditional manufacturing processes. It represents a significant advancement from conventional factory automation to a fully integrated, intelligent, and adaptable system. It is a revolutionary step up from intelligent manufacturing (Ghobakhloo, 2020). It is based on non-symbolic, intelligent, and human-like artificial intelligence (AI), as opposed to conventional intelligent manufacturing, which depends on symbolic AI-based manufacturing technology (Yao *et al.*, 2017).

A smart manufacturing system connects all aspects of the product design and analysis, the manufacturing process, the stocks and supply chain system, product customization, real-time machines, the product delivery system, and the end customer through the utilization of cloud computing. As a result, on-demand manufacturing, customizing products, and maintaining demand and supply ecosystems have become more efficient (Phuyal *et al.*, 2020). Digital transformation and smart technologies are now the pillars of next-generation industries, which are fusing physical entities through the internet for example, Industry 4.0 by Germany, Made in China 2025 by China, Industrial Internet by the USA, and Society 5.0 by Japan are the major announcements of the leading countries in technology (Li, 2018). These technologies differ in terms of implementation methodology, target group of industry, and projected timeline for its achievement, however they have the common objective of implementing smart and digital technology in order to boost the current manufacturing systems (Phuyal *et al.*, 2020).

This transformative approach is not only reshaping traditional manufacturing sectors but is also making significant waves in the healthcare industry, particularly in the medical device industry. These technologies are a game-changer for industries as it leverages interconnected systems and intelligent automation to create a highly adaptable and efficient production environment. A number of significant advantages such as enhanced efficiency, greater flexibility, accelerated innovation and improved quality can be seen in medical device sector through the integration of digital technology across the manufacturing lifecycle, from design and prototype to production and distribution. These technologies, which are pillars of smart manufacturing are crucial for leveraging Industry 4.0 technologies in the medical device sector.

These pillars of SM rely on the infusion of AI to analyse vast amounts of production data, which is made accessible through the Industrial IoT. Cloud computing centralizes data and enables smooth communication, while big data analytics yields insightful information. Autonomous robots, working collaboratively with humans, execute complex tasks and feed real-time information into the system, enhancing decision-making. Technologies like augmented reality (AR) and virtual reality (VR) are revolutionizing product design and development. System integration, both horizontal and vertical, overcomes organizational disconnects and promotes interaction. Additive manufacturing (AM) and supply chain digitization optimize production and distribution. Technological innovations are leveraged by new business models, and cybersecurity protects these networked systems. Together, these pillars empower Industry 4.0 to deliver unprecedented efficiency, productivity, and agility across the manufacturing spectrum (Haiston, 2023).

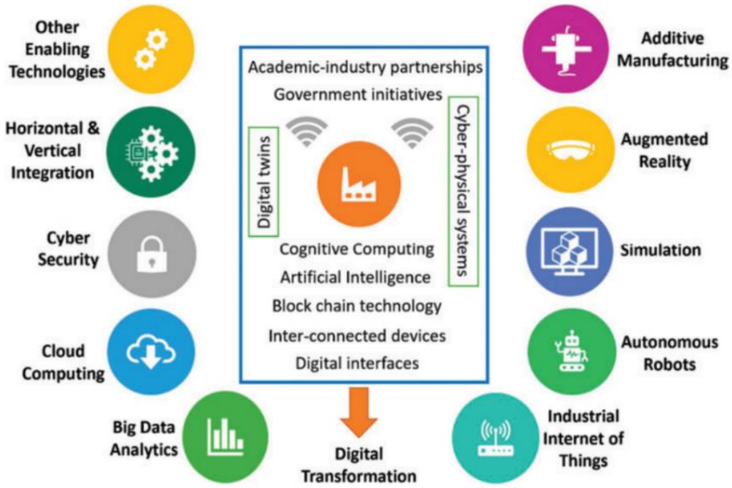

Figure 1: Pillars of Smart Manufacturing (Asif *et al.*, 2021)

Impact of Smart Manufacturing on the Medical Device Industry

The implementation of smart manufacturing in the medical device industry has the potential to significantly impact various aspects of the industry, including product availability, innovation, and patient safety (Vasiljeva *et al.*, 2020). Using technologies such as 3D printing facilitates the design and prototyping of medical devices, which provides a precise and personalized manufacturing, reduces waste, is cost efficient, and faster production times, making it an attractive medical solution for manufacturers (Mamo *et al.*, 2023). In future, synergistic contributions of AM and AI will give life to “5D printing”, in which AI will assume the role of the fifth dimension which will dramatically shorten the assembly operations and the associated energy costs, with enormous benefits for the environment (Milazzo and Libonati, 2022). Additionally, these technologies can help enhance quality control measures in the medical device industry by utilizing advanced analytics and real-time data monitoring. Overall, the integration of smart manufacturing in the medical device industry has the potential to revolutionize the production and delivery of medical devices, leading to improved patient care, better outcomes, and increased efficiency in the healthcare system (Kasoju *et* *al.*, 2023). Further, SM facilitates end-to-end traceability, regulatory compliance, and safety requirements, which allows companies to scale up production, reduce time-to-value, and maximize asset utilization. Manufacturers of medical devices can enhance collaboration, knowledge management, and workflow efficiency by implementing smart manufacturing solutions, ensuring continuous innovation and competitiveness for the long term.

2.3 Digital Maturity

In today's digital world, an organization's ability to leverage technology effectively, known as digital maturity, is a key differentiator for success. Digital maturity is a holistic concept reflecting technological and managerial aspects (Teichert, 2019). In the scientific field, there are different definitions of digital maturity; table 2 lists several definitions compiled by different authors(Aslanova and Kulichkina, 2020).

Table 2: The definition of digital maturity by different authors (Aslanova and Kulichkina, 2020; Aras and Büyüközkan, 2023)

Sr.no	Definitions	Authors
1	Digital maturity is closely related to organizational digital transformation (DT) and is defined as the extent to which a firm consistently implements DT processes to achieve the desired level of achievement of DT maturity, which is evaluated by assessing achievement of the specified process capability levels for a defined profile of processes.	(Gökalp and Martinez, 2021)
2	According to Hägg and Sandhu definition has two insights: firstly, it indicates that being digitally mature means that some form of transformation of processes, talent engagement and business models has taken place, where digital technology is the tool and secondly, the end state of the transformation process.	(Hägg and Sandhu, 2017)
3	Digital maturity as the status of a company's digital transformation and a description of the company's	(Prakasa et al., 2020)

	achievements in the context of applying a digital transformation business.	
4	Digital maturity is about integrating your organization’s operations and human capital in digital processes and vice versa.	(WalkMe, 2017)

The medical device industry is undergoing a transformative shift, driven by the confluence of scientific advancements and the growing pervasiveness of digital technologies. Maturity models are conceptual models that outline anticipated, typical, logical, and desired evolution paths towards maturity (Wendler, 2012). These models serve as a basis for evaluation and comparison in order to arrive at a well-informed approach to increasing the capability of a specific area within an organization (de Bruin *et al.*, 2005). Digital Maturity Models (DMMs) are often used as a reference point to conceptualize digitalization pathways (Ladu *et al.*, 2024). DMMs are used to determine an organization's strengths and weaknesses in a given domain, which are further used to identify gaps between the current state of the organization and the expected state that can be bridged by development activities (Barry *et al.*, 2022). These models will provide a structured framework for companies to benchmark their digital capabilities, measure their journey towards digital maturity, and ultimately guide their strategic investments.

DMM includes dimensions and sub-dimensions that can help to outline the areas of improvement and create a roadmap for digital transformation. Dimensions refers to a measurable and isolated element that portrays an essential, independent aspect of digital maturity and there are some key components to consider:

1. **Data Strategy and Infrastructure:** This dimension assesses a company's ability to collect, store, manage, and analyse data effectively. It considers factors like the presence of a robust data governance policy, the utilization of cloud computing platforms, and the adoption of data analytics tools.
2. **Digital Integration:** This dimension evaluates the level of connectivity and data flow across the organization. It considers factors like the integration of enterprise resource planning (ERP) systems, product lifecycle management (PLM) software, and manufacturing execution systems (MES) with other digital tools. Additionally, it assesses

the seamless exchange of data between R&D, engineering, production, and regulatory departments.

3. **Smart Manufacturing Practices:** This dimension focuses on the level of automation and digitalization adopted within the production process. It considers factors like the use of IoT sensors, machine learning algorithms for predictive maintenance, and digital twins for process optimization.
4. **Digital Product Development:** This dimension evaluates a company's ability to leverage digital tools throughout the product lifecycle. It considers factors like the use of computer-aided design (CAD) and computer-aided engineering (CAE) software, digital simulation tools for product testing, and the integration of feedback from connected devices during the design process.
5. **Cybersecurity and Data Privacy:** This crucial dimension assesses a company's ability to protect sensitive patient data and ensure the security of its digital infrastructure. It considers factors like the adoption of robust cybersecurity measures, compliance with relevant data privacy regulations, and employee training on cybersecurity best practices.

The first step towards achieving digital maturity is to **assess the current state** of the organization's digital capabilities and can be done using DMMs. Secondly, it also necessitates a shift towards **connected devices**. By incorporating digital capabilities, medical devices can transmit real-time data, allowing for remote monitoring of patients, proactive maintenance, and personalized treatment plans. Thirdly, **advanced analytics** can unlock valuable insights from the collected data.

Furthermore, digital maturity necessitates a **cultural shift**. Organizations needs to have a collaborative and innovative environment where employees are comfortable learning new technologies and adapting to change. A **customer-centric focus** is also crucial. Digital tools allow organization to understand customer needs better, personalize experiences, and provide efficient service, ultimately leading to higher satisfaction and loyalty.

The influence of smart manufacturing on digital maturity extends beyond the factory floor. The interconnectedness created within the production system provides data integration across all departments within a medical device industry. This enhanced data flow cab be helpful for collaboration between R&D, engineering, quality control, and regulatory teams, streamlining product development cycles and accelerating time-to-market for new medical devices.

Some of the key aspects that influences smart manufacturing on digital maturity are:

1. **Data-Driven Decision Making:** Smart manufacturing fosters a data-centric culture. Sensors embedded in machines collect real-time data on performance, resource utilization, and potential quality issues. This data is then channelled into advanced analytics platforms, where it is transformed into actionable insights. With access to such rich data, medical device companies can make informed decisions regarding production processes, inventory management, and preventive maintenance. This data-driven approach fosters continuous improvement and optimizes overall equipment effectiveness (OEE) (Singh *et al.*, 2013).
2. **Enhanced Connectivity and Visibility:** Smart manufacturing facilitates seamless communication and data exchange between various components of the production line. Machines, robots, and even medical devices themselves can communicate with each other and with central control systems. This real-time visibility allows for proactive identification of bottlenecks, equipment failures, and potential quality control issues. Additionally, it enables remote monitoring and control, empowering manufacturers to optimize production from any location (Lawson, 2023).
3. **Personalized and Agile Production:** Smart manufacturing paves the way for mass customization in the medical device industry. By leveraging AI and machine learning algorithms, production lines can be dynamically adjusted to accommodate variations in product specifications and patient needs. This allows medical device companies to cater to a wider range of patient profiles and niche markets, fostering innovation and meeting the growing demand for personalized healthcare solutions (Özceylan *et al.*, 2018).
4. **Improved Quality and Traceability:** Smart manufacturing bolsters quality control measures within the medical device industry. Real-time monitoring of production processes allows for the identification of potential defects as soon as they occur. Integration of machine learning algorithms can further enhance this, enabling predictive maintenance and preventing defects before they affect finished products. Additionally, smart manufacturing facilitates comprehensive product traceability, allowing for rapid

identification and recall of potentially faulty devices. This not only improves patient safety but also strengthens regulatory compliance (Li *et al.*, 2015).

Furthermore, digital platforms enable personalized customer interactions, fostering loyalty and growth. It allows organisation to explore emerging technologies and adapt to changing market dynamics, gaining a competitive advantage.

To ensure the success of the digital transformation journey, organizations need to measure their progress and adjust their strategy as needed. This involves tracking key performance indicators (KPIs) that align with the organization's business objectives. Organizations that measure their digital maturity are more likely to achieve their desired outcomes and sustain their digital transformation efforts over time.

Achieving digital maturity is an ongoing process. As technology evolves, so do the considerations. AI and the IoT are generating vast amounts of data that companies need to harness effectively. Additionally, cybersecurity threats become more sophisticated, requiring robust measures and employee training. Companies must adopt an agile mindset, constantly reevaluating their strategies and adapting to ensure success in this ever-changing digital landscape.

2.4 Key factors contributing to the digital maturity of medical device industry in the terms of smart manufacturing

The key factors contributing to the digital maturity of medical devices in the context of smart manufacturing include organization and structure, resources and information system, technology integration, strategy, Human factor (customer engagement, employee readiness, and cultural adaptation) (Stark and Chin, 2022). The **organizational and structural** dimension encompasses changes in business processes, management readiness for change, internal organization and dynamic network collaboration, and continuous learning. **Resources** are guided by the principles of regulated communication and digital capability. This involves the ability to use cyber-physical systems for data processing and collection as well as the ability to access, collect, process, and analyse data.

Information systems comprise data processing and system integration, which includes automated data analysis and context-relevant supply of information. The integration of **advance technologies** such as IoT, AI, wearable devices, robotics, and VR are some of the key technologies revolutionizing medical device design. This integration enhances patient monitoring systems, connectivity products, and data management solutions (Plumb, 2023). Successful **customer engagement** involves understanding user needs, providing effective training, and ongoing support for end-users. Transitioning to digital processes often involves a cultural shift within the organization. **Employee willingness** is essential for navigating the shift to digital operations; it requires for skill development and efficient change management. **Cultural adaptation** within the organization, fostered by leadership support, innovation, and a commitment to continuous learning, plays a pivotal role in embracing and integrating digital technologies.

