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The Impact of Industry 4.0 on the Medical Device Regulatory Product Life Cycle Compliance

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Abstract: The fourth industrial revolution, also referred to as Industry 4.0, has resulted in many changes within the MedTech Industry. The MedTech industry is changing from interconnected manufacturing systems using cyber-physical systems to digital health technologies. The purpose of the study is to establish how Industry 4.0 can understand the impact Industry 4.0 is having on product lifecycle regulatory compliance and determine the effect Industry 4.0 is having on product lifecycle regulatory compliance. A qualitative research approach was utilised to gather data from the MedTech industry by conducting interviews with Medtech industry leaders. This research demonstrates that Industry 4.0 is easing product lifecycle regulatory compliance and that the impact is more positive than negative. Industry 4.0 offers many benefits to the MedTech Industry. This research will support organisations in demonstrating how digital technologies can positively impact product lifecycle regulatory compliance and support the industry in building a business case for future implementation of Industry 4.0 technologies.

Keywords: medical device; medtech; Industry 4.0; regulations

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1. Introduction

The Medical Technology Industry, or MedTech Industry, is one of the largest growing industries in the world. This growth is driven by the ageing population and the advancements in technology within the industry [1]. The fourth industrial revolution, or Industry 4.0 as it has become known, started in Germany in early 2000 [2]. Industry 4.0 uses digital technologies to gather data from multiple sources and then uses that data to transform how decisions are made within an organisation [3]. Industry 4.0 technologies are being used within the MedTech Industry and are already impacting the products offered, the manufacturing processes, and how products are produced and delivered to the end customer [4]. The use of digital technologies can deliver many benefits for an organisation, including efficiencies, reduction in operational costs and supporting organisational decisions through the use of big data and big data analytics [5].

Digital technologies have also resulted in the need for new and revised regulations and standards, particularly around cybersecurity and the use of software as a medical device (SaMD) [6,7]. However, even with the release of new and revised regulations and standards, there is still a gap in the regulatory framework that allows manufacturers to use some of the technologies, such as big data analytics and artificial intelligence [7]

Many digital technologies have been researched, providing insight into both the benefits and challenges associated with their use within the MedTech Industry [7–10]. However, digital technologies impact on product lifecycle regulatory compliance has not been widely researched. Product lifecycle regulatory compliance, also referred to as regulatory compliance throughout this study, is how manufacturers comply with the

different regulatory requirements to ensure their products, processes, and services deliver a product that is safe and effective, meets customer requirements and expectations and meets country-specific regulatory requirements [11].

The compliance requirement for organisations can be statutory, mandatory, or voluntary, depending on the industry and organisational function [1,12]. The effect of digitalisation on Medtech regulatory affairs and compliance to regulations while touched upon in Industry 4.0 literature as a benefit of digitalisation has not been studied. The regulatory benefits or Regulatory 4.0 are limited in published research unlike the quality benefits via Quality 4.0 which has been recognised through the publication of multiple research articles [13,14].

This study will utilise a case study in a multinational medical device manufacturer with several global sites. This research aims to investigate the impact Industry 4.0 is having on regulatory compliance within the MedTech Industry using the case study organisation as a reference. This area has been understudied to date with the focus of Industry 4.0 mainly on manufacturing process enhancement and some focus on quality enhancement via Quality 4.0 or the digitalisation of quality [3–5]. This research will address the following research questions:

RQ1: What impact (positive and negative) is Industry 4.0 having on the Total Product Lifecycle and Regulatory Compliance in a Medical Device manufacturer?

RQ2: What types of projects are being implemented and what are the associated challenges with Industry 4.0 implementation?

Thus the research will demonstrate for the first time the influence Industry 4.0 can have on improving and enhancing Regulatory compliance.

The research proposes to conduct semi-structured interviews to gather opinions from MedTech Industry Leaders on the topic of Industry 4.0. Section 2 reviews the published literature that is currently available on Industry 4.0 in Medtech. Section 3 discusses the research methodology, while Section 4 documents the findings and results. Finally, the discussion and conclusion are outlined in Sections 5 and 6.

2. Literature Review

2.1. What Is Regulatory Compliance in the MedTech Industry?

The MedTech Industry is one of the largest growing industries in the world; this is due to the world's ageing population [1]. This drives the need for advancements in existing medical technologies and the development of new medical technologies to support the ageing population and this ever-growing industry [15]. Therefore, the MedTech Industry is a highly regulated industry with many different regulatory requirements globally, from the Medical Device Regulation (MDR) and In vitro diagnostic medical devices Regulation (IVDR) in Europe (EU) Code of Federal Regulations (CFR) in the United States of America (USA), the Pharmaceutical and Medical Device Act (PMD Act) in Japan, the Regulation on the Supervision and Administration of Medical Devices, Order 739 in China, and the Therapeutic Goods (Medical Devices) Regulations 2002 in Australia, to name just a few. Regulations set out the regulatory requirements, including pre and post-market requirements, to ensure that only safe and effective medical devices are produced, sold and used [16].

