

Article

Readiness for Industry 4.0 in a Medical Device Manufacturer as an Enabler for Sustainability, a Case Study

Olivia McDermott ^{1,*} , Dudley Luke Stam ¹, Susana Duarte ² and Michael Sony ³ ¹ College of Science & Engineering, University of Galway, H91 TK33 Galway, Ireland² Unidade de Investigação e Desenvolvimento em Engenharia Mecânica e Industrial Department of Mechanical and Industrial Engineering, NOVA School of Science and Technology, Universidade NOVA de Lisboa, 2829-516 Caparica, Portugal; scd@fct.unl.pt³ Oxford Brookes Business School, Oxford Brookes University, Oxford OX3 0BP, UK; emailofsony@gmail.com

* Correspondence: olivia.mcdermott@universityofgalway.ie

Abstract: This research aims to determine the state of Industry 4.0 readiness and to identify the best practices, challenges, and barriers to implementing Industry 4.0 technology in a medical device manufacturer, thus aiding in improving sustainability. Semi-structured interviews were completed with 12 senior executives representing a wide array of functions in a single large medical device manufacturer. Convenience sampling was used to analyse the interview transcripts to draw out themes that were then discussed and analysed with findings from the literature review. This research determined the state of Industry 4.0 readiness in the case study of medical device manufacturers. This research identified several best practices, challenges, and barriers to implementing Industry 4.0 technology. Currently, there are few case studies in the literature that have a medical device manufacturer as the case study for Industry 4.0 readiness. There are even fewer articles that tackle Industry 4.0 implementation across the entire medical device industry. There is currently no published literature that analyses the best practices for implementing Industry 4.0 in a medical device manufacturer. The best practices for Industry 4.0 implementation identified in this study can be beneficial to stakeholders in the medical device industry and within the healthcare sector, help them plan current and future Industry 4.0 programmes, improve sustainability in their companies, as well as optimise patient treatment and approaches.



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1. Introduction

The medical device industry is one of the fastest-growing industries in the world. In 2019, the global medical device market was valued at around USD 530 billion [1]. An ageing population and technological developments drive this growth to meet clinical needs [2]. Fourteen of the top 15 MedTech companies have manufacturing facilities based in Ireland. In 2022, it was estimated that there were around 450 medical device companies in the country, exporting about EUR 12.6 billion in medical device products [1]. The medical device industry is highly regulated [3]. This is due to the intended use of the product and to ensure the safety of the patient. Industry 4.0 technologies can free up resources in Medtech manufacturing to focus on innovation and boost competitiveness via greater production flexibility and productivity to meet the global market demands for devices.

The high regulation of the medical device industry results in the implementation of new and innovative technology to improve the speed and efficiency of processes, which is challenging [4]. Regulatory compliance is seen as a barrier to innovation and continuous

improvement within the industry [5]. Regulatory compliance, by its very nature, is associated with “paperwork”, which has an environmental effect due to the enormous amounts of records and documents generated as well as offsite storage, transport, and retrieval of these for audits [6,7]. The automotive industry is also highly regulated but can still be innovative and utilise Industry 4.0 technology [8]. The same benefits that the automotive industry has received from Industry 4.0 technology can be adopted in the medical device industry as well [9].

Quality 4.0, Regulatory 4.0, and Lean 4.0 are three concepts that are related to Industry 4.0 and have been adopted by the medical device industry [10]. Digitalisation can aid regulatory affairs functions within a medical device manufacturer to speed up regulatory assessments, have quicker regulatory submission times, and improve the time to market [6].

The medical device industry is a huge sector in the world economy and will continue to grow as the population ages [1]. New medical technology enabled via Industry 4.0 has advanced significantly, ranging from mobile computing to cloud computing, over the previous decade. Industry 4.0 technology in Medtech can now be employed as commercially accessible, networked systems [11]. This digital transformation enables patient data to be electronically collected from devices and utilised by technology to better understand and diagnose them and implement new treatments and techniques with a new digitally enabled patient-centric paradigm [11,12]. For example, additive manufacturing can be used to “print” or provide a customised orthopaedic implant for a patient in a “point of use” clinic or hospital environment [12]. Within the literature, there are sparse published case studies on medical device companies and Industry 4.0 implementation [6,7,13,14]. Regulated industries, such as the Medtech industry, tend to be more conservative, relying on established technology to meet their business goals [8]. Given the limited availability of published case studies, the investigation into a prominent medical device company and its practices in implementing Industry 4.0 projects becomes pivotal. Such an examination is essential for gaining insights into the challenges and barriers faced by medical device companies in effectively integrating Industry 4.0 technologies. The FDA has recognised that there is an overfocus on “compliance” within this industry and not enough focus on “digitalisation and innovation” and has introduced a “Case for Quality” framework to address as well as public–private partnerships to carry out more research in the area of digitalisation [15–17]. Thus, there is recognition of the restricted use of Industry 4.0 technologies by medical device manufacturers despite their prospective advantages for the industry. According to the American FDA, innovative technologies can aid advanced manufacturing, improve device product quality, improve manufacturing efficiencies, aid in avoiding product shortages, and increase the time-to-market. They may also enable entirely new approaches to creating devices and, as such, unlock the possibilities to improve the protection and promotion of public health [17].

Thus, this study of a large medical device company and its practices in implementing Industry 4.0 projects can aid in understanding the challenges and barriers to assist other medical device companies in implementing Industry 4.0 technologies more effectively. This study aims to assess the current state of implementation and readiness for Industry 4.0 in an Irish medical device manufacturer and establish if there are specific industry sector challenges.

This study’s research questions are the following:

RQ1: What is the state of Industry 4.0 readiness in the case study organisation in a medical device manufacturer?

RQ2: What is considered the best practice for implementing and adopting Industry 4.0 technology in a medical device manufacturer?

RQ3: What challenges and barriers does a medical device manufacturer have to overcome to implement Industry 4.0 technology?