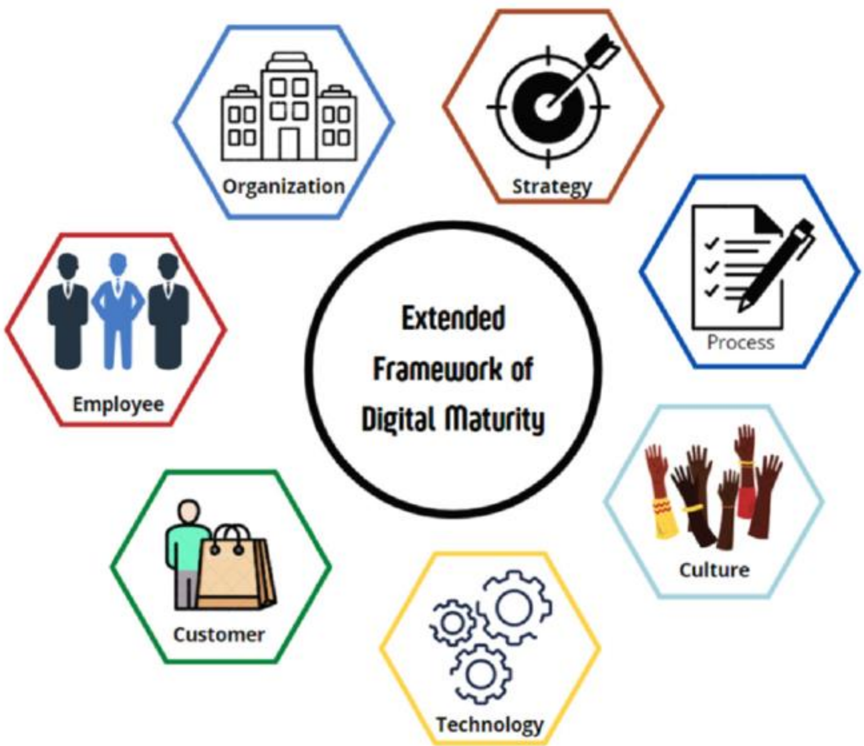

Figure 2: Extended Framework of Digital Maturity (Haryanti *et al.*, 2023)

2.5 Benefits and challenges of increasing digital maturity in the medical device industry in context to smart manufacturing

The medical device industry can benefit greatly from increasing digital maturity, which involves moving from manual processes to digital, automated processes. According to McKinsey research, the digital maturity of the pharmaceutical and MedDev sector was 28 out of 100, compared to an average of 34 across all industries, while leading sectors such as retail achieved a score of 40.3 (Bartlett et al., 2021). Increasing digital maturity can lead to enhanced product quality through real-time monitoring and automation, improved efficiency via streamlined processes and cost savings, and accelerated innovation with faster product development cycles. In detail benefits are included in table 3.

Table 3: List of potential benefits

	Potential benefits		
1	Improved efficiency	Upgrading the manufacturing facility with digital transformation in the upstream and downstream of the industry with data as the key element, through automation and intelligence can reduce product research and development, streamline processes, reduce manual labour, and analyzing operational data continuously, making it easier to identify and eliminate process-performance bottlenecks, resulting in increased productivity and overall operational efficiency.	(Sjödin et al., 2018; Xiao, 2022)
2	Reducing response time	Technologies like real-time quality control system designed to provide real-time suggestions or post-assessment feedback in the manufacturing process which can be helpful in identification of issues and quicker troubleshooting, leading to reduced response times.	(Duan and Yan, 2020)
3	Enabling customization	Digital technologies allow for more flexibility and agility in production, making it easier to customize medical devices to meet specific patient needs or market demands. For example, recent developments in additive manufacturing (AM) have moved the focus from mass manufacturing of implants to customized pre-operative implant manufacturing based on a digital 3D patient model.	(Paritala et al., 2017)
4	Increased product quality	It is achieved through real-time monitoring and the continuous optimization, allowing for prompt interventions and adjustments. Moreover, enhanced predictive and detective approaches allow quality defects to be spotted sooner than	(Sjödin et al., 2018)

		later, which can help to minimizes downtime and ensures consistency and quality of product.	
5	Product innovation	Implementing of technologies like AI and IoT promotes data integration and accelerate the development leading to introduction of new, innovative products	(Dowling et al., 2019)
6	Increased safety and sustainability	It is achieved through operational efficiencies that reduce the factory's environmental impact compared to conventional manufacturing processes. Firstly, increased process autonomy may reduce the potential chances of human error and secondly, repetitive and time-consuming work activities may be replaced by more satisfying tasks that may result in a greater sense of job satisfaction.	(Sjödin et al., 2018)
7	Improved decision-making	Access to accurate and timely data empowers manufacturers to make informed decisions based on comprehensive insights. Predictive analytics and AI-driven algorithms enable proactive decision-making, leading to streamlined production time.	(Panday, 2023)

Transition from traditional to digital mature industry comes with **challenges**. The substantial initial investment required for infrastructure, technology, and training is a key hurdle. The medical device industry faces several challenges, primarily due to its heavily regulated nature (Cummins and Schuller, 2020). This also include the lack of evidence-based standards, privacy concerns, data governance issues, ethical considerations that impede the progress of digitalisation in MedDev sector (Mumtaz et al., 2023). Therefore, it is important to carefully consider regulatory requirements and take steps to mitigate challenges to ensure a successful digital transformation which will increase the digital maturity of the medical device industry. In detail challenges are mentioned in table 4.

Table 4: List of potential challenges

Potential challenges

1	Organizational culture and resistance to change	Organizations can become very comfortable with their legacy processes and systems. They see digital disruption and change management as a challenge to their roles and responsibilities, and at worst, as posing a threat to their jobs.	(Albukhitan, 2020; Levia, 2023)
2	System integration	Integration of new technology equipment with the existing ones is a challenge as the compatibility of existing devices to the new devices can cause various problems during implementation.	(Phuyal *et al.*, 2020)
3	Interoperability issues	Interoperability is ability of different systems to understand and access each other's functions independently. Thus, constraints related to operational aspects, standards, guidelines, hardware and capabilities, mode of communication for systems can determine the limitations of interoperability of the system.	(Phuyal *et al.*, 2020)
4	Data security and Privacy issues	Cyberattacks are likely to become more common, when the data is generated and shared by CPS and IoT devices throughout the organisation.	(Senna *et al.*, 2022)
5	Regulatory challenge	Technology innovation might find it difficult operate in existing regulatory frameworks. Burden of filing regulatory applications across multiple global jurisdictions for new manufacturing technologies can also be challenging government support and other legal issues can be a barrier in implementing digital technologies.	(Arden *et al.*, 2021; Sayem *et al.*, 2022)
6	Lack of vision and leadership	Lack of leadership and support from superiors, along with a lack of understanding related to digital operations, applications, can hinder the adoption of advance technologies in the industry.	(Bakhtari *et al.*, 2020)

2.6 Adoption Strategies and Best Practices

As mentioned in section 2.3, the MedDev industry continues to evolve, it is crucial for companies to enhance their digital maturity through the adoption of smart manufacturing technologies and best practices. For this it is necessary to develop a digital strategy and implementation roadmap. (P. Senna *et al.*, 2023). Transformation involves a strategic shift towards integrating digital tools, optimizing processes, and leveraging data analytics to improve efficiency, quality, and compliance. Assessing the current level of digital maturity within the organization. This helps to understand and evaluate how these new digital technologies will be used to support the product development process (Sassanelli *et al.*, 2019). Further, it also helps to identify gaps and areas for improvement, providing a clear baseline for planning further digital initiatives. Another one of the adoption strategies could be integration of SM technologies that assist to change traditional product-based business models into service-oriented ones to offer value-added services, such as remote monitoring, predictive maintenance, and personalized patient care, especially, for the small or medium sized industries (Paschou *et al.*, 2020). Organization needs to specify goals and objectives for increasing digital maturity which could include digitalization manufacturing processes using automation, smart factories, and remote solutions to shorten time-to-value, enhance efficiency, and ensure products meet safety criteria. Identify advanced technologies and methods that align with the organization's goals and objectives. This could include updating software, training employees, and optimizing processes. By following these steps, medical device manufacturers can develop and execute a strategic plan for increasing digital maturity, including the selection and implementation of appropriate smart manufacturing technologies.

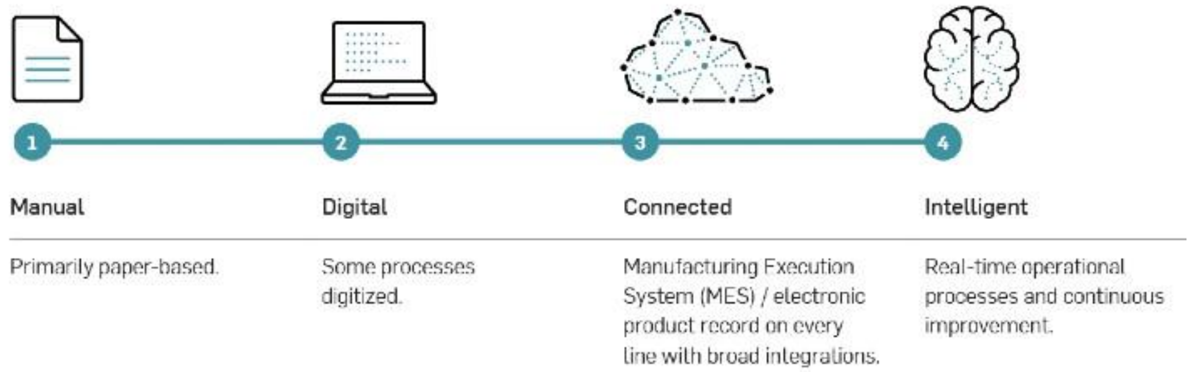

Figure 3: A digital maturity model to differentiate between maturity levels and outline a digital adoption strategy (Curran and Savo, 2023)

2.7 Key gaps and /or areas for opportunities for further research

The discussion on smart manufacturing and digital maturity in the medical device industry presents a comprehensive overview, yet several research gaps and opportunities for exploration emerge. The literature review highlights the integration of advanced technologies such as IoT, AI, and data analytics into the manufacturing processes of medical device companies. However, there may be a gap in understanding how these technologies are strategically integrated to drive digital maturity. Therefore, further research could delve deeper into the strategic decision-making processes involved in selecting, implementing, and scaling smart manufacturing technologies within medical device companies. Moreover, the importance of digital maturity in the medical device industry, there may be a lack of comprehensive understanding regarding the specific dimensions and criteria that define digital maturity in this context. So, this research will be helpful in assessing the overall maturity level of medical device industry. A review of the literature highlights both benefits and challenges associated with enhancing digital maturity within the context of smart manufacturing. This study seeks to bridge the knowledge gap by examining whether the identified benefits outweigh the potential challenges. Overall, further research in these areas will provide general recommendations to a more resilient, efficient, and sustainable future for the medical device manufacturing industry.

Rationale for Country Selection:

- According to Indian Brand Equity Foundation, India's medical devices sector market grow to US$ 50 billion by 2030 alongside achieving a 10-12% global market share over the next 25 years (IBEF, 2024).
- Ireland's exports MedTech products worth €12.6 billion annually to over 100 countries have a global impact, in which 80% of the world's stents and 50% of the world's acute hospital ventilators are being manufactured (Behan, 2023).
- **Therefore, India and Ireland have significant medical device industries that play important roles in the global market.**
- **Feasibility of study because of the existing connection and access.**

CHAPTER 3 RESEARCH METHODOLOGY

The research methodology section serves as a blueprint detailing the systematic approach undertaken to investigate the research questions corresponding with objectives to assess the impact of smart manufacturing on the digital maturity of the medical device industry. In any research study, the methodology outlines the specific methods and techniques to be used in gathering and analyzing the data. This chapter provides a comprehensive understanding of the methods, techniques, and procedures utilized throughout the research process. This section aims to offer transparency and clarity regarding the validity and accuracy of the study's findings by outlining the methodological framework used.

To meet the aim and objectives of the study an appropriate methodology for research was required. A proven research tool, Research Onion (figure 4) was used for the purpose of the study. It serves as a tool that assists in understanding the decisions and stances that are required in order to make an appropriate research design and methodology. Consequently, a strategy, a philosophical standpoint, and an approach are investigated and considered.

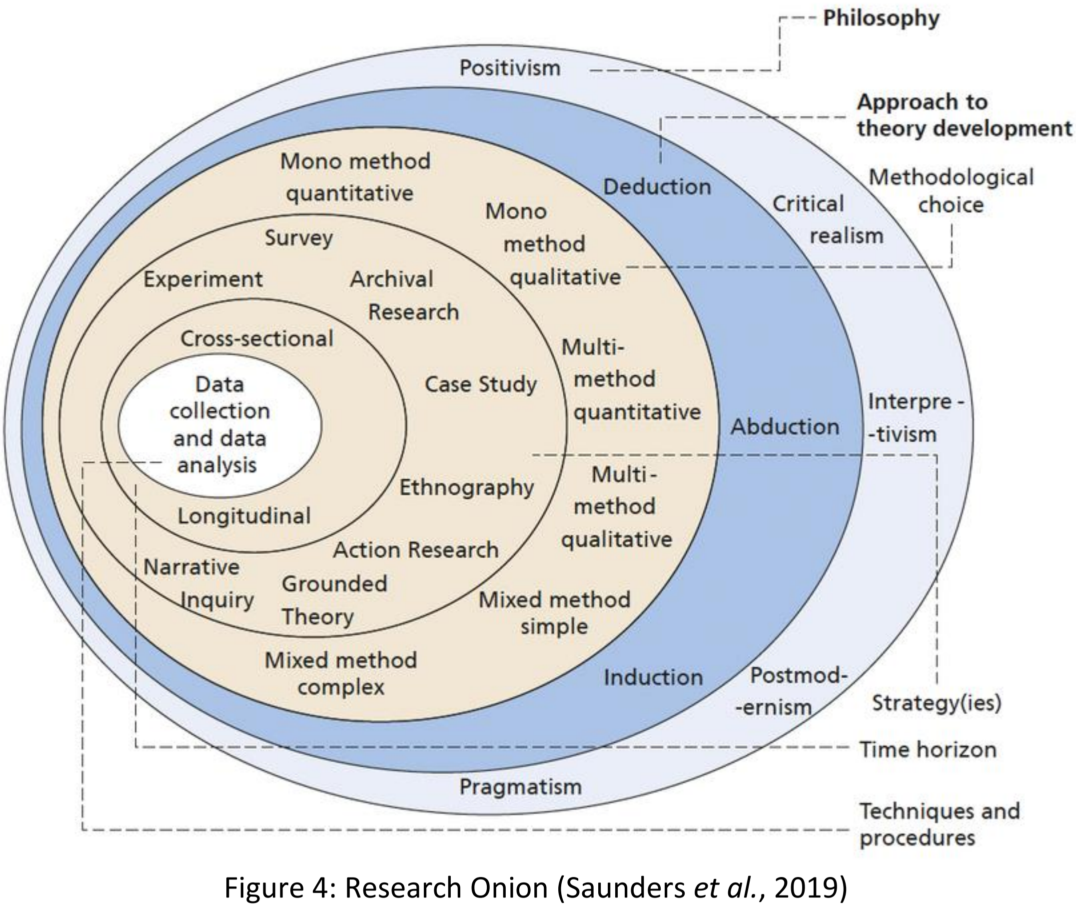

Figure 4: Research Onion (Saunders *et al.*, 2019)

3.1 Research Philosophy

Research philosophy serves as the fundamental framework around which the entire study is constructed and it is the outermost layer of the Saunders' research onion. It outlines the researcher's guiding principles, viewpoints, and assumptions on the nature of knowledge, reality, and the research process itself. Typically, there are four main types of research philosophies: positivism, realism, interpretivism, and pragmatism.