However, the regulatory landscape is always changing with new or revised regulatory requirements. For example, the global pandemic caused by COVID-19 resulted in regulators having to think and react quickly to ensure that products and services needed to tackle the disease were made available as quickly as possible through the use of digital technologies and new or revised regulatory requirements such as the Emergency Use Authorization (EUA) process in the USA [17].

Other changes that have impacted the industry are the implementation of the new EU- MDR and IVDR with many changes, including the definition of a medical device, new classification rules, the general safety and performance requirements (GSPR), Technical Documentation, clinical data and evaluation requirements and increased post-market surveillance (PMS) requirements. The advancements in medical device technology have played a big part in the need for these new regulations within the EU, ensuring appropriate

systematic reviews of products and processes for patients and users [18]. In addition to these new regulations, there have been other significant changes in Canada, Saudi, the United Kingdom (UK) [19] and Switzerland. New standards and regulations are also being developed and implemented because of Industry 4.0's digital transformation, particularly around cybersecurity and software as a medical device (SaMD) [20]. The standards and regulations introduced to govern cybersecurity and SaMD include data protection and are required given the vast networks and systems used throughout the industry in production and the medical devices themselves [21]. Cybersecurity is used to protect data from cyberattacks, where software is considered a medical device protecting it and ensuring its safety and performance are maintained and are free from external threats that could negatively impact someone's life [22].

Regulatory compliance is how manufacturers comply with the different regulatory requirements to ensure their products, processes, and services deliver a safe and effective product, meet customer requirements and expectations and meet the country-specific regulatory requirements [12]. Digital transformation through the use of digital technology builds regulatory intelligence and automation, ensuring data is collected, stored, and maintained globally; it will support complex regulatory strategies ensuring the most up-to-date regulatory requirements are available and met, resulting in a faster turnaround time for activities such as registrations, enabling a more effective and efficient and compliant RA function that is aligned with the rest of the organisation [23].

Regulatory 4.0, or the digitalisation of regulatory affairs, is not a term that has been used, unlike Quality 4.0, which has been recognised through the publication of multiple research articles [5,24,25] which would suggest that the Quality (QA) function is further on their Industry 4.0 or digital transformation journey than its partnering function RA. Like Industry 4.0 and Quality 4.0, the same components can be used to support Regulatory 4.0. The RA function, as suggested in the "Veeva MedTech 2021 Regulatory Pulse Benchmark Report", where nearly one hundred organisations globally completed surveys, suggests just that. The RA function is not as far on as from QA and lags on its Industry 4.0 journey. However, the report also suggests that the MedTech Industry is taking much-needed steps toward digitalising regulatory affairs through digital technologies [26].

The digitalisation of regulatory affairs or Regulatory 4.0 can be achieved through digital technologies, such as the Internet of Things (IoT), cloud computing, and wireless communication that support tools such as Regulatory information management systems (RIMs) [23]. RIMs provide secure access to real-time regulatory data and visibility across regions globally, including Latin America (LATAM), Asia-Pacific (APAC) and Europe, the Middle East, and Africa (EMEA), supporting industry in achieving regulatory compliance throughout a products life cycle [27]. In addition, RIMs support streamlined regulatory processes resulting in quicker submission times and registrations, leading to speedier market access, unification and connectivity across an organisation leading to global alignment and compliance. Figure 1 below shows the elements that constitute a Regulatory Information Management System.

The European database on medical devices (EUDAMED), is one example of an RIM that Regulators use to access medical device-related data to assist in the understanding of how a device is performing in the market, its risks and benefits, and if action is required based on pre and post-market information that has been inputted into the system by the different economic operators as required by the European Union Medical Device Regulations (EU-MDR). There are six modules, including actor registration, unique device identification (UDI), device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and post market surveillance (PMS), and market surveillance [6].

Regulatory intelligence can be obtained and managed using digital technology. Moving away from Industry 3.0 tools such as Excel, which is used for tracking and trending Regulatory Impact Assessments (RIAs), change notifications (CN), licenses, submissions, and registrations. Instead, using RIMs to manage and control an organisation's regulatory data is key in supporting RA moving forward on its Industry 4.0 journey. The lack of

a proper system with the capabilities to store data, analyse it and track and trend key performance metrics results in inconsistencies, which is ineffective and inefficient. Capable RIMs will drive consistency, effectiveness, and efficiency at the touch of a button. Systems that inform when there are changes to guidance documents, standards and regulations as opposed to sifting through websites and blogs to find out the latest changes, systems that can manage regulatory information, such as British Standards Institute (BSI's) Compliance Navigator, are key to supporting the RA function on its Industry 4.0 journey. Standards are used to demonstrate regulatory compliance; therefore, having access on demand to the latest revisions is very important [28].