Section 2 outlines the literature review; Section 3 outlines the methodology, and Sections 4–6 present the Results, Discussion, and Conclusions, respectively.

2. A Literature Review

This section aims to discuss, firstly, the Irish Medtech industry and then the current applications of Industry 4.0 within the Medtech industry. The readiness, benefits, challenges, barriers, and critical success factors of Industry 4.0 within the Medtech industry will then be analysed and discussed in more detail.

2.1. Readiness for Industry 4.0 in a Medtech Manufacturer

Buy-in from senior leadership for investment, providing deployment resources, driving digitalisation changes within the organisation, as well as providing effective communication and training for the digitalisation strategy, are very important in deployment [6]. Tortorella and Fetterman [18] also echoed Foley et al.'s [6] study findings as they discussed the importance of making employees aware of the technological changes, having the appropriate financial support to complete the Industry 4.0 roadmap and appropriate skillsets and technology resources to ensure a successful deployment. Wei and Alius [8] purported that the strict regulation of the medical device industry was not the fundamental factor in obstructing the implementation of Industry 4.0 technologies since implementation was possible and even very successful in other regulated industries, such as the automotive industry. The financial costs can be overcome, and recruitment of the right talent can address the skill set shortage within the industry [9].

The theme of change management as a fundamental critical success factor or CSF for Industry 4.0 in all sectors, not only the Medtech sector, has been put forward as a key ingredient for Industry 4.0 by many authors [19]. The common mindset within the medical device industry is to be satisfied with the current way of manufacturing and be regulatory compliant, so the status quo needs to shift to embrace Industry 4.0 [20]. A method of ensuring this shift is for a transfer of knowledge and tested Industry 4.0 processes used in other industries, e.g., the automotive industry to the Medtech industry, to enable this. Antony et al. [21], in their study on early versus late adopters of Industry 4.0, found that the advantage of being a late adopter is that the technology is tried and tested by early adopters before you deploy it. Based on the studies above, the Medtech industry would be considered a late adopter. In a case study on Industry 4.0 deployment in an Irish-based multinational Medtech manufacturer, the manufacturer identified the implementation of a global change management process that will be a foundation of other Industry 4.0 technologies in the organisation as the key to success [7]. These technologies require significant capital investment by companies. A total of 50% of respondents to a recent survey of the Medtech sector suggested that data-intensive AI projects failed due to the high cost involved in having the right infrastructure in place [13].

2.2. The Medtech Sector in Context

The Medtech industry is one of the most regulated industries in the world. Medical devices range from bandages and band-aids to contact lenses and complex radiological equipment or invasive cardiovascular devices [2]. The Medtech sector is highly regulated to ensure patient and customer safety. Ireland has a thriving Medtech industry and cluster with over 45,000 people employed within this sector [1,2]. Varied regulatory frameworks governing different countries and economic areas around the world that are enforced by different global jurisdictions can complicate the Medtech industry. Industry 4.0-type

applications, including smart technology, digitalisation, and artificial intelligence, are increasingly being integrated into both the medical device design where applicable and manufacturing processes. The US FDA has approved many devices with artificial intelligence that can collect data for remote monitoring of patients in recent years [22]. They have also encouraged Medtech manufacturers through their Case for Quality programme to increase digitisation and innovation in their manufacturing processes [16].

2.3. Benefits of Industry 4.0 to Medtech Industries

The digitalisation of regulatory data such as regulatory impact assessments, change notifications, licences and submissions into a digitalised Regulatory Information Management, an e-QMS or PLM system can make the organisation leaner, according to Foley et al. [6]. Foley et al. [6] highlighted that the digitisation of their IT systems, removing manual tasks, significantly increased the available time for value-added work and improved their compliance rates. The rationale for pursuing increased digitalisation by the Medtech organisation in the Foley et al. [6] study was improved product quality and compliance, recall reduction, revenue growth, improved time to market, operational efficiency, re-registration cost savings, reduced effort during quality and regulatory audits, cycle time reduction for product management, and cost of goods sold reduction, including scrap reduction and acceleration of cost improvement projects. Benefits were also identified for Medtech device patients as Industry 4.0 technology will speed up the time a device will reach the market and help identify quality issues more quickly [7]. Patients will, thus, receive safe and effective devices that are innovative in a timely manner.

The literature has discussed the sustainability benefits of Industry 4.0 technologies. During the manufacture of a medical device, many paper records are generated, and regulatory authorities mandate that these be kept for audit, traceability, and compliance purposes [6].

The benefits of Industry 4.0 to medical device industries can also include fault detection, predictive maintenance, communication, virtualisation, human–machine interference, data governance, predictive analytics, and quality, amongst others [4]. In their study on Industry 4.0, Wei and Alius [8] highlighted that the medical device industry participants saw vast potential to utilise Industry 4.0 technologies across the entire product life cycle. This potential included benefits to sales and marketing by having customised medical devices for individual patients offered through the use of online design and ordering tools. Also, using predictive analytics, medical device supply chains could improve supply planning. The introduction of further intelligent identification, automatic control, data-based optimisation, and more human–machine interaction would greatly improve production efficiency in the medical device industry [8].

For example, tools such as Microsoft Power BI, which is “a collection of software services, apps, and connectors that work together to turn your unrelated sources of data into coherent, visually immersive, and interactive insights”, can be utilised for improving data analytics via increased data availability, managing performance metrics, and improving in aiding and assisting in root cause and corrective action programmes [23]. Data can be stored on Excel spreadsheets or a collection of cloud-based and on-premises hybrid data warehouses. Another very popular enterprise resource planning or ERP system is the Manufacturing Execution System (MES), which is a “specialist class of production-oriented software” [24]. MES aids businesses in monitoring and synchronising the execution of the real-time physical processes used in turning raw materials into intermediate or finished goods [25]. MES allows for the material and products to be tracked electronically and enables a “paperless” manufacturing and administrative environment through electronic

documents, parts, and component tracking via electronic signatures. It also enhances data integrity, which is very important for regulatory compliance.