Positivism is a research paradigm that emphasizes the use of objective and empirical data, focusing on observable facts and verifiable evidence. This approach is often associated with quantitative research methods, where researchers aim to establish causal relationships and make generalizable conclusions (Park *et al.*, 2020).

Realism, on the other hand, acknowledges that reality exists independent of human perception and emphasizes the importance of understanding the social and cultural context in which research takes place (Hafsa, 2019). It often involves methods chosen based on the subject matter, with a focus on understanding the underlying reality of the phenomenon being studied.

Interpretivism, is a research paradigm that emphasizes the importance of subjective meanings and interpretations. It typically involves small samples, in-depth investigations, and qualitative methods, with a focus on understanding the meanings and interpretations of the participants involved in the study, such as interviews and observations, to gain a deeper understanding of the participants' perspectives (Jansen, 2023).

Pragmatism, another research paradigm, focuses on practicality and usefulness. Researchers who adopt the pragmatic approach prioritize the application of knowledge and value the practical implications of their research. They often engage in mixed methods research, combining both quantitative and qualitative approaches to gather comprehensive data that can inform practical solutions to real-world problems (Jansen, 2023).

The philosophical approach to the proposed primary research is influenced by **positivism and interpretivism** research philosophy to explore the impact of Smart Manufacturing on the Digital Maturity of the Medical Device Industry. Positivism emphasises the existence of an objective reality that can be measured and understood through scientific methods. This aligns with the research aim of assessing the extent to which smart manufacturing contributes to digital maturity. By employing a positivist approach, data collected through surveys, to measure the impact of smart manufacturing technologies on objective metrics of digital maturity like Industry 4.0 maturity index model. An interpretivism philosophy, may offer valuable insights into the subjective experiences of participants within the medical device industry.

The chosen positivist philosophy will analyse the survey results through the quantitative analysis of the results and presentation of the findings through statistics and an interpretivist approach will be used to analyse the data of a qualitative nature from the open-ended questions in the survey. Ultimately, the chosen philosophies will guide the research design, data collection methods, and analysis techniques employed in this study to establish generalise conclusions about the relationship between smart manufacturing adoption and digital maturity.

3.2 Research Approach and Strategy

This section outlines the research approach and strategy employed to investigate the impact of smart manufacturing on the digital maturity of the medical device industry. It will detail the chosen methodology and justification for its selection.

In this research, to study the impact of smart manufacturing on the digital maturity of the medical device industry, a mixed methods approach was used. Mixed methods research combines both qualitative and quantitative techniques to gain a comprehensive understanding of the phenomenon under study. This study explores multiple dimensions of the relationship between smart manufacturing and digital maturity in the medical device industry. By using a quantitative approach, it will be possible to measure the extent to which smart manufacturing has improved digital maturity indicators that include connectivity features, advancements in technology, and overall industry lifecycle benefits. On the other hand, by using qualitative approach, it will capture insights into the key factors, potentials, results, and challenges industry professionals face regarding integrating smart manufacturing technologies and advancing digital maturity. Through these qualitative questions, researcher can delve into how medical device industry employees perceive the smart manufacturing's' influence on digital maturity and what is their understanding of the current state of digital maturity. In addition, surveys and statistical studies will offer quantifiable data to complement and validate qualitative findings, enabling a more comprehensive understanding of the phenomenon under study.

Based on the research methodology and literature review, it is appropriate to say that study attempts to take an inductive approach. This approach involves collecting data, identifying patterns, and forming concepts and theories based on these observations. In the context of this study, the mixed methods approach allows for the collection of both quantitative and qualitative data, which can be used to inductively develop a theory on the impact of smart manufacturing on digital maturity in the medical device industry. The inductive theory development process enables the researcher to identify patterns, generate concepts, and develop theories based on the data, ultimately contributing to research study.

Justification: The chosen research approach aligns with the research aim of quantifiably assessing the impact of smart manufacturing on digital maturity. The combination of literature review, and survey allows for a comprehensive understanding of the research study. The literature review provides a theoretical foundation, the survey allows for generalizable data collection. This integrated approach helps in gathering information from a variety of perspectives and from targeted experts, to draw conclusions about the opinions on their experience, thoughts, and ideas on smart manufacturing and it influence on digital maturity.

3.3 Data Collection, Sourcing and Analysis

Data collection serves as the backbone for any research methodology. It is the process of gathering information, be it quantitative (numerical) or qualitative (descriptive), to answer the research questions and ultimately achieve research objectives. This chapter delves into the specific methods employed to collect such data for assessing the impact of smart manufacturing on the medical device industry's digital maturity. This study utilizes both secondary and primary sources of data to facilitate the research.

The secondary source of data is obtained through a systematic literature review on the subject matter. Extensive searching of keywords and examination of relevant material from reputable sources such as books, journals, articles, websites, and blogs were carried out to gather a comprehensive understanding of the topic. These sources can provide valuable background information, relevant benchmarks, and historical trends to contextualize the primary findings. This information, highlights how medical device companies are integrating advanced technologies like IoT, AI, and data analytics into their manufacturing processes, information related of the digital maturity index model. Additionally, these sources offer valuable insights by revealing trends, identifying potential research gaps, and prompting new perspectives. By examining past research, we gain a deeper understanding of the data and information relevant to the study, allowing further analysis and validate findings. Furthermore, secondary data provides a preparatory framework for structuring primary research.

For primary research, the data collection will involve a survey questionnaire with eligible participants who have experience in medical device industry in India and Ireland.

Survey design: The questionnaire design of the survey consisted of both open and closed-ended questions in order to perform quantitative and qualitative analysis. It was created using Google Forms. The format of the closed-ended questions in the survey will be ‘Yes' or 'No’ or 'Maybe' where the participants can provide one answer, or in the form of multiple-choice questions, where all options that apply can be selected. The open-ended questions will allow the participants to type their opinions or perspectives into the open space provided. The questionnaire comprises 22 questions and is divided into four sections.

The first section, Professional Background and Experience, will gather demographic information about the participants and assess their familiarity with smart manufacturing technologies in the medical device industry. The second section, Digital Maturity in Medical Device Industry, will delve into participants' perceptions of digitalization within their workplaces. This section will explore aspects like the use of manufacturing software, data connectivity within the organization, and how smart manufacturing practices have impacted operational efficiency and data utilization. The third section, Opportunities and Challenges of Digital Maturity, will explore participants' views on the potential benefits and challenges associated with deepening digital maturity in the medical device sector. This section will utilize ranking and selection question formats to gauge participant preferences for potential outcomes and the challenges they perceive as most significant. Finally, the fourth section, Digital Maturity Readiness, will assess the current state of digital maturity within participants' organizations. This section will evaluate factors such as the level of integration between smart manufacturing technologies and core business processes, employee skillsets and training frequency, and how they perceive the overall digital maturity level of medical device companies in their country.

Target Participants: The target participants for the survey are employees in the medical device industry in India and Ireland. The survey was generated online and was distributed to 70 participants through email, WhatsApp and LinkedIn. The participants were asked a qualifying question as for the survey to determine if they are eligible to participate in the research, which will ask if they have experience in employment in the medical device industry in India and Ireland.

Analysis of data: Data analysis is a critical step in unlocking the valuable insights hidden within your survey questionnaire. The data analysis process started with examining and cleaning the data to verify its accuracy, consistency, completion, and uniformity. Therefore, the data collected through the survey will be analysed using separate approaches for both quantitative and qualitative data, which will come from the mix of open- and closed-ended questions within the survey.

A quantitative approach will be used to analyse the initial closed-ended questions. This will be conducted by exporting the data collected from Google Forms to Microsoft Excel to perform numerical analysis to determine the significance of the data and will also use statistical software to identify trends, correlations, and relationships between variables. Different forms of data analysis will be performed depending on the nature of the question and the subsequent data collected.

A qualitative approach will be used to analyse the open-ended questions from the survey and will be analysed using an interpretivism approach to assess if there are any common themes that emerge from the data.

3.4 Ethical Consideration

Conducting research ethically is paramount to ensuring the well-being of participants, the integrity of the data, and the validity of findings. Possible ethical implications are well considered and performed in compliance with the ethical principles of Innopharma and Griffith College throughout the research study.

The protection and privacy of participants were given a high priority over the entire course of study. A simple strategy was devised to maintain the anonymity and confidentiality of participants. So, at the beginning of the survey a brief introduction was provided with an explanation of the study's purpose as well as the questionnaire. In the first section of the questionnaire, there was a consent question where options 'Yes' and 'No' were provided, where willing participants who agreed to complete the survey were directed to next section to complete the questionnaire and those participants who declined were politely directed to the end of the survey and thanked for their time and consideration. Personal identifying information such as name, age, or email that is not relevant to the research were not requested. This aided in achieving the necessary level of anonymity. Additionally, for the purpose of confidentiality, the identities of the companies where the participants worked were not gathered. To ensure the integrity of the data and prevent misrepresentation of the findings, only responses from participants meeting the inclusion criteria will be considered in the analysis process.

The handling and storage of the data will be controlled throughout to ensure the confidentiality and integrity of the data. All data generated will be handled in line with General Data Protection Regulation (GDPR). All the data recorded during the course of the research study and will later be submitted to Griffith College as part of a thesis submission. After submission, if it is considered useful research data may be retained for a period of two years and Griffiths College will have the discretion to decide how to dispose of the data after it has been turned over.

CONCEPTUAL FRAMEWORK

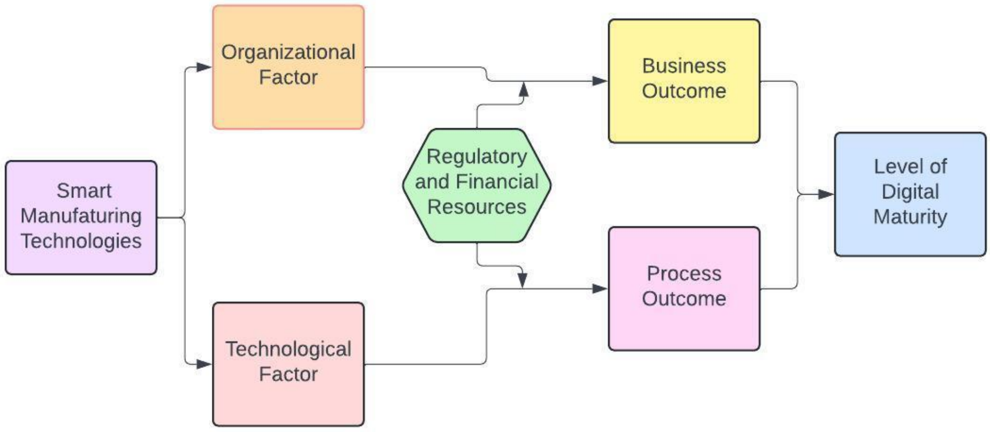

Figure 5. Conceptual Framework

This conceptual framework examines how smart technologies are shaping the medical device industry's manufacturing processes. The core concept is the "Digital Maturity of the Medical Device Industry" which reflects a company's ability to leverage digital tools for optimal production. Several factors drive this digital maturity. On one hand, organizational factors like leadership support for digital transformation, a flexible organizational structure, and a skilled workforce all contribute to successful technology adoption. Additionally, integrating smart manufacturing technologies (IoT, AI, Big Data) alongside robust cybersecurity and data management infrastructure are crucial technological aspects. These independent variables are believed to lead to improvements in process and business outcomes. Process outcomes encompass increased efficiency, improved quality control and traceability, and faster innovation cycles. Business outcomes, on the other hand, can include enhanced customer satisfaction, a competitive advantage, and better compliance with regulations. However, the strength of these relationships can be influenced by moderating variables like the regulatory environment and financial resources. Stringent regulations and data privacy concerns can slow down technology adoption, while limited financial resources might restrict investment in new technologies and workforce training. This framework provides a foundation for further research by allowing for a deeper investigation into the connections between these variables and ultimately identifying key factors that lead to adoption smart manufacturing technologies in the medical device industry that impacts overall digital maturity.

CHAPTER 4 FINDING AND ANALYSIS

This section will present the findings from the survey conducted as part of primary research. The approach outlined in Chapter 3 was followed for analysing the data to ensure that the results are aligned with the aim and objectives of the research study.

Through the data analysis, a deeper understanding was generated regarding adoption of smart manufacturing technologies, digital maturity readiness, key factors, potentials, and challenges experienced by medical device industry professionals. Based on the opinions acquired from experts in the field, the study's conclusions were made to assess the impact of smart manufacturing on the digital maturity of medical device industry.

The survey proceeds with a brief introduction of the research study followed by a participants consent question to continue to the first section of the questionnaire.

4.1 Professional Background and Experience

4.1a Response Rate

A Google Form survey was distributed to professionals working in the medical device industry. An estimated 70 questionnaires were shared electronically via email, professional networking sites like LinkedIn, and WhatsApp. Reminder messages and follow-up invitations were sent via text and email to increase response rates. This strategy resulted in a prompt increase in responses and completed surveys. While an estimated response of 53-60 participants was anticipated, the final number of respondents upon survey closure was 48. This translates to a positive response rate of 68.5%.

4.1b Level of Experience

With respect to the experience of participants, out of 48 participants who took part in the survey, 3 (6.3%) had more than ten years of experience, 11 (22.9%) had experience between five and ten years, 15 (31.3%) had two to five years, 9 (18.8%) had one to two years, and 10 (20.8%) had less than a year. Table 5 summarizes the participants level of experience in medical device sector.

Table 5: Level of experience in the MedDev Industry

Years of Experience	Total Number of Participants	(%)
Less than 1 year	10	20.8
1-2 Years	9	18.8
2-5 Years	15	31.3
5-10 Years	11	22.9
More than 10 Years	3	6.3

4.1c Geographical Data

As the survey was distributed in two different countries, no. of participants who took part in the survey, 27 people are from India and 11 from Ireland as shown in figure 6.