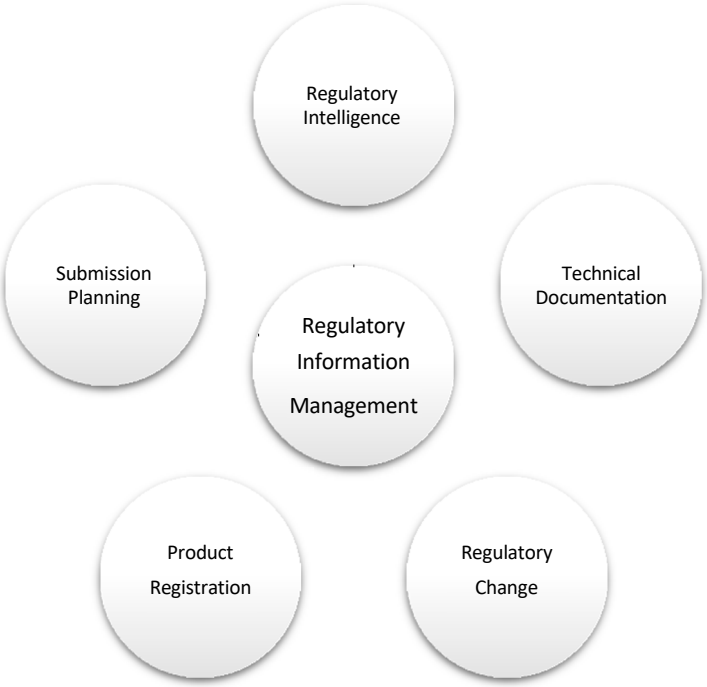

Figure 1. Regulatory Information Management System (Authors own work).

Several governing legislations are in place around the protection of data, cybersecurity and SaMD, and the standards and guidance documents that can support their implementation [29]. There are different levels of data security, some that have been around a lot longer than others, from the use of a digital signature, time stamping and data encryption which are relatively simple and easy to implement and maintain, to more complex technologies like blockchain technology that make it almost impossible for hackers to gain access to data that is secured using such technology [30]. Both regulators and multinational organisations, such as the International Organization for Standardization (ISO), American National Standards Institute (ANSI), European Committee for Standardization (CEN), American Society for Testing and Materials (ASTM) and European Telecommunications Standards Institute (ETSI) are responsible for ensuring the appropriate regulations, standards and guidance documents are developed and put in place to support the industry in delivering safe and effective devices, which includes data security [31,32]. For example, the ISO has published 220 standards on information security, cybersecurity, and privacy protection, with a further 68 under development.

2.2. Industry 4.0 Opportunities and Challenges

Industry 4.0 is not without its challenges. However, the opportunities offered by digital technologies far outweigh the challenges [33]. Without digital data and technologies, organisations could not deliver such innovative solutions for the MedTech Industry and, more importantly, its customers. Some challenges include lack of good quality data [34] and data security [35]; however, through the implementation and development of new

regulations around computer security and data protection, the challenge around data security is being considered and addressed which will have a positive impact on regulatory compliance [36]. Furthermore, advances in cybersecurity technologies such as blockchain technology could provide the industry with the level of security and compliance required to ensure data is protected and devices remain safe and effective, supporting the continued use of digital data, digital technologies and SaMD throughout the production process, products and services [37].

Another challenge for the MedTech Industry is the new European Medical Device Regulation (EU-MDR) [38]. The EU-MDR is not Industry 4.0, but it is a major stumbling block for the MedTech Industry in implementing it [39]. Many resources are tied up with EU-MDR. Therefore, the industry struggles to get approval for the different systems needed that can ultimately support them in their Industry 4.0 journey [40]. The EU-MDR covers end-to-end manufacturing and considers different actors within the supply chain. This means that Industry 4.0 tools such as intelligent Manufacturing Execution Systems (MES) [41], data analytics used to determine accurate forecasting, and predictive maintenance are used throughout production, and the supply chain support compliance with the EU-MDR can also have a positive impact on regulatory compliance. Digitisation throughout the manufacturing and the supply chain results in faster, more flexible, more granular, more accurate, more efficient, and more compliant products, processes, and services [42]. Studies have demonstrated that having a Lean program is an enabler for Industry 4.0 [43,44]. There is a synergistic benefit between lean and digital technologies, and each benefit the other [44].

Other studies have been conducted and have shown that Industry 4.0 is a strategy used to gain a competitive advantage and improve performance through innovation and research and development [45]. This study advocates that by embarking on the journey of Industry 4.0 and implementing digital technologies, Industry 4.0 will positively impact regulatory compliance.

3. Research Methodology

This study is a qualitative research study involving a case study of an individual medical device company. This research aims to demonstrate through research and discussion with MedTech industry leaders that Industry 4.0 has a more positive than negative impact on regulatory compliance. As an organisation moves from Industry 3.0 to Industry 4.0, the organisation and its employees see a transformation of the tasks and technologies as they move from automation to digitisation, digitisation to digitalisation and then to digital transformation [46]. This research utilises interviews to support and provide the required information to address the research question. Using a mixed method approach allows the researcher to use more than one method or strategy to collect data that will support the validity of the research [47]. Qualitative research allows the researcher to explore, describe and interpret a real-world problem using a flexible study design [48].