2.4. Challenges and Barriers to Industry 4.0 Implementation in Medtech

Lepasepp and Hurst [4] highlighted several obstacles to the implementation of specific Industry 4.0 technologies in the medical device industry in their systematic literature review study of Medtech adoption of Industry 4.0. These included the cost of implementation for the Internet of Things, data ownership, governance, and security in smart manufacturing, centralisation, and data traceability for digital twin applications. They further highlighted barriers from a technical perspective rather than organisational-related or human-specific factors. Other published literature focused on the organisational and human factor challenges and barriers [13]. Educating employees and making them aware of the strategy for digitalisation and the benefits that it would bring is important for fostering employee collaboration. Inadequate skill sets and the need for more awareness of individuals to manage Industry 4.0 technologies are also highlighted in the literature as barriers to Industry 4.0 implementation [26]. High investment requirements coupled with unclear economic payback and the time it takes to implement such technologies before the benefits are seen is an obstacle. Medical Device companies will only green-light Industry 4.0 projects if paybacks are defined and time-bound [27]. A total of 50% of respondents to a survey in the Medtech sector by Sweeney et al. [13] stated that data-intensive AI projects failed due to the high cost involved in having the right infrastructure in place.

Sweeney et al. [13] also found other barriers to scaling new Industry 4.0 technology in Medtech related to the cybersecurity and data protection issues as well as not having strategic change management processes and skills for updating the workforce and inclusion of changes required from a regulatory compliance perspective, such as the requirement of re-certification, validation, and changes in quality documentation and operational procedures which influence such projects. Cybersecurity as a barrier was also reiterated by Narula et al. [26]. The deployment of Industry 4.0 technologies, such as cyber-physical systems and cloud networks, allows for more far-reaching effects of hacking and cyberattacks on the organisation.

2.5. The Current State of Industry 4.0 Deployment in Medtech

Stark and Chin [28] conducted a quantitative research study using a 32-question survey answered by 54 employees from the same medical device manufacturer to determine the Industry 4.0 maturity of that manufacturer, which they found to be 2.66. Industry 4.0 maturity could be determined by measuring the responses to questions related to a six-value-based stage of maturity developed by the Acatech Industrie 4.0 maturity index model [27]. Similarly, Wei and Alius [8] found that in their study of Industry 4.0 deployment in medical device and automotive industries in Germany, maturity or adoption levels in Industry 4.0 were higher in automotive than in medical devices with Medtech organisations at a maturity or competency level of only 2.5. Achieving the connectivity level of 2 means a complete integration between information technology and operative technology levels has yet to take place; however, interfaces to business IT are provided by parts of implemented OT [29,30].

2.6. Summative Analysis of the Literature

Based on the literature related to Industry 4.0 in the Medtech sector, there are few studies compared to other sectors. However, the Medtech sector is embracing digitalisation, albeit slowly, with lower adoption and maturity levels than other sectors. There are mixed views on the regulated nature of the industry as a barrier to Industry 4.0 deployment. However, the benefits, challenges, and critical success factors of Industry 4.0 to the Medtech

industry align with other sectors. A summary of some of the literature related specifically to Industry 4.0 deployment in the Medtech Sector is outlined in Table 1. There is a gap in the literature related to the Medtech sector and its application of Industry 4.0 technologies, as well as the fact that the industry is lagging in digitisation adoption compared to other sectors.

Table 1. The literature themes in relation to the deployment of Industry 4.0 in Medtech.

CITATION	Title of Articles	Themes
[4]	A Systematic Literature Review of Industry 4.0 Technologies within Medical Device Manufacturing	Benefits, challenges, and barriers to Industry 4.0 identified via a literature review.
[6]	Implementation of a Lean 4.0 Project to Reduce Non-Value Add Waste in a Medical Device Company	A case study of a medical device supplier showed that improved regulatory compliance was observed as a result of automating and digitising the Regulatory Product Lifecycle Management System.
[8]	Industry 4.0 Analysis of the implementation of Industry 4.0 in a medical technology enterprise with a comparison with automotive enterprises and options for improvement	A quantitative survey was utilised to establish that the Medtech industry had a lower maturity level than the automotive industry in adopting Industry 4.0.
[29]	Industry 4.0 Maturity Assessment in a Medical Devices Manufacturing Industry	It assessed the maturity of Medical Device Industry 4.0 deployment, which was found to be low.
[30]	Modelling and Analysis of challenges for industry 4.0 Implementation in the Medical Device industry to Post COVID-19 Scenario	Presented challenges and benefits to Industry 4.0 in the Medtech sector.
[13]	Scaling AI-Based Industry 4.0 Projects in the Medical Device Industry—An Exploratory Analysis	A quantitative survey of the Medtech sector identified challenges to Industry 4.0 deployment.
[7]	The Impact of Industry 4.0 on the Medical Device Regulatory Product Life Cycle Compliance	A case study using qualitative interviews identified barriers, challenges, as well as benefits to Industry 4.0 deployment.

3. Methodology

3.1. Case Study

This study used a single case study approach [31]. A single case study was used as it helps in holistic understanding, in-depth exploration, contextual insights, and longitudinal perspective of the phenomenon. The single case study allowed us to access an Irish Medtech company and assess its implementation and readiness for Industry 4.0. We specifically chose an organisation which is one of the top 15 largest medical device companies in the world and has multiple facilities within Ireland, a global medical device hub [1]. Thus, this organisation is very representative of the global Medtech multinational population and aids in the generalisability and applicability of the learnings of this study as a comparative study. We chose a case study with a qualitative research design to investigate and analyse the current state of Industry 4.0 readiness and what is considered the best practice to

implement and adopt Industry 4.0 in the organisation. A qualitative study allowed for access to leadership and other stakeholders at senior management and functional levels who are fully aware of the Industry 4.0 strategy and deployment. Thus, we had access to rich data and opinions [32]. In addition, secondary data from the organisation was also analysed. The data from qualitative studies are non-standardised and are usually categorised with coding techniques [33]. Individual interviews with cross-functional executive leaders in the Irish-based medical device manufacturer were planned and executed. The semi-structured approach was taken as this gave the researcher flexibility to ask follow-up questions and give prompts to gain more insight into interviewee responses [34].