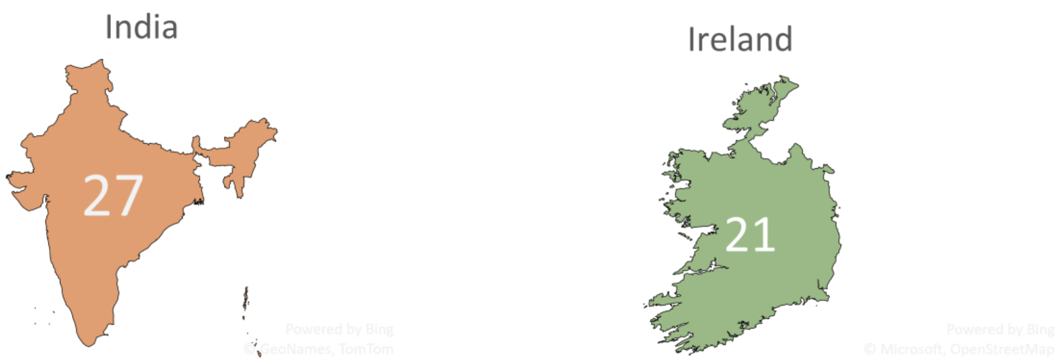

Figure 6: Number of participants based on countries

4.1d Smart manufacturing in MedDev Industry: Knowledge and Experience

To understand the knowledge of participants regarding smart manufacturing technologies in the MedDev industry, the response to question number three of the survey indicates that a majority of participants in both India and Ireland are familiar with smart manufacturing technologies used in this sector. Overall, (31.3%)15 participants are quite familiar with the implementation of digital technologies, (19%) 23 participants are fairly familiar, (18.8%) 9 are slightly acquainted with these technologies being used in the industry and (2.1%) 1 has no experience of the technologies being implemented. Figure 7 shows respondents' familiarity with smart manufacturing technologies.

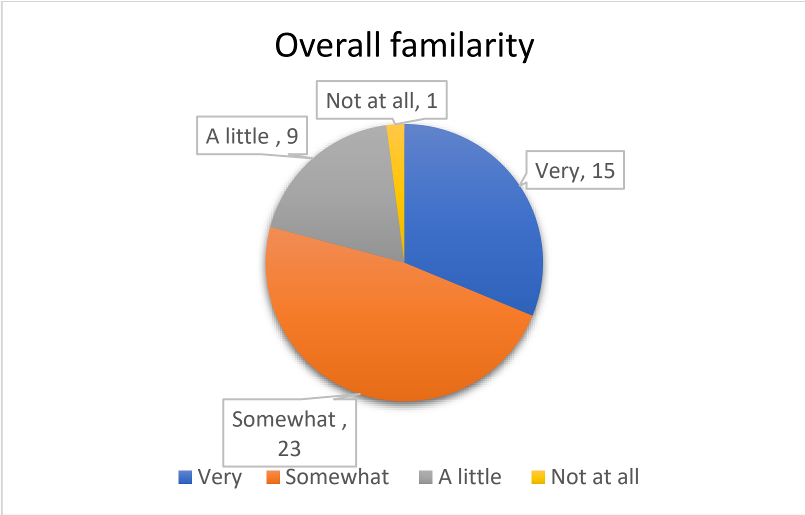

Figure 7: Respondents' familiarity with smart manufacturing technologies

From responses to the survey, professionals in the medical device industry report diverse experiences with a range of smart manufacturing technologies. 39 professionals indicate having experience with Artificial Intelligence (AI) and Machine Learning (ML). Followed by the Internet of Things (IoT), with 31 responses, highlighting its importance in enhancing connectivity and data gathering capabilities within manufacturing processes. Technologies such as Cloud Computing and Big Data Analytics both reflect experience from 27 respondents, indicating significant use in processing and analyzing large datasets for better decision-making Additionally, Robotics and Cybersecurity each have 23 professionals reporting experience, underscoring their roles in automating tasks and securing manufacturing data respectively. Additive Manufacturing, which allows for rapid prototyping and production, is experienced by 18 professionals, the same number as those familiar with Augmented Reality (AR) and Virtual Reality (VR), technologies that are increasingly used for training and simulation in manufacturing setups. Less experienced but still noteworthy are Digital Twin and Blockchain technologies, indicating emerging trends that are beginning to take hold in the industry. While 3 participants selected "other," one notably mentioned experience with a Manufacturing Execution System (MES) which helps to optimize the manufacturing process such as monitoring, tracking, documenting, and controlling. This spectrum of technology adoption illustrates a robust engagement with digital tools that are critical to advancing manufacturing efficiency and innovation in the medical device sector. Figure 8 shows number of respondents with experience in smart manufacturing technologies.

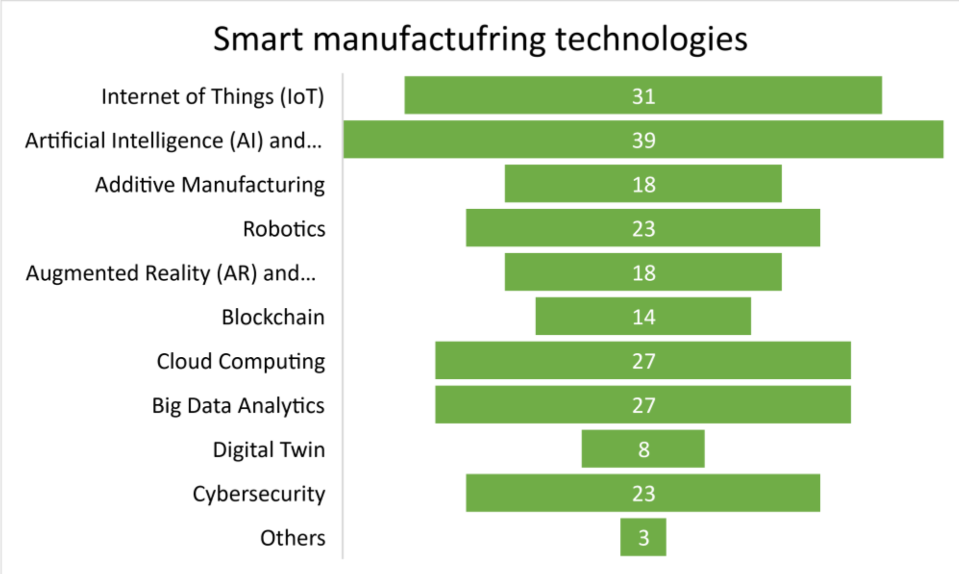

Figure 8: Number of respondents with experience in smart manufacturing technologies

4.2 Digital Maturity in Medical Device Industry

4.2a Primary objectives in implementing smart manufacturing

In response to question number 6, the survey data provides valuable information related to the primary objectives of implementing smart manufacturing technologies in the medical device industry. Out of 48 participants, 42 people find operational efficiency enhancement and quality improvement as a key goal for implementing digital technologies. As these objectives are central to the industry's efforts to streamline operations and enhance the standard of products. Enhanced agility in production is another significant objective, highlighted by 34 participants, reflecting the need for flexible and adaptable manufacturing processes that can rapidly respond to market changes and demands. Cost reduction and better regulatory compliance are also critical, as indicated by 33 and 31 participants respectively. as these objectives indicate a strategic focus not only on reducing operational costs but also on ensuring products meet stringent regulatory standards, which is crucial in the highly regulated medical device sector. Overall, from responses to this survey it suggests a multi-faceted approach to smart manufacturing adoption in the medical device industry. Responses from the participants were analysed and summarised in figure 9 below.

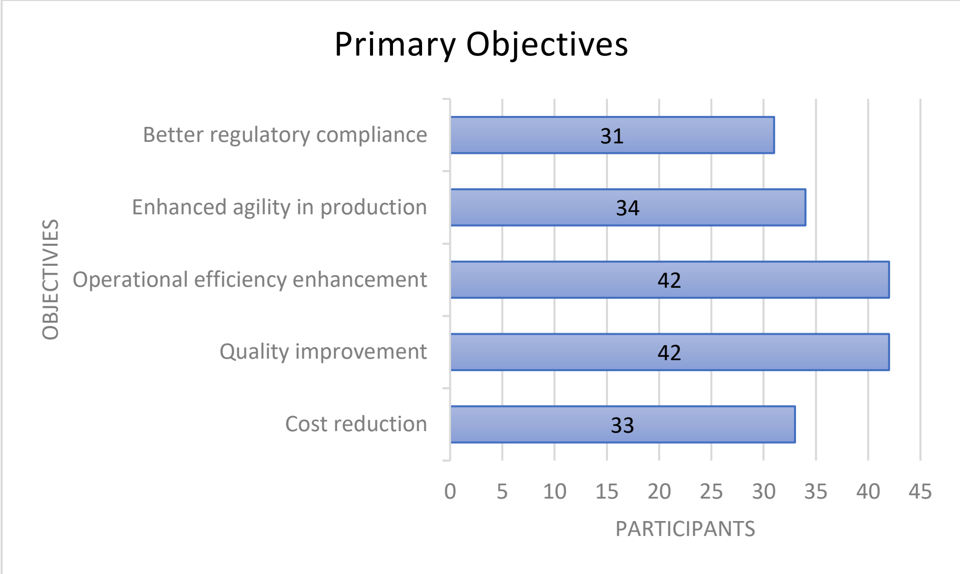

Figure 9: Primary objectives in implementing smart manufacturing technologies

4.2b Prioritizing Digitalization and Technology Adoption

In response to question 7, of the 48 participants, 23 consider increasing digitalization as a high priority. This implies that for many, advancing technology use is integral to their strategic operations and competitive positioning for an organization. Another 12 participants view it as one of many priorities, indicating a balanced approach to digitalization alongside other organizational goals. Additionally, 9 respondents view it as the highest priority, emphasizing a strong pursuit of technological advancement as central to their digital strategy. On the other hand, smaller numbers reflect lower urgency, with 3 participants considering it a low priority and only 1 explicitly stating it is not a priority. Finally, responses to this question are summarized in figure 10, it highlights a broad recognition of the importance of digitalization in the industry, though the degree of focus varies, with the majority leaning towards greater integration and utilization of advanced technologies.

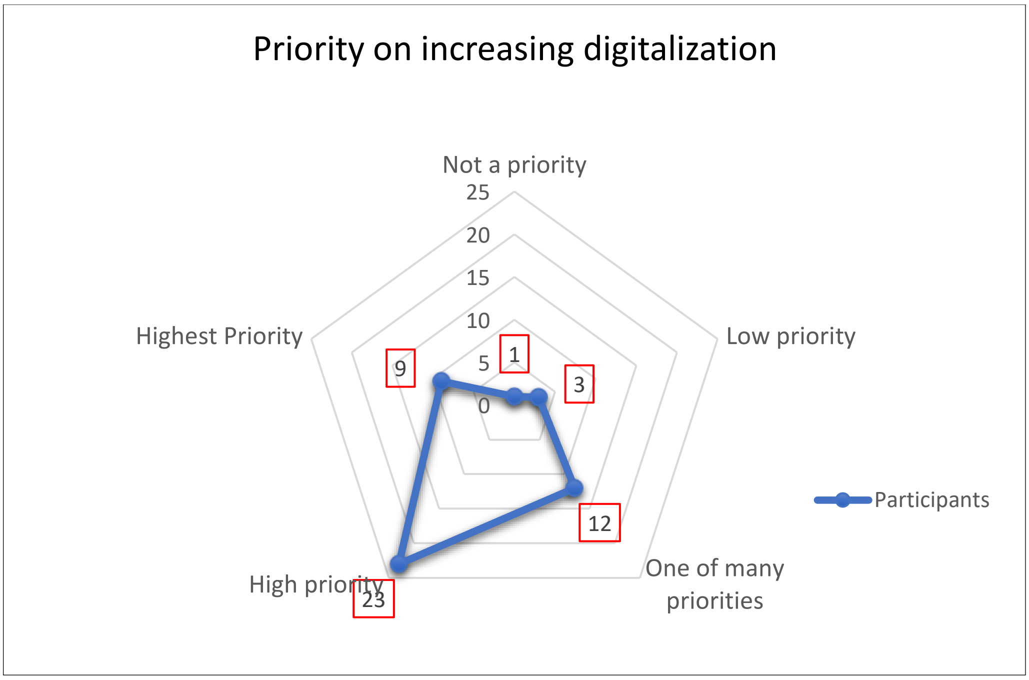

Figure 10: Priority on increasing digitalization and technology adoption

4.2c Evaluating Manufacturing Operations in the MedDev Industry

For question 8, according to 31 participants it can be said that companies have invested in manufacturing software to digitalize core processes, although this has only been implemented in some production lines. This indicates a significant but partial integration of smart technologies, suggesting a transition phase towards fuller digital maturity. Another 7 responses indicate full implementation of manufacturing software across all lines and the integration with an API-driven network, highlighting a smaller number of companies that have achieved comprehensive digital integration. In contrast, 8 respondents indicated that some companies still rely on basic digital tools like Word or Excel to create digital documents, while 1 participant selected use of manual processes and paper-based documentation exclusively. These findings reflects that the medical device industry is adopting advance technologies and moving towards more sophisticated digital solutions but varying significantly in the extent and depth of their implementation. The analysis of findings is shown in figure 11

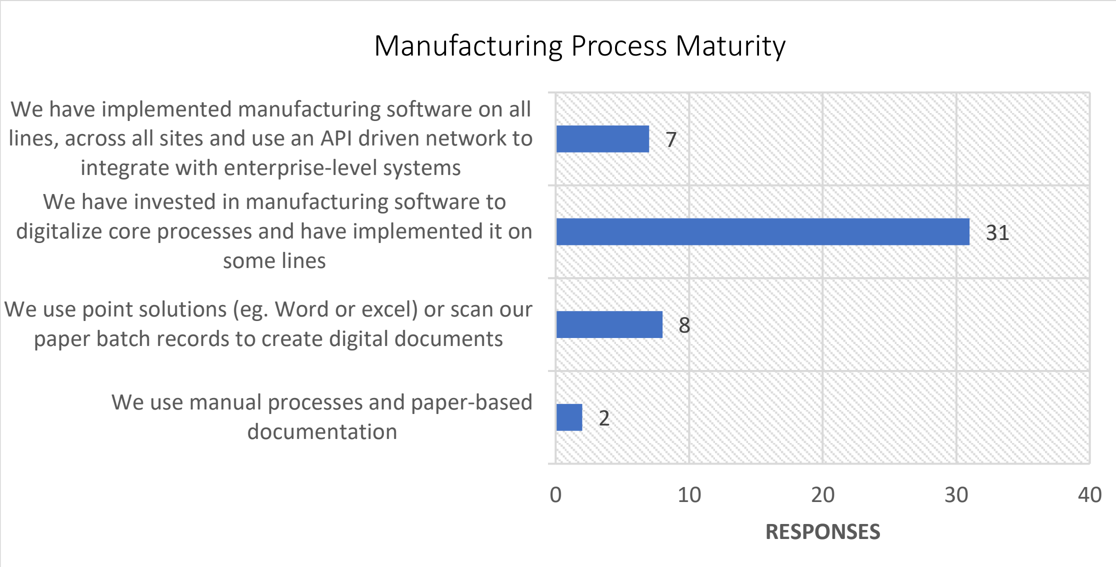

Figure 11: Manufacturing process maturity

4.2d Evaluating data connectivity in the MedDev Industry

In respect to question 9, 16 participants, reports widespread use of digital solutions where all data is available, yet the solutions remain disconnected or siloed, indicating an intermediate stage of digital integration. This suggests considerable digital adoption that has not yet achieved full connectivity. 10 participants highlight a more advanced state where digital solutions are fully integrated across manufacturing and organizational processes, enabling data-driven decision-making. However, there are still companies at the early stages, with 7 using a mix of manual and digital solutions, with some data accessible but most still on paper, reflecting early stages of digital adoption and 2 relying solely on manual processes, showing minimal digital integration. At the higher end of digital maturity, 5 participants indicates that their operational intelligence is fed by real-time data which contributes to continuous process optimization, predictive production quality, and autonomous production, indicating the highest level of digital integration. These results highlight that, most of companies are progressing towards a significant level of digital connectivity and few have already achieved seamless data connectivity across the facility as shown in figure 12.