The case study will focus on one particular medical device organisation's Industry 4.0 journey. The interviews will provide insight into the organisation's leaders' understanding of what Industry 4.0 is, the types of initiatives that have been or are being worked on across the organisation and the organisation's leaders' opinions on whether Industry 4.0 is having a more positive than negative impact on regulatory compliance.

A focused qualitative case study can help the reader understand the researched topic [47]. Semi-structured interviews are a commonly used qualitative approach to gathering research data [49]. Therefore, the interviews conducted as part of this research will be semi-structured. In addition, semi-structured interviews allow for a freer-flowing, flexible interview where interviewees can openly discuss points of interest [50,51].

The interviews will focus on each department in the case study organisation, focusing on past and present plans for implementing Industry 4.0 tools. The interviews will also be used to determine where the case study organisation is on its digital transformation journey and its impact on regulatory compliance. Below, Table 1 provides the final topic guide and the questions that will be presented to the interviewees during the interview process.

Table 1. Interview Questions.

No.	Question
Q1	How would you explain Industry 4.0 in layman's terms?
Q2	Do you currently have any Industry 4.0 type projects or initiatives within the organisation/department/function?
Q3	What are the motivating factors for adopting Industry 4.0 within the organisation/department?
Q4	What organisational readiness factors would need to be considered for you to embrace and adopt Industry 4.0 within the organisation/department?
Q5	What are the Critical Success Factors for the implementation of Industry 4.0? (present or future)
Q6	What do you see are the benefits and opportunities of implementing Industry 4.0?
Q7	What are the challenges or barriers to adopting Industry 4.0 within the organisation/department?
Q8	What tools of Industry 4.0 (e.g., cybersecurity, Cyber physical systems (CPS), cloud computing, mobile technologies, machine to machine, 3D printing, also referred to as additive manufacturing, advanced robotics, big data/analytics, IoT, RFID technologies, and cognitive computing, AI, etc.) do you think might help the organisation/department?
Q9	Has the implementation of Industry 4.0 positively or negatively impacted regulatory compliance within the organisation?
Q10	Are you planning on implementing any Regulatory Intelligence tools or RIMs? If so, why do you need to do this, and what benefits can be achieved from this implementation? What might the potential benefits be from implementing such a system within the organisation?

The Interview Process

Interviewees were initially contacted via email to confirm the purpose of the interviews, then via Microsoft Teams to confirm dates and times. The interviews were recorded using Microsoft Teams. The Microsoft Teams platform was chosen because of its recording and transcription capabilities. Using this platform meant the recordings and transcripts could be accessed and used for data analysis and to confirm or recall discussion points and responses when writing up the findings and results [52]. Each interview lasted approximately forty minutes.

Convenience sampling was used to select the interviewees. This type of sampling was used as interviewees were easily accessible to the researcher. Consideration was also given to who could provide the best insight and information on the topic of Industry 4.0 [53]. Interviewees were selected nonrandomly based on their position, leadership experience and function within the organisation. In this study, 13 senior managers participated in this study. The sample size was judged to be enough as the data were saturated and no new themes were emerging [54]. Each interviewee must be at director level or above and have >10 years of experience in a leadership role. In addition, interviewees must not all come from the same department to achieve a cross-functional perspective. Participants, as listed in Table 2 below, are at the director level and from various departments across the organisation.

The framework approach consists of five stages that involve preparing the data, exploring the data, analysing the data, presentation of the data and validating of the data [55]. To conduct data analysis, the researcher must catalogue the data, look for recurring themes, code and group the themes, interpret and write up the findings using quotes to support and finally validate the data [48]. Utilising Atlas.Ti 22, the interviews we coded under different themes. Three techniques of open coding were utilised by creating a list of themes (interview topics) within data, axial coding by categorising theme subcategories and finally selective coding by condensing specific categories into higher-

order themes [56]. Open coding consisted of identifying individual meaning themes or units, in axial coding these were sub-categorised and then selection of master themes or selective coding were linked [57]. The data was verified using the member checking technique, utilising memoing to track the themes while the coding and triangulation was carried out by multiple researchers to ensure consistency [58].

Table 2. List of interviewees.

No.	Interviewee	Function	Experience in Leadership Role
1	Corporate Vice President (VP) Quality Assurance & Regulatory Affairs	QARA	>10 years
2	Corporate VP Manufacturing and Supply Chain	Operations	>10 years
3	Corporate VP of Strategic Projects	Strategic Projects	>10 years
4	VP of Quality Assurance (QA) (Manufacturing)	QA	>10 years
5	VP of Regulatory Affairs (RA)	RA	>10 years
6	VP of Human Resources Global Ops	HR	>10 years
7	VP Global Quality Engineering (QE)	QE	>10 years
8	Senior Director of Quality Systems (QS)	QS	>10 years
9	Senior Director Operations Excellence (OE)	OE	>10 years
10	Senior Director QA, Global Supplier Quality, Logistics and Distribution (SQLD)	SQLD	>10 years
11	Senior Director, Global Scientific Affairs	Clinical Medical Affairs	>10 years
12	Senior Director of Shared Services Europe Middle East & Africa (EMEA) Controller and Site Director	Finance	>10 years
13	Director, IT–Global Operations & Quality Assurance & Regulatory Assurance (QARA/Global Information Technology (IT) Applications	IT	>10 years

4. Results

The findings from the thirteen semi-structured interviews and reviews are summarised below in Figure 2.