3.2. Question Design

Table 2 lists the questions chosen for the interviews. These questions were framed and clarified based on the literature review. A list of the literature sources that informed the questions is also outlined in Table 2, and that could result in responses that would address the study's research questions.

Table 2. Interview Questions.

No	Question	A Literature Review Source
1	How do you explain the term 'Industry 4.0' in layman's terms?	[7,8,19]
2	What Industry 4.0 technologies has your organisation/department adopted?	[8,29]
3	Does your organisation/department currently have or plan to have any Industry 4.0-type projects?	[8,29]
4	What would be the motivating factors for the adoption of Industry 4.0 in your organisation/department?	[6–8,18,27]
5	What Organisational Readiness Factors need to be considered for you to embrace and adopt Industry 4.0 in your organisation/department?	[6–8,13,29]
6	What are the Critical Success Factors for the implementation of an Industry 4.0 project? (present or future)	[7,27,29]
7	What essential skills (hard skills and soft skills) does your organisation/department require to implement an Industry 4.0 project?	[6,8,27,29]
8	What are the benefits of implementing Industry 4.0 for your organisation/department?	[6–8]
9	What are the challenges or barriers to the adoption of Industry 4.0 in your organisation/department?	[6,15]
10	What specific Industry 4.0 technologies do you think might help your organisation/department?	[6,8]
11	Has the implementation of Industry 4.0 positively or negatively impacted regulatory compliance within the organisation?	[6,7]

3.3. Interviewee Selection Process

Purposive sampling was used because interviewees worked for the same company as the researcher and were easily accessible [35]. Their selection was non-random and was

based on their positions within specific functions in the company. In total, 12 executive leaders participated in this study. The researcher decided this sampling size to be adequate. After 10 interviews, no new themes were emerging, so the sample size of 12 was deemed enough [36]. As similar themes were repeated by interviewees, there was confidence that the research category was saturated. The sample was, thus, deemed saturated, and sufficient data were obtained from the transcripts [37]. Saturation means that no additional data are found, whereby the researcher can draw any new conclusions [36]. The researchers endeavoured to look for new themes of data diversity after the 10th interview to ensure that saturation was based on the widest possible range of data in the research category before they made their decision to stop interviewing after the 12th interview [37].

Table 3 summarises the details of the 12 interviewees who are to be interviewed.

Table 3. List of interviewees, their position, organisation, function, and experience within the medical device manufacturer.

NO.	Interviewee	Organisation	Function(s)
1	Director of Complaint Handling and Regulatory Reporting	Division	Complaints and post-market RA
2	Director of Quality Management Systems	Operations	Ireland QMS
3	Vice President of Regulatory Interactions	Division	Pre-market and post-market RA, field actions, division audits
4	Vice President of Clinical Affairs and Divisional Operations	Division	Clinical affairs, divisional operations
5	Director of Quality Operations	Operations	Ireland QA
6	Vice President of Manufacturing	Operations	Global manufacturing
7	Senior Director of Project Management Office (PMO)	Division	PMO
8	Senior Director of Supply Planning	Operations	Global supply chain
9	Director of Packaging Engineering	Division	Packaging design
10	Director of Product Support Engineering	Division	Product design
11	Senior Director of Marketing	Division	Marketing
12	Director of Regulatory Affairs	Division	Pre-market regulatory affairs

3.4. Data and Thematic Analysis

The data from this study were taken from the Microsoft Teams transcript generated from each interview. Each interview transcript was downloaded as a Microsoft Word file and then edited by the researcher to remove any terms that would identify the manufacturer [38]. The transcripts of respective interviews were shown to the participants again to confirm their viewpoints, improving the reliability of the data.

The transcripts were then uploaded to an online qualitative analysis software tool called ATLAS.ti 22 for data analysis. The grounded theory method was used in this process [39]. There are three coding stages in grounded theory that form a hierarchy. ATLAS.ti 22 tools were used to identify open and selective codes in the transcripts, which then allowed the researcher to identify themes and meta-themes. Coding improves transparency, validity, and credibility in qualitative research [40] and involves adopting rigorous method-

ologies and practices. We maintained a detailed audit trail documenting our research process, decisions, and changes made during this study. This includes recording methodological choices, data collection instruments, coding procedures, and analytic decisions.

To ensure that there was no research bias in thematic coding, 4 researchers were used to code the interview results under the thematic terms. Their coding and thematic classifications were then compared. Inter-rater reliability was tested using Cohen's Kappa and found to be 0.91. Cohen's Kappa Statistic is used to measure the level of agreement between two raters or judges who each classify items into mutually exclusive categories, and anything over 0.81 is deemed as a near-perfect agreement between raters [39,40].

Further, as the interviewees were all from the same company, there was an awareness of potential bias in their answers in terms of how "ready" or "not ready" the organisation was for Industry 4.0. This was overcome by firstly emphasising the anonymity of the case study organisation and by association interviewee confidentiality assurance in this research [38]. This allowed the interviewees to be franker and more honest in their viewpoints. The research, as a qualitative case study, aims to fully articulate the current status of Industry 4.0 within their system and to show that "bias" can be measured by the researchers via an evidence-based decision-making lens to improve output and understanding [41]. The aforementioned coding and thematic analysis processes aid this analysis.

4. Results

The results were analysed based on the interview questions, and the 11 interview questions were categorised and merged into six themes based on their commonality and similarity for the purposes of presenting the results.