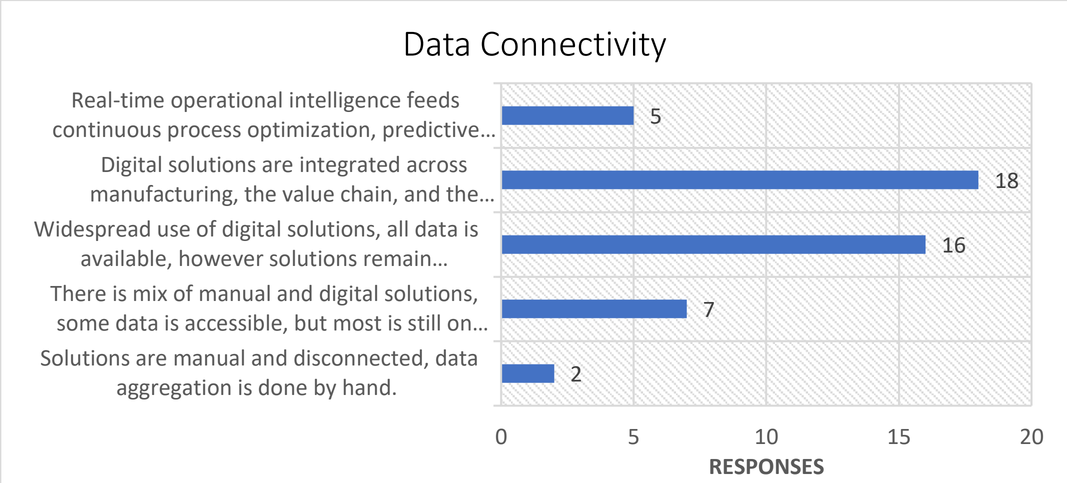

Figure 12: Data connectivity in the MedDev industry

4.2e Impact on operational efficiency since implementing smart manufacturing

According to survey data for question 10, a strong majority (77.1%) 37 respondents believe that the medical device industry has experienced increased operational efficiency since implementing smart manufacturing practices. Therefore, it can be said that smart manufacturing has had a positive impact on the industry's ability to produce medical devices more efficiently. Additionally, (16.7%) 8 respondents expressed uncertainty regarding the effect of smart manufacturing on operational efficiency. Lastly, it is noteworthy that a small minority (6.3%) 3 respondents believed that the industry has not experienced increased efficiency. Impact on operational efficiency is summarized in form of pie chat in figure 13.

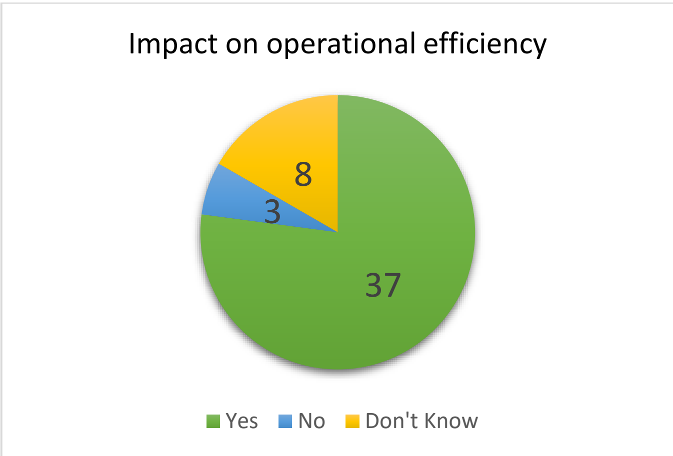

Figure 13: Impact on operational efficiency

4.2f Data-Driven Devices: Effectiveness of analytics in the MedDev Industry

In response to question number 11, the majority of responses 27 (56.3%), feel that data analytics tools are utilized to a moderate extent, suggesting that while data analytics are used, they may not be fully leveraged to improve manufacturing processes and quality control. 18 (37.5%) responses report a highly effective integration of advanced analytics tools, that fully aids in decision-making and operational improvements. However, a small number i.e., 3 (4.2%) responses indicate that data analytics are not used at all, indicating areas where the industry still needs to enhance their digital capabilities. This distribution reflects further efforts to integrate more advanced data analytics tools to optimize areas in the medical device sector. Effectiveness of data analytics to improve manufacturing processes and quality control is shown in figure 14

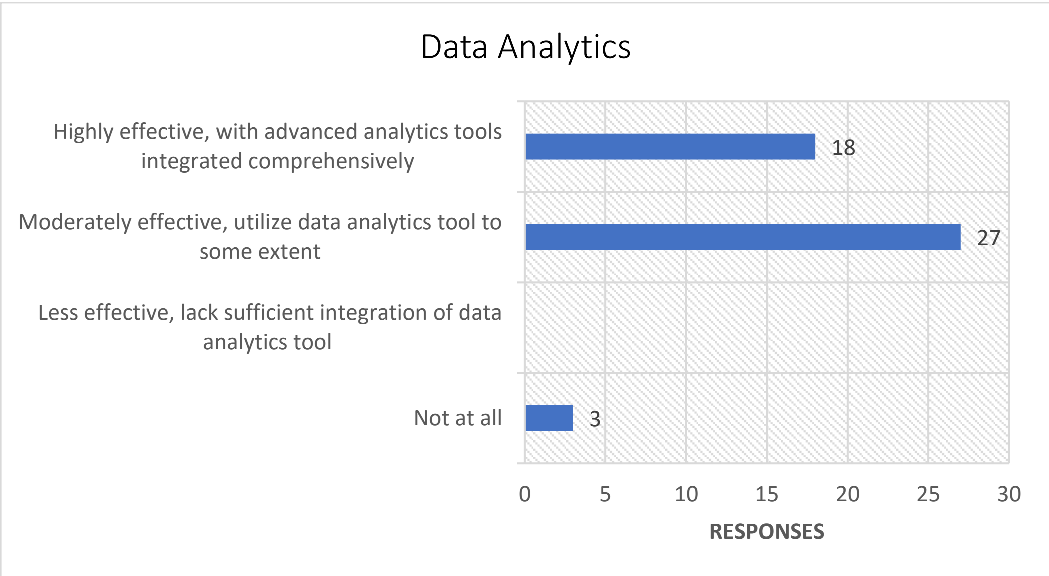

Figure 14: Effectiveness of data analytics

4.2g Importance of regulatory compliance in the MedDev Industry for smart manufacturing

In response to question 12, the survey data shows that regulatory compliance is considered highly important in driving digital maturity within the medical device industry, with the majority of responses residing at the upper end of the scale (21 rated it as important and 24 as extremely important). This shows that industry strongly recognizes compliance not only as a legal necessity but also as a driver for adopting advanced digital technologies in smart manufacturing. Only a few respondents (3) rated it as moderately important, emphasizing the critical role of compliance in ensuring safety, meeting international standards, and utilizing digital technologies to enhance operational efficiencies. Thus, regulatory compliance is pivotal in fostering and facilitating the digital transformation of medical device manufacturing. Regulatory compliance in the MedDev Industry for smart manufacturing can be seen in figure 15

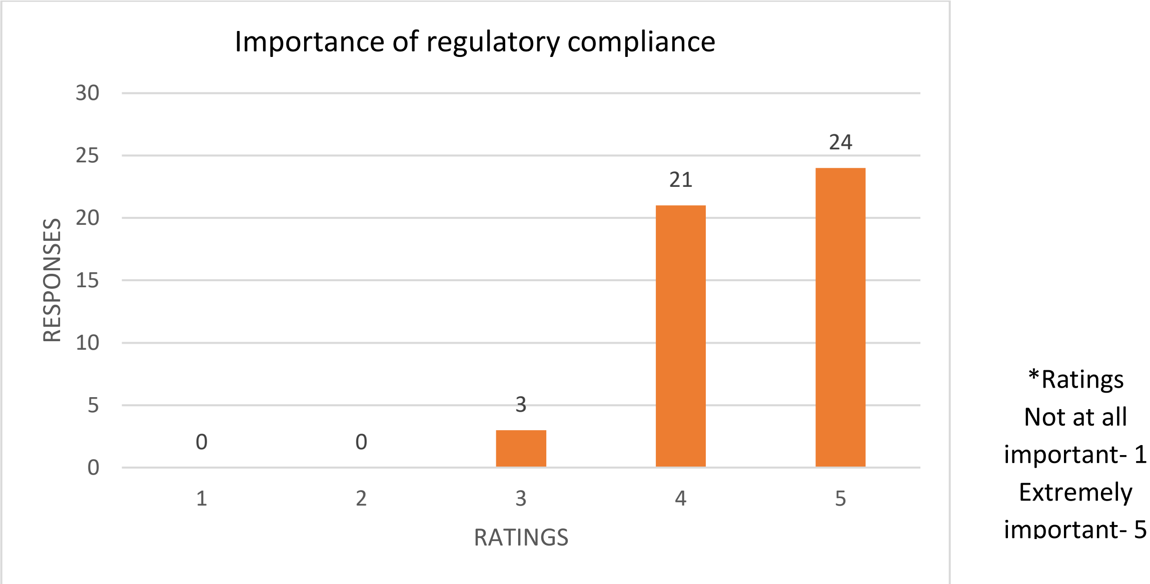

Figure 15: Importance of regulatory compliance in the MedDev Industry for smart manufacturing

4.3 Opportunities and Challenges of Digital Maturity

4.3a Considering benefits and risk of Deepening Maturity in MedDev Industry

In response to question number 13, a significant number of participants, 36 out of 48, believe that the benefits of increasing digital maturity clearly outweigh the potential risks. It implies that employees in this sector values advanced digital tools and processes bring to the industry, likely in terms of enhanced efficiency, improved product quality, and compliance with regulatory standards. 7 participants, on the contrary don't see the benefits as outweighing the risks, which might point to concerns about costs, implementation challenges, or security issues associated with digital technologies. Additionally, 5 participants are unsure, reflecting either a lack of information or uncertainty about the potential impacts of digital transformation. Overall, the majority supports the strategic push towards greater digital integration in the medical device industry, highlighting its significance and advantage despite some inherent challenges to achieve higher digital maturity is shown in figure 16.

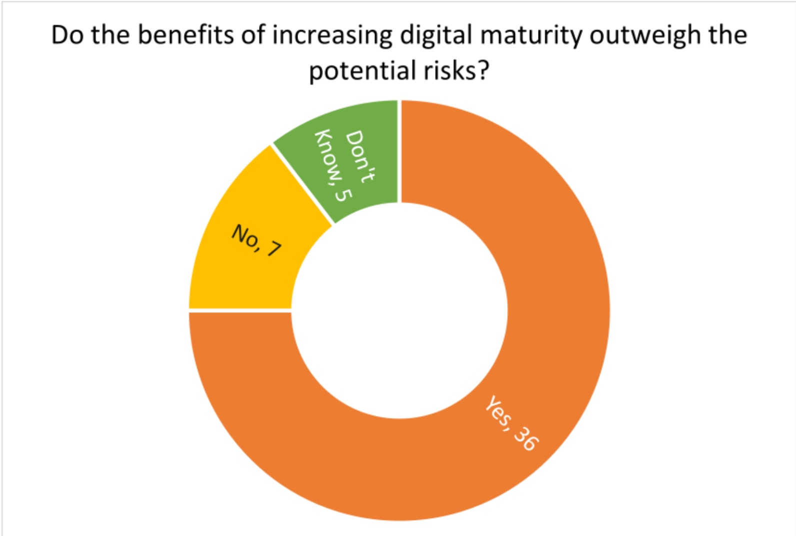

Figure 16: Do the benefits of increasing digital maturity outweighs potential risks

4.3b Ranking the potential results of Digital Maturity in MedDev Industry

In respect to question number 14, from the survey data, the accompanying figure 17 outlines the most and least significant benefits derived from deepening digital maturity in the medical device sector, as ranked by industry professionals.