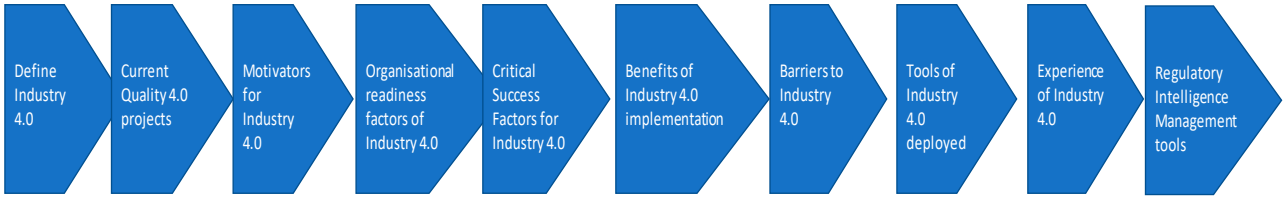

Figure 2. Thematic analysis map of interviews (Source: Authors own diagram).

Q1. *How would you explain Industry 4.0 in layman's terms?*

There was a broad understanding of what Industry 4.0 is, and many of the interviewees had a similar understanding, using such words or terms as *"industrial revolution", "transformational use of technology", "computerisation and digitalisation", "connectivity", "collection and reporting of data", "data analysis, "data-driven, intelligent decisions"* and *"artificial*

intelligence" to explain Industry 4.0. Others had a better understanding and provided more in-depth descriptions using examples to explain the concept of Industry 4.0 (Table 3 below). One interviewee stated, *"At the executive level, it is not referred to or called industry 4.0; at the executive level, we talk about the digital environment; we talk about Project XXX, which is mainly around the change management process."* (Note: XXX is used to refer to project names to protect the anonymity of the case study organisation).

Table 3. Examples of Industry 4.0 definitions from interviews.

"I would probably describe it as the next step in computerization and digitalization, where now you've got more direct connectivity between systems. And I suppose it's probably getting to a lesser human interface between systems, more of a system-to-system connection."
"Really all-around digitalization in terms of the industry, you know, obviously we've gone through a number of different phases in the industry over many years. But you know I think 4.0 is really about digitalization and making sure our systems and processes are all connected and from a digital perspective, but it's more than just, let's say having your computer systems in place, it's really about making sure things are connected and in terms of reporting of metrics from a manufacturing perspective that it's the collection and the reporting of data is all digital.
"I think it's just embracing the whole digital revolution and applying that to the way we go about running our manufacturing plants, our supply chains from a smart factory perspective. So really looking at autonomous systems, the whole Internet of Things as well and AI machine learning. It's the whole digital revolution that's taking place and applying that then to how we can do things smarter more efficiently, virtually and in real time."
"You know industry 4.0. I think people's understanding of this has evolved. It's a buzzword that's been around 10 or 15 years for sure. You know from my perspective how it interprets in terms of applications for Company X rather than what its broader meaning is, it's really how we can best optimize all elements of our manufacturing and supply chain right from an intent, and you've heard me use the phrase end-to-end supply chain perspective and Factory 4.0. *If you've been here a couple of years ago prior to the early days of our command centre. It was Excel files; people were doing data extraction. Nothing was real time. You were depending on someone then doing analysis. Whereas what we've now developed in the command centre is a much more real time automated reporting and so on so forth. So that certainly from our Company X perspective, I think that's our real focus. I'm more into the supply chain rather than the intricacies of manufacturing per se. But when I'm thinking about 4.0 from our perspective, I really think about it more in the context of the control tower, the command centre.*

Q2. *Do you currently have any Industry 4.0 type projects or initiatives within the organisation/department?*

The candidates interviewed were across ten departments within the organisation, including I.T, Finance, Clinical Medical Affairs (CMA), Operations, Quality Assurance (QA), Quality Engineering (QE), Human Resources (HR), RA, Strategic Projects and Supplier Quality/Logistics and Distribution. 8 out of 10 departments had already implemented or are working on implementing some Industry 4.0 type projects. Some interviewees felt that the organisation was a late adopter and is in the early stages of its Industry 4.0 journey. One interviewee stated, *"You know, we are at the early stages of our journey of Industry 4.0 and digitalisation. However, we certainly have a lot of good initiatives underway."* Cloud computing is one technology that is used throughout the organisation, and another is big data analytics.