Theme 1—Awareness and Understanding

Question 1 was "How do you explain the term 'Industry 4.0' in layman's terms?" and was chosen as the opening question to the interview in order to determine the level of knowledge interviewees had of the term. The researcher is an employee of the case study company and is aware that Industry 4.0 is not a term used internally in the company. The email requesting interviews provided some in-house examples of Industry 4.0 projects ongoing in the company to help with engagement with the interviewees and explain that this was not a term outside their knowledge, only that it was named differently within the company [6].

Some interviewees had very concise responses to this question and demonstrated prior knowledge of the concept, which was to be expected given that these interviewees were functional leaders in Manufacturing Operations. This finding was similar to other studies where manufacturing-based personnel were more familiar with Industry 4.0 than other functional staff [7,8]. Five interviewees admitted that they had not heard the term before, but these five were leaders of divisional functions. Eight out of the twelve interviewees responded that Industry 4.0 was about the utilisation of data. Four interviewees said that Industry 4.0 would lead to better data-driven decisions, while five other interviewees correctly mentioned the integration/connection of data systems. Examples of Industry 4.0 technology they were aware of were also given, including artificial intelligence, virtual reality, augmented reality, and additive manufacturing.

Theme 2—State of Implementation

Virtually all interviewees had the impression that the company was behind the curve with Industry 4.0 implementation. Three interviewees gave a nuanced assessment of the state of implementation. Examples were given of MES and Ignition systems implemented at certain sites that provide real-time data from equipment and improve the capability of processes. Data analytical systems such as Power BI were a common tool mentioned by

interviewees that was used across the organisation, and it behaved as a “bolt-on” to existing technology. Interviewees said that these were likely not Industry 4.0 technologies by themselves but mentioned existing technologies such as Windchill, Trackwise, and Oracle.

One true Industry 4.0 technology implemented in the division was given as an example. This was machine learning implemented in complaint handling, where some elements of the complaint report writing process were automated in the company.

However, interviewees shared that there were several Industry 4.0 technologies in the pipeline. The automated complaint handling system will be expanded, and regulatory reporting will be assessed if the same machine learning tools from the complaints system are deemed to benefit this function as well. The Quality Operations function is working on a project to automate all quality data inputs across all sites.

Many interviewees made the same point that to even begin considering Industry 4.0 technology on a large scale, the company must first standardise its databases and disparate ERP systems. There is a programme known as Project Accelerate that replaces all legacy ERPs used in the company into one SAP system. This has been rolled out at some manufacturing sites and divisions but only partially across the multinational organisation. Digitisation and standardisation are prerequisites for Industry 4.0 technology [27–29].

The general sense from interviewees is that implementation of Industry 4.0 across the organisation is patchwork, and there is a need for a common goal or vision in the company to transform it into an Industry 4.0 leader. When comparing interviewees’ responses to the literature, the organisation may not be as “behind the curve” with Industry 4.0 implementation as interviewees perceived. There are examples of other case studies of medical device companies where the same sentiment is felt by their employees [7,8]. There is one study in the Medtech industry where the level of Industry 4.0 implementation is quantitatively measured as receiving a low maturity index score [28].

Theme 3—Best Practice to Implement

All interviewees were enthusiastic about the potential benefits of Industry 4.0 technology to the company. During the interviews, many shared their thoughts on what the company needs to succeed in implementing Industry 4.0.

Many interviewees suggested that big change management skills from leadership were critical for Industry 4.0 projects. People generally do not like change [18]. Industry 4.0 technology is known to be disruptive and can radically change how people work [42–44]. Leadership needs to ensure that employees are comfortable with change and can adapt to it [45]. They need to be effective communicators to build trust in the organisation and be honest that the benefit of Industry 4.0 is cost reduction through improved productivity [18]. This could result in redundancies, but mainly, it will result in reduced growth in headcount to maintain the profit margin of the company as it grows. Change management aligns strongly with the literature review, where it has been raised as best practice for Industry 4.0 implementation in many articles [18].

Interviewees also highlighted leadership support from the highest level of the company as critical for the successful implementation of Industry 4.0. Interviewees of this study were leaders of divisional functions such as clinical research, regulatory affairs, and product development or operations leaders of multiple manufacturing sites across the USA and Ireland. They were referring to leadership support at the divisional president or CEO level of the company to drive and encourage Industry 4.0 programmes. This is absent in the company, and interviewees explain that there are other priorities for the company, such as supply chain issues and acquisitions. Leadership support is critical for Industry 4.0 technology implementation since the cost of investment is typically high for such projects [6,13,27].

Effective planning was also brought up as a best practice to implement Industry 4.0. Interviewees from the Operations organisation considered that all the benefits of the Industry 4.0 technology are identified up front and have a way to measure and track it. Interestingly, none of the selected articles in the literature specifically raised effective planning as useful for implementing Industry 4.0 technology [8,27,29].

Interviewees also discussed upskilling the workforce in the company by either retraining existing employees in programming languages such as Python or hiring new talent into the company with an already existing skill set in AI or machine learning. There was general agreement from interviewees that the company currently had a deficiency in these skill sets, and the business would need to hire AI/machine learning experts as consultants to work with existing employees who have the process knowledge. One interviewee highlighted that such experts were scarce and would be in demand from other medical device manufacturers. In the literature, there is wide agreement that skills and knowledge need to be improved for successful Industry 4.0 implementation in the medical device industry [2,6].

Many interviewees saw the standardisation of ERPs and digitalisation of all data as critical prerequisites before implementing Industry 4.0 technology. Digitisation and standardisation are prerequisites for Industry 4.0 technology [30]. Data fed into IT systems need to be digitised for any analytical tasks to be automated. Paper and scanned PDFs cannot be utilised effectively by Industry 4.0 technology. Transitioning to fully electronic DHRs and electronic Standard Technical Documents is required for ERP and change management systems to connect and work together automatically. One interviewee stated that the company “needed to be smart in choosing what process to enhance with Industry 4.0 technology”. In contrast, another stated, “that there is no point automating an incapable process, so the company must work to make the process as capable as possible first using more traditional methods of validation”. However, Industry 4.0 digitalisation can result in the automation of existing waste if processes are not capable or streamlined [18].