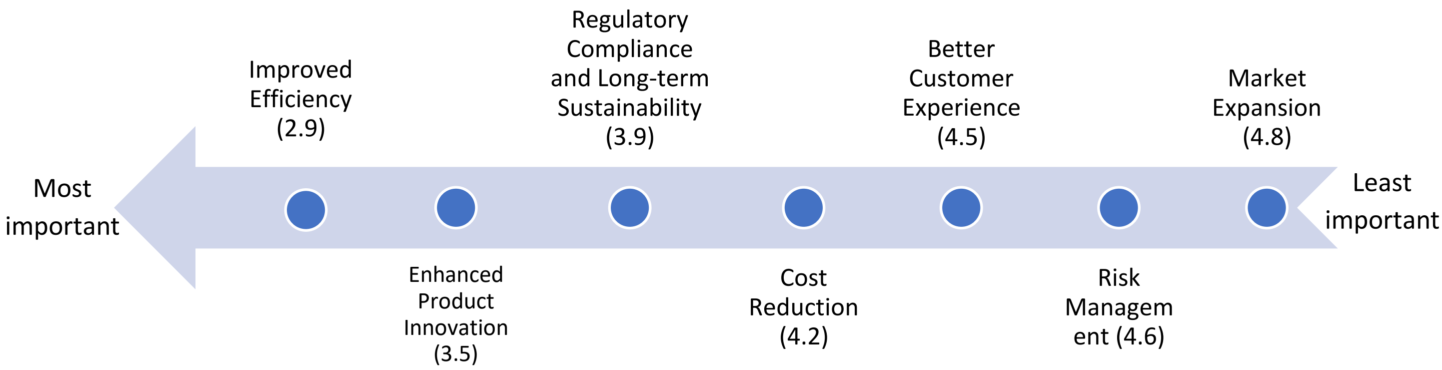

Figure 17: The most and least significant benefits

The analysis involved 48 participants who evaluated 8 potential benefits. Each participant ranked the benefits from 1, indicating the most important, to 8, signifying the least important. The average ranking (mentioned in above figure 17) for each benefit was then calculated to determine their relative importance. This methodical approach allowed for a clear quantification of priority areas by the participants, highlighting 'Improved Efficiency' as the top benefit and 'Market Expansion' as the least prioritized outcome of enhancing digital maturity within the sector.

The ranking indicates that operational efficiencies and product innovation are at the forefront of digital maturity benefits. Compliance and sustainability are also crucial but are not the primary focus. cost reduction is also a significant benefit, but ranks lower compared to other factors as it is seen as a secondary result of efficiencies gained from other digital advancements rather than a direct goal. On the contrary hand, although risk management, customer experience, and market expansion are beneficial, they are seen as less direct outcomes of digital maturity. This hierarchy of priorities reflects a pragmatic approach to digital adoption, focusing on immediate operational improvements that can lead to broader benefits over time.

4.3c Ranking the potential challenges of Digital Maturity in MedDev Industry

In respect to question number 16, from the survey data, the figure 18 outlines the most and least challenging derived from deepening digital maturity in the medical device sector, as ranked by industry professionals.

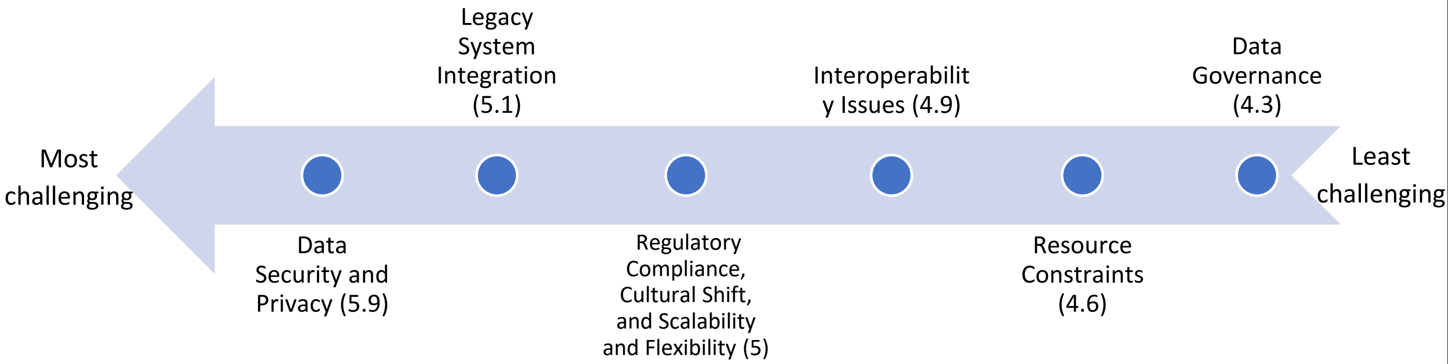

Figure 18: The most and least challenges

Participants were instructed to rank these challenges from 1 (most challenging) to 8 (least challenging). However, for ease of calculation and interpretation, the rankings were reversed during analysis; thus, a ranking of 1 was recalculated as least challenging and 8 as most challenging. This analysis involved collecting and evaluating responses from 48 participants and average ranking (mentioned in above figure 18) was calculated for each challenge to determine their relative difficulty. This method allowed for a clear depiction of which challenges are viewed as most and least challenging in the context of advancing digital maturity in the medical device industry.

This analysis shows that data security and privacy are viewed as the biggest challenges, emphasizing the importance of protecting sensitive information in the highly regulated medical device industry. Second most challenges according to the response were legacy system integration and interoperability issues, reflecting the technical and organizational complexities involved in upgrading manufacturing and operational infrastructures. Other challenges such as regulatory compliance, cultural shift, scalability and flexibility are in the middle of the scale, indicating considerable difficulties, to stay compliant with evolving regulations, adapt to new digital workflows, and ensure systems are scalable and flexible to meet future demands. Resource constraints and data governance are little lower in the ranking compared to others, still they are one of the crucial challenges to achieve when there is limited resources and data management strategies are necessary to enhance operational effectiveness respectively.

The findings from the survey emphasizes the importance of addressing a wide range of challenges to successfully deepen digital maturity. Organizations need to strategize effectively to mitigate these issues, prioritizing areas such as security, system compatibility, and regulatory adherence, while also considering organizational and resource-based constraints.

4.3d Identifying Key Impacts of Digital Maturity in MedDev Industry

Response to question number 15, large percentage of participants 75% (36), believe that product design and development will benefit the most, emphasizing the crucial role of digital tools in enhancing innovation and precision in this area. Similarly, regulatory compliance and post-market surveillance and monitoring also received considerable attention, with 70.8% (34) and 66.7% (32) of participants respectively, understanding the improvements that digital maturity can bring in terms of meeting regulatory standards more effectively and monitoring products post-launch. Also, 62.5% (30) of participants viewed supply chain management as a key beneficiary, as digital solutions can provide improvements in efficiency and transparency. Further, according to 47.9% (23) of responses it can be stated that compare to others areas clinical trials and research are least affected, but it is still significantly impacted. This data illustrates a general believe that digital maturity can drive significant improvements across multiple fields of the medical device industry, particularly in enhancing product development, compliance, and monitoring processes. Figure 19, summarizes the impact of digital maturity on the different areas in MedDev sector.

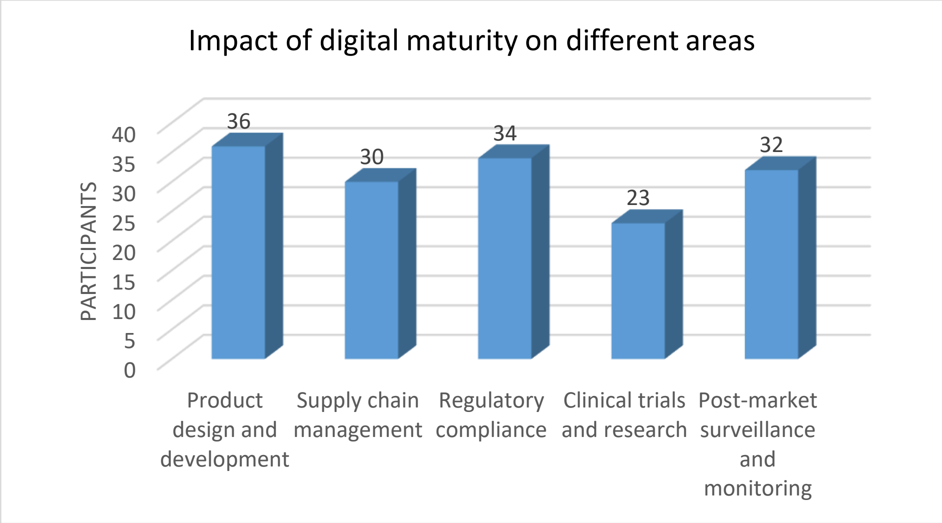

Figure 19: Different areas impacted due to digital maturity

4.3e Identifying Critical Aspects for Digital Maturity in MedDev Industry

In regards to question 17, 37 participants believes that continuous training and upskilling of the workforce is one of the essential aspects for ensuring the success of digital maturity initiatives. This indicates a strong recognition that an educated and staff proficient with technology are important for effectively implementing and leveraging digital technologies. Strong leadership and strategic vision also rank highly as selected by 35 participants, emphasizing the need for clear direction and commitment at the leadership level to drive digital initiatives forward. Another valuable aspect identified by 33 participants is Robust cybersecurity Measures, indicating that the importance of protecting data integrity and securing digital operations within the sector. Flexibility in adapting to a changing regulatory landscape and collaboration among stakeholders are seen as relatively less critical but still significant, with 30 and 22 responses respectively. These findings suggest that while technological and operational components are crucial, the human factors like training and leadership are considered even more essential for the success of digital transformation to drive the digital maturity to the fullest in the medical device industry. Figure 20 summarizes the critical aspects of digital maturity.

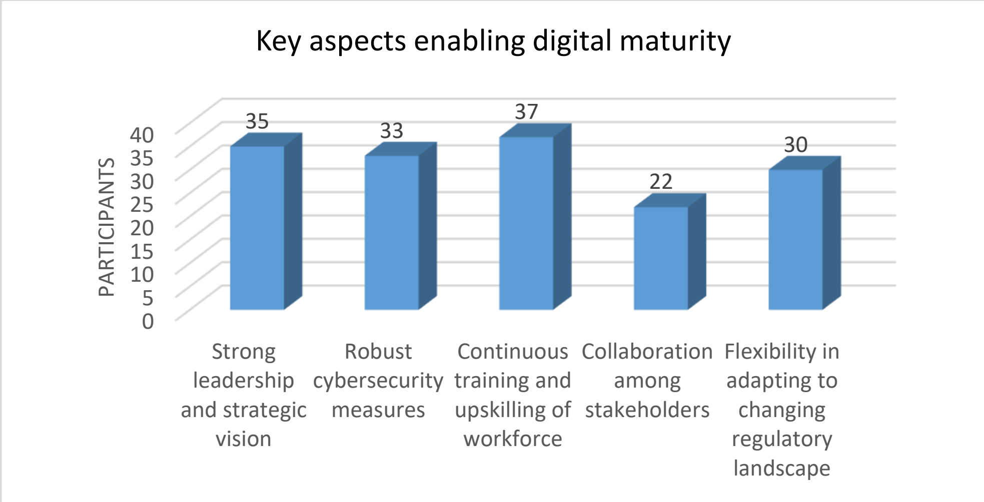

Figure 20: Key aspects enabling digital maturity

4.4 Digital Maturity Readiness

4.4a Key Drivers for Digital Maturity in MedDev Industry

In response to qualitative question 18 regarding the main drivers for digital maturity in the medical device industry, thematic analysis approach was used which reveals several interconnected themes that highlights the push towards smarter manufacturing processes. Table 6 below summarize key drivers for digital maturity in which sub themes are marked with light yellow colour under main theme according the participants response.

Table 6: Key drivers for digital maturity

Main theme/ Sub theme	Operational efficiency and cost reduction	Quality and safety	Innovation and technological advancements	Data-driven decision making	Leadership and investment	Customer and market orientation	Security and compliance
Use of AI, IoT, Machine Learning, Digital Twin							
Data Analytics and Integration across facilities							
Efficiency							
Cost reduction							
Continuous improvement and agile production							

Improvement in product quality and safety							
Regulatory compliance							
Strong leadership and strategic vision							
Investment in smart technologies							
Customer data accessibility and product handling							
Meeting market demands with high-quality, cost-effective products							
Data security and privacy							
Paperless work							
Enhanced Clarity in Medical Device Standards with Digital Maturity							
Total Response	**13**	**11**	**10**	**3**	**3**	**4**	**5**

Many participants identify operation efficiency and cost reduction as primary drivers for digital maturity. This involves simplifying production lines to minimize waste, using continuous improvement methods and flexible production techniques to boost efficiency, and ultimately lowering overall manufacturing costs. High quality products with ensured safety can be developed with integration of digital technologies, therefore significant number of participants this as one of the main drivers of digital maturity. The responses imply a high emphasis on innovation as a driver for digital maturity, with advancements in IoT, AI, machine learning, and digital twin technologies seen as essential. Participants pointed that these technologies facilitate better product designs, improve patient outcomes, and support continuous innovation. The ability to make informed decisions based on real-time data and analytics is another significant theme highlighted by few participants. Strong leadership and a clear strategic vision are considered essential for driving digital maturity. Some participants emphasize the importance of focused and motivated leader to invest in smart technologies and guide their strategic implementation. Few participants also acknowledge the importance of meeting customer needs and market demands, which include ensuring customer accessibility to data and designing products that are both high-quality and cost-effective. To ensure a secure and reliable manufacturing environment which is highly regulated, participants also consider security and compliance as a key driver. Digital technologies, such as cybersecurity, data analytics, and AI are seen as key to maintain data privacy, meeting safety standards, and adapting to regulatory pressures respectively.

4.4b Assessing Integration of Smart Manufacturing into core business processes

In answer to question 19, Out of 48 participants, 24 say that smart manufacturing technologies are moderately integrated into their business processes, suggesting some engagement with smart technologies, yet these systems are not fully central to their operations. 19 participants indicate that there is high level integration, demonstrating a deeper, more extensive use of these technologies throughout their business process. On contrary, 2 participants feel that their integration is partial, indicating that they are in initial stage of incorporating advanced technologies, their use remains minimal and peripheral. Additionally, 1 indicated that the integration of smart manufacturing technologies is not applicable to their operations, which could suggest either irrelevance to their specific sector or that they are at very preliminary stages of consideration. Figure 21 illustrates integration of smart manufacturing into core business process.