One interviewee stated, "I would not say that they are on the forefront of digitalisation, but they are getting some systems in place". Another stated, "if I think about the industries that are at the forefront of 4.0, just as a digression for a second, automotive electronics are two, if not three decades ahead of where medical devices and pharma are".

Company X has really embraced the use of big data analytics in its supply chain that controls what product is made, where and when and how it gets to the end customer. The tool used to support this throughout its supply chain is SAP Business Warehouse (BW). BW is used to gather, store, analyse and report data which has really supported supply and demand, particularly over the past two years. One interviewee stated, *"I can honestly say*

there is no way we would have got through the last 12–18 months without all the work we have done in the supply chain we just would not."

Other projects include the implementation of an Electronic Quality Management System (eQMS), Regulatory Information Management Systems (RIMs), and Manufacturing Execution Systems (MES). Some projects might not be considered Industry 4.0 however, more Industry 3.0, which are also underway, such as the implementation and use of Statistical Process Control (SPC) across manufacturing sites globally and upgrading the SAP ERP system from SAP ECC 6 to S4, having these will strengthen and support other Industry 4.0 projects in the future.

One key Industry 4.0 project impacting the entire organisation is 'Project XXX' the organisation's Enterprise Change Management (ECM) program. The ECM program is putting in place the foundations that will allow the organisation to be truly integrated and have a globally automated Change Control process extending across functions, from engineering to manufacturing, quality, regulatory and external partners.

The projects underway are in different stages, from exploration and testing to planning and implementation. For example, the organisation is currently exploring and testing an Optical Character Recognition (OCR) technology to support the transfer of paper documents such as Device History Records (DHRs) and Device History Files (DHFs).

Projects in the planning stage include eQMS and RIMs. The MES project is in the pilot stage at two of the main manufacturing facilities in Europe. Both Global Labeling Systems (GLS) and ECM are in the implementation phase. Other departments have also implemented programs such as Company X Connect, a cloud-based HR system containing all employee data and Veeva Vault Clinical Data Management Suite used to support the CMA team.

One interviewee elaborated, "*So we have invested in a clinical package, an electronic data capture system called Veeva, and before using Veeva, we were reaching out to clinicians to give us clinical data and were using manual paper-based systems. However, with this software package or electronic data capture (EDC) system, we can now build a case report from a chart review survey, get it to the clinician electronically, and they can give us real-time feedback on our product once they use it. So, they can give us performance and safety data immediately*"; the Interviewee then went on to state, "*that was a massive game changer for us in moving from paper to electronic and so much so that we have got funding now. We have a three-year license starting this year for the next three years. Company X approved the investment, and we invested monies and we see massive efficiencies in getting both clinical trials and Post Market clinical follow-up (PCMF)using this system.*".

Q3. *What are the motivating factors for the adoption of Industry 4.0 within the organisation department/function?*

Many interviewees listed the same or similar motivating factors and provided examples of where or how Industry 4.0 technology could impact the current tasks within departments. For example, the motivating factors discussed included "*higher efficiencies*", "*improved regulatory compliance*", "*enhanced change management effectiveness*", "*improved time to market*", "*having access to real-time data*", and "*having systems that are connected that support the business and help meet the needs and requirements of the customer*".

One participant best summarised the motivations and benefits succinctly "*If we were able to take full advantage of that* (Industry 4.0)*, I think it will allow us to get better access to real-time information and give you greater insights, allow you to make faster decisions. So, you can better serve the customer, improve quality, be more efficient, improve profitability for the organisation, and you know the key factor for me in all this is real-time and efficiency.*"

Others included maintaining a high-performing adaptable workforce supported rather than led by the technologies of Industry 4.0 and sustainability. For example, "*I think the introduction of any technology, and this is just another level of technology, has to be done in the context of actually trying to help our employees. So I would always advocate for human-centred design, and technology has to be there to help the people rather than having the people work for the technology, right? So it has to be about making our job simpler.*"

Table 4 below lists the comments from the interviewees related to the motivating factors for the adoption of Industry 4.0 within the organisation.

Table 4. Comments from interviewees related to Industry 4.0 motivations.

"I suppose it is always efficiencies, isn't it? You are always looking to see if we can do things better, smarter, quicker, and can we reduce errors.".
"I suppose the motivational factor is the quickest, easiest, most reliable way to assess product data and change management; it is also a huge part of that. So again, with us making products that are the same in different locations, making products labelled differently but the same from different locations". The change management activities to keep changes aligned is critical and trying to do that with a human interface to say, you know Mary Jane has her checklist, so she will remember to check with Mexico when making this change in Europe. It is just not, and we know this–that is not a robust process. So, for me, that is a huge motivational factor."
"I mean, like most things in business, time, money, resources, that is what a lot of it comes down to and the transparency and the visibility to global data".