Theme 4—Motivating Factors and Benefits of Implementation

All interviewees said that increasing efficiency was a motivator for implementing Industry 4.0. Examples of how this would be achieved were varied. Interviewees brought up the elimination of repetitive tasks, reduced time and effort to manage systems, streamlined management review, and reduced manual data input to free up resources for innovation. Increased efficiency is often noted as a major benefit of Industry 4.0 [42,43].

Better decision-making was a benefit many interviewees also mentioned. Industry 4.0 would drive 100% accurate live data, which would aid the business in making better decisions in multiple functions [44,45], particularly supply planning. Better decision-making was not strongly highlighted in the literature related to Industry 4.0 in Medtech but has been a feature of Industry 4.0 and digitalisation in other sectors [46–49].

Reduced costs were brought up by most interviewees as being driven by a reduced headcount. Interviewees explained that an incremental increase in headcount as the business grows will reduce profit margin, so technologies that can increase productivity are desirable. Interviewees believed that Industry 4.0 technology that can automate repetitive tasks would help reduce costs.

Interestingly, job satisfaction was a benefit that some interviewees suggested. This has yet to be featured in research related to Industry 4.0. However, some authors have suggested that the automation of formally manual tasks has removed non-value-added work that employees carry out [6]. Several interviewees explained that if technology could reduce the mundane, repetitive tasks employees were currently doing, it could free up their time to focus on innovation. Interviewees said that if all data were digitalised, all systems were connected and could self-correct, it would give greater confidence to the user to make the right decisions for the company with the information. Interviewees

also remarked that, at times, it was difficult to locate important information or data. One interviewee suggested that if systems were standardised, AI could assist users in finding the information they want.

Theme 5—Challenges and Barriers to Implementation

The question “What are the challenges or barriers to the adoption of Industry 4.0 in your organisation/department?” was chosen to directly ask the interviewees what they saw as the obstacle to the successful implementation of Industry 4.0 technology in the company. These challenges or barriers include the following:

- Lack of leadership support;
- Low priority for business;
- Outdated software systems;
- Cost to implement;
- Fear of redundancy/resistance to change;
- Skills gaps;
- Siloing in departments and functions;
- Lack of resources.

Lack of leadership support and a low priority for digitalisation as a strategy are closely related. Interviewees agreed that leadership at the highest level had not set a single vision for the company to implement Industry 4.0 technologies but were aware that there was a reason for this. It was felt that the company had to address more urgent problems first, such as supply chain challenges and backorders. Agostini and Nostella [45] also highlighted in a study on SMEs and MEs that digitalisation could be a challenge in organisations due to them working on daily operational and tactical issues and that management needed more time to plan. Interviewees explained that the most capable employees were allocated to solving these operational issues and needed more bandwidth to support a major Industry 4.0 project, such as rolling out a single ERP across the entire company.

Outdated software systems, particularly ERPs used at different manufacturing sites, were considered a major barrier to Industry 4.0. These ERPs cannot connect and transfer data between each other and are difficult to link with MES and SCADA systems. Other articles have also highlighted that not having an adequate IT base is a barrier to successful Industry 4.0 technology implementation [18,48]. This prevents a prerequisite for Industry 4.0 implementation from being achieved that of standardised systems [30].

The cost was a challenging factor brought up by all interviewees. This is a common challenge identified in the literature [10].

Interviewees explained that it was difficult to obtain a budget for Industry 4.0 projects. They are long-term projects requiring dedicated resources and can reduce turnover in the short term. One interviewee gave an example of when a facility was expanding the capabilities of MES or ignition at a manufacturing site; there was a downtime of commercial manufacturing in order to have resources allocated to implement a new process.

There is the fear of redundancy that comes with Industry 4.0. From the literature review, only one other article identified this as a challenge [26], while other articles grouped it under change management [6,7,13]. Interviewees acknowledged the concern that automation of processes that currently require a skilled person to operate may make their skill set redundant and cause resentment because they may no longer feel valued. This was always followed up by the interviewees stating the importance of change management to mitigate this challenge, i.e., as a best practice in Industry 4.0 projects.

The skill gap is another barrier to Industry 4.0 implementation. Interviewees were aligned in their view that the company did not have the right or enough of the appropriate hard skills in predictive analytics, AI, or machine learning to work on Industry 4.0 projects in

any large way. One interviewee noted that they had seen many job requisitions that required these skills, so this may be an indication that the company will be more focused on the future advantages of Industry 4.0 technology. The need for hard skills to implement Industry 4.0 technology in the medical device industry is a common concern in the literature [13]. One article that compared Industry 4.0 implementation between the automotive and medical device industries suggested that higher skills from the automotive industry could transfer to the medical device industry to its benefit [8].

Siloing is also seen as a barrier to Industry 4.0 implementation. Siloing is where various functional groups in an organisation focus primarily on their immediate performance rather than contributing to the objectives of the organisation as a whole [48–51]. One interviewee raised the point that the implementation of an improved companywide change in the management system was a missed opportunity due to siloing. The reason the interviewee gave was that different divisions had different interpretations of the processes around the new change management system that was initially set out by the corporate policies. Siloing was not a barrier raised specifically in the literature review; however, rigid organisational structure and policies have been identified as barriers [26].

Allocating resources to Industry 4.0 projects is difficult in the current environment of the company. Interviewees noted that you needed the most talented people in the organisation to work on these types of projects, and they needed more bandwidth to be completely dedicated to them. They have their “day job”, or they are assigned to higher-priority short-term projects.

A challenge/barrier to Industry 4.0 implementation that was frequently brought up in the literature was cybersecurity [47]. Industry 4.0 technologies, particularly the Internet of Things, are sensitive to hacking. So, any organisation rolling out this technology must have robust cybersecurity systems [52,53]. Interestingly, none of the interviewees raised or discussed the concern of securing the organisation’s data in the case of a cyber-attack.