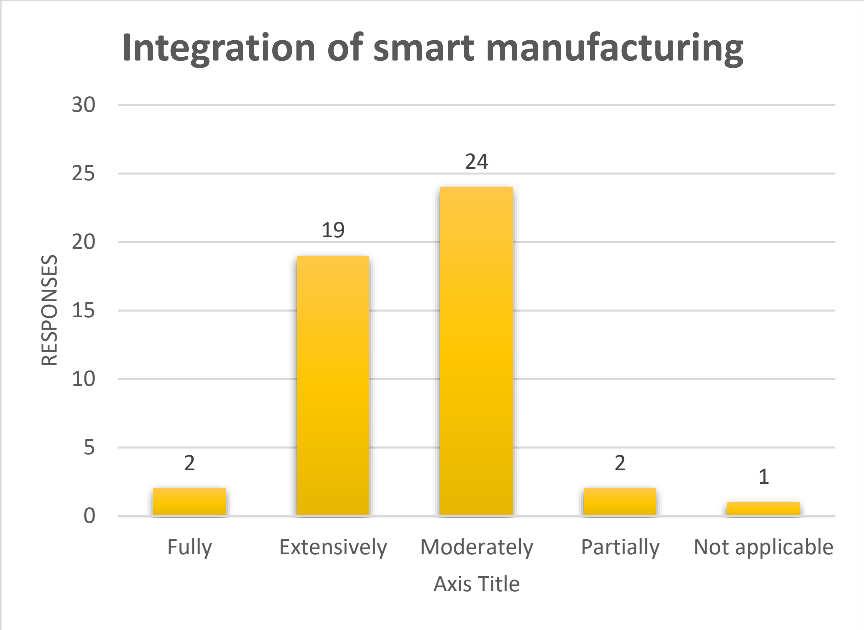

Figure 21: Integration of smart manufacturing into core business

This spread of responses illustrates that while there is a considerable move towards the adoption of smart manufacturing technologies within the medical device industry, full and extensive integration remains a work in progress for most.

4.4c Evaluating Employee Skills and Expertise

For question number 20, 35 participants consider their organization's digital skill level as moderate, indicating a strong foundation of digital capabilities but there is still room for further development and enhancement. However, a smaller group of 8 participants believe their organization holds a high level of digital expertise, suggesting that their employees are well-equipped with advanced digital skills which likely facilitate them in using smart manufacturing technologies more effectively. On the contrary, only 5 participants believe that the digital skill level within their organization is low, highlighting a need for improvement in training and skills development. Data from the survey highlights a general trend towards moderate digital proficiency in the sector, with ongoing opportunities for growth in digital expertise to fully leverage the benefits of digital transformation in medical device manufacturing. Column graph in figure 22 shows current level of digital skill and expertise in MedDev industry based on response to the survey.

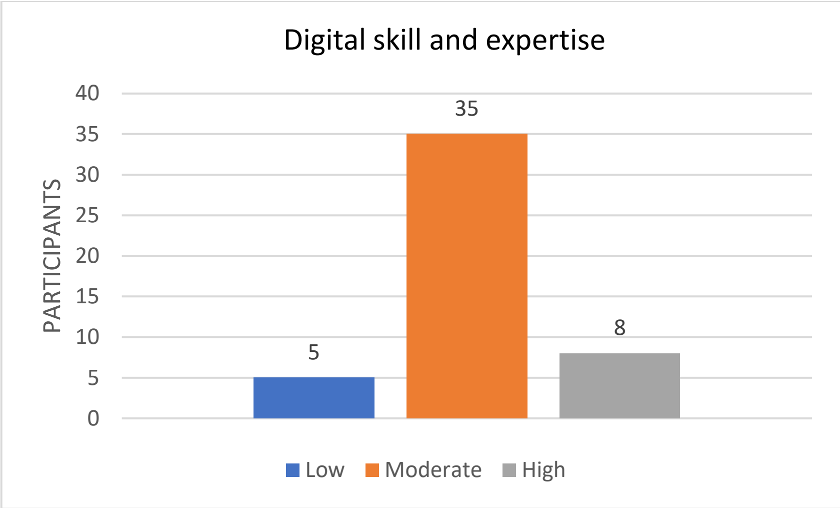

Figure 22: Current level of digital skill and expertise in MedDev industry

4.4d Determining the Frequency of Digital Skills Training

In response to question 21, on the extent of digital skill training in organizations within the MedDev sector reveals a strong emphasis on regular training, with 69% of respondents are in favour of frequent sessions. This high percentage of response emphasizes that regular training is essential for keeping pace with rapidly evolving digital technologies and ensuring that employees remain proficient and competitive in their roles. On the other hand, 31% of respondents feel that digital skill training should be conducted occasionally, suggesting a more situational approach depending on specific needs and technological updates. The absence of responses indicating 'never' emphasizes the necessity for digital training in today's tech-driven environment. Figure 23 below highlights the responses to the frequency of digital skills training.

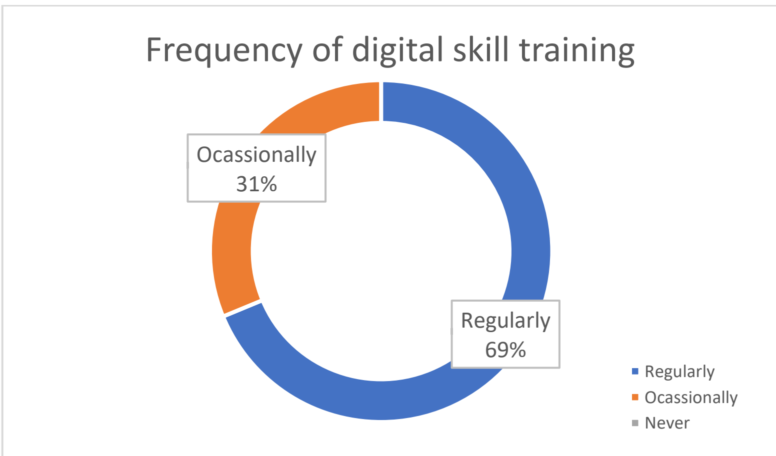

Figure 23: Response to the frequency of digital skills training

4.4e Analyzing Digital Transformation in the MedDev Industry

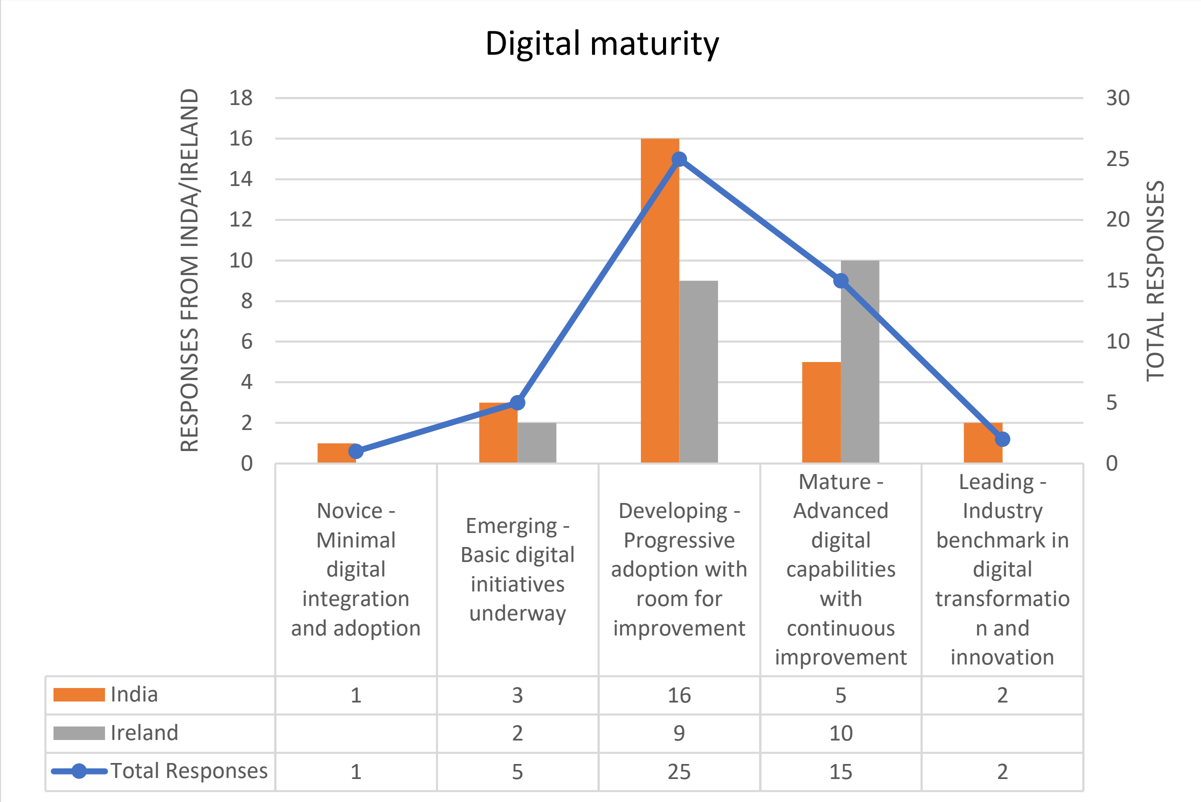

Figure 24: Analysis of digital maturity in MedDev industry

For question 22, survey data shown in figure 24 above depicts the digital maturity levels of medical device companies in both countries, reflects a range of development stages. For category Novice, minimal digital integration and adoption has the lowest number of respondents, only 1 response from India indicating that only a small fraction of companies are at the very beginning of their digital journey. For category Emerging- basic digital initiatives underway, overall, 5 participants (3 and 2 from India and Ireland respectively). These figures indicate that a few companies are taking initial steps towards digitalization but are still in the early stages of implementing digital initiatives. Maximum respondents i.e., 25 in total chose Developing- progressive adoption with room for improvement, especially in India with 16 responses indicating that many companies are actively implementing digital technologies but are not yet fully mature. Overall, 15 participants a significant number, particularly in Ireland (10 responses), highlights that these companies have not only integrated smart manufacturing technologies but are refining and expanding their digital capabilities. Very few responses (2) indicate there are some companies in MedDev Sector have achieved a leading status, establishing benchmarks in digital transformation and innovation.

In general, findings to the survey data suggests that the medical device industry in both India and Ireland has a wide spectrum of digital maturity, with a significant concentration in the developing stage. Particularly in India, it indicates that there is active adoption of digital technologies, highlighting that full potential integration and optimization are works in progress for future. Ireland seems to appear slightly more advanced in terms of companies reaching maturity in digital practices, possibly due to different market dynamics, regulatory environments, or investment levels in technology.

However, the analysis is limited by sample sizes that is not fully representative of the entire industry and the subjective nature of participants assessments, which could vary based on individual experience and understanding of digital maturity. This analysis highlights that there is still a lot of potential for MedDev industry, especially in achieving and expanding advanced digital capabilities, placing it midway between developing and mature.

4.4f Future Evolution of Digital Maturity in MedDev Industry

The thematic analysis of participants' responses regarding the future evolution of digital maturity in medical device manufacturing facilities reveals several key themes focused on improving industry standards and operations which is shown in figure 25.

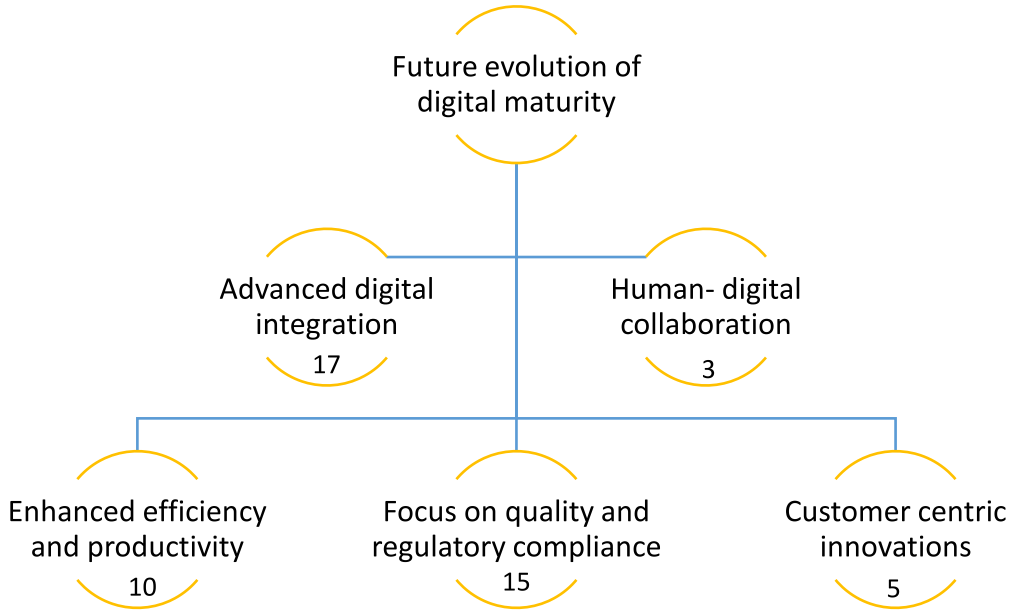

Figure 25: Future evolution of digital maturity in MedDev industry

*Number represents responses from the participants

Majority of participants indicates that in future there will be more integration of various digital technologies and real-time data analytics throughout the manufacturing process. This could allow for tasks like predictive maintenance, quality control, and process optimization which in turn help in making more informed decision-making and potentially lead to faster innovation cycles. Several responses emphasize the importance of bridging the gap between human capabilities and digital technologies through continuous investment in workforce training to thrive in a digitally mature environment. Maximum response anticipate that digital maturity will streamline production processes, reduce manual labour, and enhance overall productivity, leading to increased efficiency and cost savings, as seen in responses that highlight the use of real-time data analytics for predictive maintenance and quality control, which reduce downtime and improve outcomes, also moving towards more use digital documentation to reduce paper work and increase efficiency. According to the responses, it is seen that digital maturity is seen as a critical factor in improving product quality and ensuring regulatory compliance. Participants also believe that more customer-oriented product development will be made possible by digital maturity in near future. For example, few participants mentioned use of additive manufacturing for customized treatments.

4.5 Summarization of data analysis and findings from primary research

Analysis of the survey data reveals a strong trend in the medical device industry of integrating advanced technologies like AI, IoT, ML, Digital Twin, Cloud Computing, BDA, robotics, and software such as MES. While data analytics tools are not yet fully utilized, they are already improving manufacturing processes and leading to better decision-making. These technologies are transforming the industry by enhancing operational efficiency, product quality, adaptability in production, and regulatory compliance. This digital transformation paves the way for medical device companies to become more mature and successful.

The transition to a digitally mature organization requires strong leadership with a clear vision, as they must invest in smart technologies and guide their effective implementation. Regular training and upskilling of the workforce are emphasized to ensure proficiency in advanced digital tools. Regulatory compliance remains a top priority, and digital solutions can streamline meeting these stringent requirements. Ensuring data security and privacy, integrating outdated systems, and creating a culture of digital adoption are key hurdles on the path to digital maturity. However, the potential benefits outweigh these challenges for advancing digital maturity.

The MedDev industry is on a promising path towards digital maturity. Companies are actively adopting advanced technologies and continuously improving their capabilities. This ongoing digital transformation positions the industry for significant advancements in the future.