Q4. *What organisational readiness factors would need to be considered for you to embrace and adopt Industry 4.0 within the organisation/department?*

Leadership support and alignment and having a well-documented strategy that aligns the entire organisation on what the organisation's Industry 4.0 journey looks like and entails, and reviewing what systems are chosen are important when preparing an organisation for change. Ensuring the entire organisation is aware of the strategy and roadmap being put in place for digital transformation is important, as highlighted by the interviewees. It was highlighted that Industry 4.0 needs to be "*driven by leadership*", "*aligned with strategy*", and "*communicated to everybody*". Another key element highlighted was in relation to infrastructure, "*having the correct infrastructure in place that can support the systems and, of course, having the people to support the systems and the infrastructure*" and "*joined-up thinking -a strategy*". Finally, the importance of resourcing the digital transformation was reiterated in terms of "*investing in technology*" and "*hiring the right people*". Table 5 below are the comments from interviewees related to organisational readiness factors in the adoption of Industry 4.0.

Table 5. Comments from interviewees related to organisational readiness factors in the adoption of Industry 4.0.

"I think it is like any program; you know it has to come from the top down, bottom-up discussion. It has to be seen as a strategic intent. It has to be driven as "you know this is what we want to do", "These are the gains", "These are the short-term gains", –"These are the things we are going after".
"I would say definitely willingness. The change is hard and ensuring that we have an understanding within the organisation to understand what we are looking at in terms of infrastructure support. You cannot go digital without IT support without servers, safety measures, capability, and security; it is truly an investment. Human investment and infrastructure and then the ability to maintain it because digital transformation occurs so quickly in the regulatory world, you cannot leave the information static; there is a footprint there forever. So you need to be able to manage, update and obsolete information and have the organisation ready to do that throughout the life cycle of the product development process and having the infrastructure in place to drive it.".
"So you have got to have people strategically looking forward, hiring the right person to educate us and help us get there, you know, it is not an easy journey.".
"Listen, you know as well as anyone that culture is always one of the hardest things to change and getting folks ready for something this massive is always challenging.".

Q5. *What are the Critical Success Factors for the implementation of Industry 4.0? (present or future)*

There were differing success factors discussed depending on the projects people were working on and at what stages they were at. Some interviewees took an overall holistic

view and discussed having an infrastructure and systems "*that talk to each other*" and "*work together*" to support faster, more well-informed decisions based on real-time data. Table 6 below are interviewees' comments on the Critical Success Factors for implementing Industry 4.0.

Table 6. Comments from interviewees related to the Critical Success Factors for the implementation of Industry 4.0.

"You know, ultimately; I would say the success is that we have systems that are interconnected speaking to each other, and we can realise the benefits and the efficiencies from the systems that we move to."
"There are a lot of different answers with this, but you know, its success in this situation is really about getting a system implemented that allows us to make decisions in real-time. That is the ultimate goal.".

Other interviewees discussed success in the specific projects they were working on, such as change management. One success factor for the Project XXX Team is to have one robust global change management process and the key communication channels set up so that change is managed and communicated in the same way across the organisation. One interviewee stated, *"change management is exactly one key Critical Success factor (CSF) and communication"*. For Company X, Industry 4.0 type projects must be rolled out globally, starting with the basics. One interviewee stated, *"Because Industry 4.0 has many different facets, you could invest millions and not get any benefit over what you were looking for; you need to have very senior sponsorship buy-in; otherwise, it just does not work.".*

Many sites are still working with manual paper-based processes, so getting the basics right and bringing all sites to the same platform and level playing field will be a huge success factor for the organisation as it moves along the roadmap. One interviewee stated, *"It is not just success. It depends on what kind of horizon I think you are looking out onto, you know, but. I would say we are looking out over the next three years. This should be really about getting the basics in place. MES is one of those things.".*

Choosing the correct systems for the right reasons that will benefit the organisation, including its workers and customers, was also seen as a success factor, and doing all this with very little disruption for the end customer and the business. One interviewee2 stated, *"So really your SuccessFactors are, you know, minimal disruption to what you are doing"*.

Q6. *What do you see are the benefits and opportunities of implementing Industry 4.0?*

Like the motivating factors discussed in question 3, many interviewees saw similar benefits and opportunities. These included "*improved compliance*", "*reduction in human errors*", "*increased efficiencies*", "*standardised work*", "*on-demand access to reliable data*", "*quicker time to market and freeing up of employees' time to work on more value-add activities*" and "*innovative ideas rather than just tasks that can be done using Industry 4.0 technologies*". Industry 4.0 technologies can also impact employees and transform how and what they do, removing repetitive tasks and making the job more interesting. One interviewee2 stated, *"You know through the use of bots or automates or whatever you want to call it, but if the more repetitive transactions, you can remove, it makes people's jobs a bit more interesting"*.