Theme 6—Impact on Regulatory Compliance

The question “Has the implementation of Industry 4.0 positively or negatively impacted regulatory compliance within the organisation?” was chosen to directly ask the interviewees what their thoughts were on this important aspect of regulated companies. The responses were all positive, though some interviewees hesitated before answering and stated that it was difficult to say due to the minimum implementation of Industry 4.0 at the company. The reasons why Industry 4.0 has or will have a positive impact on regulatory compliance are centred around two points: greater accuracy of data and increased efficiency and removal of repetitive regulatory work.

From the interview transcripts, the primary beneficiary of Industry 4.0 technology would be the Manufacturing function in a medical device company. Interviewees identified that complete digitisation of inspection guide sheets, design history records, the implementation of SCADA, MES, and standardisation of ERPs would reduce the frequency of human error and provide readily available live accurate data. Many interviewees considered Industry 4.0 to impact regulatory compliance across the organisation positively. Interviewees considered that this would reduce the risk of findings during external audits and would also give higher confidence to regulatory teams in the organisation. Improved transparency, traceability, and auditability have been identified in the literature as having a positive impact on regulatory compliance [7].

Divisional interviewees saw a more direct benefit of Industry 4.0 technology with how regulatory compliance teams could work more efficiently. One example of machine learning that has benefited the complaints handling group is that it has more than halved the time of customers obtaining responses (from 80–90 days down to 40 days) through report automation.

There were responses from interviewees that cautioned the use of Industry 4.0 technologies. One concern is that when old analogue data are digitalised in preparation for Industry 4.0, non-conformances are more than likely to be found. These would then need to be addressed. One interviewee said that automated processes should also maintain a level of human intervention and should be appropriately validated. Human error is typically localised at one point in time [10]. If a whole AI system has a design flaw and misses something, it will keep missing it, and the non-conformance can become much larger in scale [54]. There is a need to have a balance between humans and technology in the medical device industry [6].

5. Discussion

This research had three RQs, all of which were met in this study.

What is the state of the Industry 4.0 readiness in the organisation?

Themes 1 and 2 drawn from the interview study address the state of Industry 4.0 readiness in the organisation. Awareness of Industry 4.0 in the company was mixed, and the consensus among interviewees was that the company was behind the curve with Industry 4.0 implementation.

Awareness and knowledge of Industry 4.0 technology are more prevalent with leadership in manufacturing operations and less so for leadership in divisional functions. This tallies with examples of Industry 4.0 technology given by interviewees where leaders in manufacturing operations gave clearly implemented examples such as SCADA and MES systems, and divisional leaders gave the name of one ongoing programme, i.e., “Blue Sky”. Communicating the strategy around Industry 4.0 deployment, rationale, and benefits is a critical success and readiness factor for an organisation [18,19].

Implementation is sporadic; the most concentrated implementation within the organisation is found within manufacturing. A mixed level of SCADA and MES system implementation across different manufacturing facilities provides interconnected data where predictive analytics is utilised. However, taking full advantage of Industry 4.0 benefits by transforming the company’s facilities into “smart factories” is hampered by outdated and disparate ERP systems. In addition, SCADA and MES represent vertical integration within Industry 4.0. This aligns with not having a clear “joint-up thinking” in terms of a deployment strategy and rationale for what systems are non-value-added and legacy systems versus a more value-added and streamlined integration of platforms [7]. All of the aforementioned integrations require significant final investment and resources as well as a clear cost-benefit analysis [6]. However, by migrating to the cloud and achieving horizontal integration across the value stream members, the organisation would become more efficient. Given the critical nature of medical devices, achieving end-to-end integration throughout the product life cycle would transform the medical device manufacturer into a smart ecosystem [55].

The divisional organisation of the company has yet to succeed in implementing Industry 4.0 principles and is at the early exploratory stages of this journey. The division would be considered a late adopter of Industry 4.0, as put forward by [20], where they have adopted a “wait and see” approach before investing in digitisation. A division-wide programme called “Blue Sky” is active for this exploratory stage, where its goal is to maximise existing systems to leverage data analytics and automation tools to drive efficiency. One divisional function has benefited already from Blue Sky; the complaint-handling process now has its audit report generation partially automated. This has reduced repetitive work and lead times to the closure of complaint investigations in the function. It has also led to a reduction in paper consumption and storage and the elimination of offsite storage facilities, which have environmental and sustainability benefits. Having

success stories is important as part of a digitisation strategy to share the benefits with the business and employees and garner support for the projects [18,19]. An added benefit was the sharing of sustainability benefits to employees.

This study aligns with the literature on the medical device industry in terms of low readiness and deployment of Industry 4.0 rather than presenting the organisation as a lagging outlier [7,8,29]. However, more case studies in the literature are needed to assess if this is truly the case. It would be beneficial to use a standardised measuring tool such as the Acatech Industrie 4.0 maturity index model [30] to compare Industry 4.0 readiness quantitatively between different case studies to make an assessment.

What is considered the best practice for implementing and adopting Industry 4.0 technology in a medical device manufacturer?

Theme 3, as drawn from this interview study, addresses what is considered best practice to implement and adopt Industry 4.0 technology in a medical device manufacturer. To make a radical change to how a company is organised and also to its work culture, Leadership support from the highest level of the company is necessary [52]. Industry 4.0 projects, such as implementing a single advanced ERP across all manufacturing sites, are not a trivial exercise. The CEO and divisional presidents need to make it the vision of the company to become a “smart company” [53].

To make such changes to an organisation, leadership need strong change management skills to motivate the workforce to embrace new ways of doing their work, which AI technology can bring, and also to allay their fears of redundancy [54]. Interviewees explained that where reduced headcount is the goal of Industry 4.0 implementation, leaders need to be honest with employees about what the result could mean at the end of the process. Leaders need to be mindful of how change is presented and communicated to staff.