CHAPTER 5 CONCLUSIONS AND RECOMMENDATIONS

5.1 Key findings to the research question

This section addresses the three research questions that were intended to study the impact of smart manufacturing on the digital maturity in the MedDev industry.

Question 1- What are the key factors that contribute to the digital maturity of medical device industry in the terms of smart manufacturing?

From primary and secondary research, it can be concluded that there are several key factors that are contributing to the digital maturity of the medical device industry in terms of smart manufacturing. To remain competitive in the evolving landscape of medical device industry operational efficiency, quality improvement, product customization and regulatory compliance are the primary objectives driving the adoption of digital technologies. Additionally, the review highlights the importance of a robust data strategy and infrastructure, seamless digital integration across the value chain, and the adoption of smart manufacturing practices. The significance of a supportive organizational culture, leadership commitment, and continuous employee training are other factors for driving digital maturity. The study underlines the positive impact of digital maturity on operational efficiency and product quality, affirming the potential benefits of further digital transformation in the medical device industry from review and survey data.

Question 2- What are the potential benefits, and challenges likely to emerge from increasing digital maturity in the medical device industry, including improvements in quality, efficiency, and innovation?

The research identifies significant potential benefits and challenges associated with increasing digital maturity in the medical device industry. Both existing research and primary data highlight several advantages, which includes enhanced product quality, operational efficiency, and accelerated innovation through the integration of advanced technologies such as AI, IoT, and big data analytics. These technologies facilitate the development of more accurate and precise medical devices, promotes innovation, streamline production processes, and foster a culture of continuous improvement and enable better regulatory compliance. However, there are challenges such as data security, system interoperability, regulatory compliance, and cultural shift like resistance to change pose as substantial barriers. Review points that overcoming challenges necessitate strategic planning and robust management practices to ensure successful digital transformation and to fully leverage the benefits of digital maturity. According to data analysis, the majority of participants believe that the benefits of digital maturity outweigh the potential challenges, with many emphasizing the positive impact on innovation and market competitiveness.

Question 3- What steps can be taken to enhance the digital maturity of medical device companies in terms of their adoption of smart manufacturing technologies?

Achieving a digitally mature and sustainable manufacturing environment in the medical device industry requires a strategic and progressive approach. Review gives insights on how to proceed on the company's road to full maturity. For example, determining the company's critical gaps, barriers and setting specific goals to achieve digital formation after evaluating the current maturity level of the organization. Further, identify smart manufacturing technologies and method that align with the organization's goals and objectives. From both primary and secondary research, it highlights that organisation could focus on integrating advanced technologies such as AI, IoT, Digital twin, additive manufacturing, MES, PLM, etc, which facilitate real-time monitoring and predictive maintenance, thereby improving operational efficiency and product quality. Survey findings indicates that most of the organisations are between progressive adoption with potential for improvement and advanced digital capabilities with continuous improvement. Finally, if organisations adopt digital strategic framework, medical device manufacturers can attain full digital maturity but also cultivate a sustainable and adaptable foundation for future advancements.

5.2 Primary and Secondary Research: Discussion and Recommendations

Primary and secondary sources play a crucial role in shaping research on the impact of smart manufacturing on the digital maturity of the medical device industry. secondary data offer details into the theoretical frameworks, key concepts, and trends that define smart manufacturing and digital maturity and primary data provide information that validate and enrich the theoretical insights gained from secondary sources. The table 7 below highlights the findings from the study.

Table 7- Summary of the primary and secondary research

	Literature Review	**Primary Findings**
Scope and depth	Provides a comprehensive and theoretical overview of smart manufacturing and digital maturity, pointing out the strategic importance of these concepts and their potential benefits and challenges.	Provides practical insights based on survey data, highlighting the current state of digital maturity and the specific experiences of industry professionals.
Focus on smart manufacturing technologies	Discusses the broad potential of various digital technologies (AI, IoT, cloud computing, big data) to transform the manufacturing process.	Examines the actual use and familiarity with these technologies among professionals, noting significant but uneven adoption levels.
Benefits and challenges	Theoretically outlines potential benefits and challenges.	Confirms the benefits and challenges outlined in literature review through empirical data, indicating that industry professionals largely agree that benefits outweigh challenges but still face practical implementation issues.
Strategic Perspectives	Highlights the importance of digital maturity models and strategic planning for successful digital transformation	Reflects on the practical strategic goals of companies, with a strong focus on continuous training, leadership, and incremental integration of digital technologies.

Fulfilling research gaps: The discussion on smart manufacturing and digital maturity in the medical device industry presents a comprehensive overview, yet there are certain research gaps and opportunities for exploration. This study tries to delves into the strategic decision-making processes involved in selecting, implementing, and scaling smart manufacturing technologies as it is crucial for developing an understanding of digital maturity in this sector. Further, it tries to bridge the knowledge gap by examining whether the identified benefits outweigh the potential challenges, offering general recommendations for a more resilient, efficient, and sustainable future for the medical device manufacturing industry. By addressing these gaps, the research contributes to a more thorough understanding and practical guidance for enhancing digital maturity in the medical device sector.

Recommendations to a successful, digitally mature organization: First, build a strong digital foundation. Invest in modernizing infrastructure to integrate digital technologies seamlessly. Second, leverage the power of data by implementing robust analytics to extract valuable insights from manufacturing data to identify areas for improvement, streamline operations, and optimize production processes. Third, develop a comprehensive digital strategy aligned with your business objectives and industry needs by adopting a maturity model specific to medical devices to assess your current digitalization level and guide improvement efforts Prioritize robust cybersecurity measures to protect sensitive patient data and ensure product integrity. Finally, invest in your workforce by upskilling employees with the necessary skills to navigate the digital manufacturing environment. By implementing these recommendations, medical device companies can gain a competitive edge to thrive in the healthcare industry.

5.3 Limitations of the study

There are several constraints to the research study. Firstly, primary research included only the employees of the medical device industry in India and Ireland, which may not fully capture the diversity of perspectives and practices in other countries. Secondly, the sample size is relatively small compared to the total number of people employed in the medical device industry in both countries. Thirdly, a comparative analysis of data between the two countries was not possible due to time and resource constraints. This can be considered a limiting factor of the results.

5.4 Future scope of the study

Further research could be extended to develop and validate a specific digital maturity model specifically designed to this sector, considering unique regulatory, technological, and operational challenges. This model could help standardize the assessment of digital maturity and provide a benchmark for companies aiming to enhance their digital capabilities. Additionally, there is a potential to explore the long-term impacts of increased digital maturity on various aspects of the medical device industry, such as innovation cycles, regulatory compliance, and patient outcomes in future. Furthermore, comparative research across different regions or countries may provide insight into the ways local regulatory framework, market conditions, and cultural factors influence the adoption and success of smart manufacturing technologies. This could help in identifying best practices and adaptable strategies for different various circumstances while, contributing to a more global understanding of digital maturity in the medical device industry. By addressing these future research opportunities, the foundations laid by this study could drive further innovation and improvement in the medical device sector.

5.5 Final conclusion

In conclusion, research comprehensively examines the impact of smart manufacturing on the digital maturity of the medical device industry. This study established that integration of digital technologies has a potential to increase operational efficiency, product quality, and regulatory compliance, despite some of the challenges. Overall, cultivating a digital mindset, bridging the knowledge gap, and understanding the strategic integration of smart manufacturing technologies were established as novel initiatives for achieving a resilient and efficient future in the medical device manufacturing industry.

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APPENDIX

The impact of Smart Manufacturing on the Digital Maturity of Medical Device Industry

Dear Participants,

I am Ankita Dattaram Solkar, studying MSc. in Digital Transformation (Life Science) at Griffith College Dublin, Ireland. I am doing a research study for my dissertation on ‘The impact of smart manufacturing on the Digital Maturity of Medical Device Industry’.

Digital maturity refers to an organization's capacity to utilize digital technologies effectively. With the integration of digitization and Industry 4.0 technologies, including AI, IoT, and cloud computing into the manufacturing processes. As a result of this transformation, the medical device industry has been significantly impacted. Therefore, this research aims to offer valuable insights into the digital maturity of the medical device industry, assessing its preparedness for adopting Industry 4.0 technologies like smart manufacturing. Additionally, it seeks to identify opportunities, challenges, and future prospects linked with digital technology adoption, providing recommendations to enhance digital maturity for medical device companies.

Participant privacy is ensured, and all data will be handled in compliance with GDPR regulations. I am happy to invite you to take part in this research study and grateful if you complete this questionnaire survey. This survey will take approximately 10-15 minutes to complete. I sincerely appreciate your participation. Thank you so much.

ankita.solkar23@gmail.com Switch accounts Not shared

* Indicates required question

Before proceeding to the questions, please confirm your voluntary participation in * this survey, understanding that your responses will be used solely for research purposes and individual responses will be kept confidential. Do you consent to participate in this study, for obtaining necessary information related to research?

- Yes
- No

Next

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- ◯ Yes
- ◯ No

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Professional Background and Experience

How many years of experience do you have in medical device industry? *

- Less than 1 year
- 1-2 years
- 2-5 years
- 5-10 years
- More than 10 years

In which country you are currently based? *

Your answer

Are you familiar with smart manufacturing technologies being implemented in medical device industry? *

- ◯ Very
- ◯ Somewhat
- ◯ A little
- ◯ Not at all

Which smart manufacturing technologies have you had experience with in your professional career? (Select all that apply) *

- ☐ Internet of Things (IoT)
- ☐ Artificial Intelligence (AI) and Machine Learning (ML)
- ☐ Additive Manufacturing
- ☐ Robotics
- ☐ Augmented Reality (AR) and Virtual Reality (VR)
- ☐ Blockchain
- ☐ Cloud Computing Big
- ☐ Data Analytics Digital
- ☐ Twin Cybersecurity
- ☐ Other:
- ☐

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Digital Maturity in Medical Device Industry

What are the primary objectives in implementing smart manufacturing in the medical device industry? (Select all that apply) *

- [ ] Cost reduction Quality
- [ ] improvement
- [ ] Operational efficiency enhancement
- [ ] Enhanced agility in production Better
- [ ] regulatory compliance
- [ ] Other:

How high of a priority does your company place on increasing digitalization and advancing the use of technology in manufacturing operations? *

- ○ Not a priority Low
- ○ priority
- ○ One of many priorities
- ○ High priority
- ○ Highest Priority

Select the answer that best describes the current state of manufacturing at your company? *

- ○ We use manual processes and paper-based documentation
- ○ We use point solutions (eg. Word or excel) or scan our paper batch records to create digital documents.
- ○ We've invested in manufacturing software to digitalize core processes and have implemented it on some lines.
- ○ We've implemented manufacturing software on all lines, across all sites and use an API driven network to integrate with enterprise-level systems.

Select the answer that best describes the current state of the data connectivity of * manufacturing solutions at your company?

- Solutions are manual and disconnected, data aggregation is done by hand.
- There is mix of manual and digital solutions, some data is accessible, but most is still on paper.
- Widespread use of digital solutions, all data is available, however solutions remain disconnected/siloed.
- Digital solutions are integrated across manufacturing, the value chain, and the organization as a whole, manufacturing data is available and drives our decision making.
- Real-time operational intelligence feeds continuous process optimization, predictive production quality, and autonomous production, making human ancillary to the manufacturing process.

According to you has the medical device industry experienced increased operational efficiency since implementing smart manufacturing practices? *

- Yes
- No
- Don't know

According to you, how effectively does the medical device industry utilize data analytics to improve manufacturing processes and quality control? *

- Not at all
- Less effective, lack sufficient integration of data analytics tool Moderately
- effective, utilize data analytics tool to some extent
- Highly effective, with advanced analytics tools integrated comprehensively

On a scale of 1 to 5, how would you rate the importance of regulatory compliance *
in driving digital maturity in the medical device manufacturing for smart manufacturing?

	1	2	3	4	5	
Not important at all	○	○	○	○	○	Extremely important

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Opportunities and Challenges of Digital Maturity

From your experience, do you think the benefits of deepening digital maturity in the medical device sector outweigh the potential risks?

- Yes
- No
- Don't know

According to your preference please rank the following potential results of deepening digital maturity in the medical device sector from most to least important? *

	1	2	3	4	5	6	7	8
IImprroved Efficiiency								
Enhanced Prroductt IInnovattiion								
Betttterr Custtomerr Experriience								
Regullattorry Complliiance								
Marrkett Expansiion								
Long--tterrm Susttaiinabiilliitty								
Riisk Managementt								
Costt rreducttiion								

Which areas do you think digital maturity will most significantly impact in terms of improving quality and efficiency in the medical device sector? (Select all that apply) *

- [ ] Product design and development Supply
- [ ] chain management Regulatory
- [ ] compliance
- [ ] Clinical trials and research
- [ ] Post-market surveillance and monitoring

According to your preference please rank the following potential challenges of deepening digital maturity in the medical device sector from most to least challenging? *

	1	2	3	4	5	6	7	8
Datta securiitty and prriivacy								
IInteroperabiilliitty iissues								
Legacy systtem iinttegrrattiion								
Regullattorry complliiance								
Cullturall shiiftt								
Scallabiilliitty and flexiibiilliitty								
Resourrce consttraiintts								
Datta goverrnance								

Which of the following do you consider to be the most critical aspect of ensuring the success of digital maturity initiatives in the medical device sector? (Select all that apply)

- [ ] Strong leadership and strategic vision Robust
- [ ] cybersecurity measures
- [ ] Continuous training and upskilling of workforce
- [ ] Collaboration among stakeholders
- [ ] Flexibility in adapting to changing regulatory landscape

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* Indicates required question

Digital Maturity Readiness

In terms of smart manufacturing, what would you consider the main drivers for digital maturity in the medical device industry?

Your answer

How would you rate the level of integration between smart manufacturing technology and your core business processes? *

- Partially
- Moderately
- Extensively
- Fully
- Not applicable

How would you rate the current level of digital skills and expertise among employees in your organization? *

- Low
- Moderate
- High

According to you, how often an organization should conduct digital skills training for employees? *

- Regularly
- Occasionally
- Never

How would you rate the overall digital maturity level of medical device companies in your country? *

- Novice - Minimal digital integration and adoption Emerging -
- Basic digital initiatives underway
- Developing - Progressive adoption with room for improvement Mature -
- Advanced digital capabilities with continuous improvement
- Leading - Industry benchmark in digital transformation and innovation

In what ways do you see the digital maturity of your manufacturing facility evolving in the future, and how will it affect the medical device industry in your country?

Your answer

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