Standardisation of ERPs and digitisation of all data inputs is a critical prerequisite before any new Industry 4.0 technology can be implemented to increase the efficiency and speed of a process [30]. Interviewees explained that Industry 4.0 benefits the most from large-scale systems, and trying to implement it by piecemeal is costly. “Analogue” data on paper or scanned PDFs can create a “hidden” factory because the information is not easily accessed and not connected to systems that could use them. Industry 4.0 benefits the most from large quantities of accurate data [30].

Upskilling the workforce is an important activity for the successful rollout of Industry 4.0 technologies. AI and machine learning skills are scarce and in demand. It is necessary to hire consultants in AI and machine learning fields to support existing employees in the company, and this is true for both early and late adopters of Industry 4.0 [21]. The existing employees are experts in their processes and need to work together with these consultants to implement Industry 4.0 enhancements.

Before any Industry 4.0 project should go ahead, effective planning is required. The benefits of an Industry 4.0 technology need to be identified upfront, and there must be a way to measure and track it. The cost and resources required to launch an Industry 4.0 project are enormous. On the other hand, other short-term challenges to the business could be focused on and resolved instead. The case for Industry 4.0 needs to be made, with the risks being mitigated beforehand, to obtain a return on the investment [7].

What challenges and barriers do a medical device manufacturer have to overcome to implement Industry 4.0 technology?

Theme 5, drawn from the interview study, addresses the challenges and barriers a medical device manufacturer must overcome to implement Industry 4.0 technology. Some challenges and barriers inhibit the case study company from embracing Industry 4.0 technology.

Industry 4.0 technologies are interdependent with each other, and thus, a full programme to implement these is needed [55]. A programme on such a scale requires leadership support at the highest level with a clear vision to make this happen. Such a programme has yet to be launched effectively due to it being a low priority for the business. Obtaining leadership buy-in and support is a challenge because there are other short-term challenges that the business must address first. Only then can the resources and finances be freed up to focus on a complex and long-term programme to make the business embrace Industry 4.0 technology. The business will prioritise overcoming back orders and supply chain issues (short-term gain) ahead of the Industry 4.0 technology rollout (long-term gain).

There are human factors that challenge Industry 4.0 implementation in medical device companies. The business must overcome siloing between functions and divisions as Industry 4.0 requires standardised processes to allow for the transfer of data between systems [30]. There is a skill gap in the business and the industry at large, where expertise in predictive analytics, AI, or machine learning is not available [6,8]. This will slow the rollout of Industry 4.0 technology. Employees can be resistant to change and may fear redundancy if Industry 4.0 technologies automate and replace their work [55]. Effective change management is a challenge during Industry 4.0 implementation.

Having an inadequate IT base in the company is seen as a barrier to Industry 4.0 implementation. Complete digitisation and standardisation of all data is a prerequisite to Industry 4.0 implementation [30]. However, the company still uses paper and PDFs to record data and uses multiple outdated ERP systems across multiple sites. Digitalisation is a huge opportunity to go completely paperless and garner sustainability benefits. There are also more opportunities for remote working should the company go paperless, as documents can be reviewed and signed remotely, thus improving the sustainability impacts of digitalisation.

These challenges and barriers have also been identified in the literature in a limited number of similar case studies, which show that there are common challenges and barriers that medical device manufacturers face with the Industry 4.0 technology implementation [8,26].

6. Conclusions

The objectives of this study were to determine the state of Industry 4.0 readiness and to identify the best practices, challenges, and barriers to implementing Industry 4.0 technology in a medical device manufacturer. This study has managerial and organisational implications as the medical device industry, and its associated healthcare sector is a huge sector of the world economy and will continue to grow as the population ages. Organisations can leverage this study to understand the readiness factors as well as the benefits of digitisation. Valuable best practices to implement Industry 4.0 technology in medical device manufacturers were identified in this study. Identifying what executives do as best practice in this study can be utilised to understand what challenges and barriers there are to successful implementation, which will help other medical device companies implement Industry 4.0 technologies more effectively. This work contributes to the limited understanding of the digitisation challenges and opportunities in the medical and healthcare sectors. It can help all Medtech product stakeholders better understand the challenges and opportunities associated with Industry 4.0 and manufacturing to better identify where to focus their IT strategy efforts to impact future adoption levels. Furthermore, this work extends the current theory of Industry 4.0 as a precursor for a data and digitised ecosystem model for medical device usage and treatment of patients with such devices. From a theoretical implications viewpoint, this study is one of the few case studies on medical device companies and Industry 4.0 implementation. The limited literature makes it challenging to know

where an individual company is compared to other medical device manufacturers and how these technologies can advance patient treatments; thus, it will add to the state-of-the-art literature and understanding.

A limitation of this study is that it is a single case study and, as such, may be seen as ungeneralisable in comparison to the rest of the Medtech sector. However, this medical device manufacturer is one of the largest contract and medical device manufacturers in the world, and thus, it is very representative of the Medtech industry. From the interviewee responses, the state of Industry 4.0 readiness in the case study was described as lagging or behind the curve. However, the case study was not atypical to other medical device manufacturers. In the literature, it has been concluded that medical device manufacturers have implemented a low level of Industry 4.0 technology and are at a low maturity level.

Other themes that emerged from the findings of this study include the motivating factors and benefits of Industry 4.0 and its impact on regulatory compliance and sustainability. There are opportunities for further research to analyse these themes so that additional research questions can be addressed in the future. Another future research opportunity would include submitting a survey to a broader network of employees in the same case study company. The questionnaire could be designed to allow for responses to be measured quantitatively. A standardised measurement for Industry 4.0 readiness, such as the Acatech Industrie 4.0 maturity index model [27,28], could be used for this purpose. The results could be compared directly with other studies conducted using the same model in other medical device companies and companies in other industries to have a more objective Industry 4.0 readiness assessment.

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