Others spoke about how there were both internal and external motivating factors. External factors are regulators and regulations and how these were motivating factors for implementation. Two interviewees both commented on the FDA, with one stating, "*Interestingly enough, there are big regulators like FDA who are exploring those (Industry 4.0) as well, and they will be mandating some of these solutions for the medical device industry because they also want to work in an efficient environment where they have access to data quicker and faster.*"

One interviewee stated, "*we could trace that product before it goes to a patient*". Finally, 7 of 13 interviewees referred to people or teams and how technology would benefit them by making their jobs easier, freeing them up to have more time to work on more value-added tasks. One interviewee stated, "*Let technology pick up and learn and manage activities that*

humans are doing now so they can focus on other things" and "*it makes people's jobs a bit more interesting*". However, another spoke about the exploitation of Industry 4.0 technologies and how that can impact people and the role of HR in advocating for the employees. One interviewee stated, "*Absolutely, but then they could be exploited as well. So, we in HR have to be the employee advocate*". Organisations have to get to the balance right so that people benefit and are not negatively impacted by Industry 4.0 technology. Table 7 below are interviewees' comments on the benefits and opportunities of implementing Industry 4.0.

Table 7. Comments from interviewees related to the benefits and opportunities of implementing Industry 4.0.

"It (Industry 4.0) would eliminate the need for us to do all this manually. We are doing a lot of work manually using email, contacting people in the particular location who have to go through the requirements and see if the requirements apply to the particular product group that we want to ship and very often, we experience errors, so I can see a certain reduction in workload and the amount of resources involved in this process and a reduction of errors which are very consequential where we have field safety corrective actions that resulted in shipping product that should not have been shipped to various countries. Moreover, if you automate this process, it will be robust enough to eliminate or reduce the majority of such incidents. This is a huge benefit."
"Faster, quicker, more reliable, more robustness there, and I think, you know, even with things like the regulatory database, you can get more data from different places more quickly. So again, it is efficiency; more information is coming in."
"First and foremost, it is quicker to market, better regulatory compliance, a centralised data system that is managing and hopefully at some point self-learning."
"It has accessible, readily available data faster, quicker, more compliant, transparent. I mean, in the end, it is also cost savings, and in the grand scheme of things, right, I mean from several different areas, you can help prevent repeat root cause recalls, you can react to issues faster and theoretically, you are saving some workforce, right? Anytime you do not have to crunch the data yourself and have a system doing it, which is also one of the challenges that come with it, is what? What do you then do with the people? Because you do not want just to let your entire workforce go. I think it transforms what the workers are doing because someone is got to maintain the system, right?"
"right first time improved, reduced, Non-conformances, reduced recalls, and transparency."

Q7. *What are the challenges or barriers to adopting Industry 4.0 within the organisation/department?*

The main challenges discussed were choosing the right systems, cybersecurity, remediation activities, data, resources, change management, financial backing, and investment. One theme that several interviewees discussed was the challenge of obtaining financial support and investment from the organisation. In addition, there were other competing priorities, such as the cost of implementing the EU-MDR and increased costs of doing business due to the economy and the global pandemic of the past two years. Some comments included *"the challenge is investment"*, *"and then also because I think the other barriers have got to be to educate the senior leadership team in the organisations that you have to invest in this"*, *"it is really getting buy-in at the at the executive level"*. The work involved in justifying new technology was cited *"there is an awful lot of PR needed around if you want investment in this in two years, there needs to be a lot of work and communication done"*.

Another challenge highlighted was data and cybersecurity and its importance given the industry in question and its impact on the health and well-being of people. Having good reliable data means a certain level of remediation is required to update existing data into the chosen system(s), and then how that data is maintained and secured is vital to maintain its integrity and safety. In addition, depending on what data is being generated, what it is used for and how it is used can impact the level and type of cybersecurity required. For example, software as a Medical Device (SaMD) requires the highest level of cybersecurity given the associated risks compared with the software used to support a quality management system [3,59].

Communication is another challenge that must be at the forefront, ensuring people know what is happening and why and that they are aware of the impact on the business and, more importantly, the impact on them and their jobs. According to One interviewee who stated *"The biggest thing is the people. It will be fear and change management and communications"*. Table 8 below are the comments from interviewees related to the challenges or barriers to adopting Industry 4.0.

Table 8. Comments from interviewees related to the challenges or barriers to the adoption of Industry 4.0.

"The challenge is you still need somebody sitting there going; what does this mean for us? However, you know, whereas again, a manufacturing system or even XXX, you know it will be data in and data out if the data does not meet the rules, it will go, hello, it does not meet the rules! So somebody needs to fix this, and so again, it depends on the type of system."
"One of the challenges is an investment. Many of these systems do not come cheap, especially when you want to roll it out across a sector of up to 20 sites, including manufacturing sites, offices, etcetera. So, it is investments; there is a big investment needed. It is challenging to state upfront what is going to be the benefit and the payback for this investment, especially when we are talking about QARA because many of our dollars are our headcount.".
"If you are fully digital, digitalised and your production systems or your systems go down, your quality management system, electronic goes down for a week or 10 days or two weeks because of a security attack, then your company pretty much stops, you know? So that is a risk.".
"We have got to pick one. However, moreover, that is just getting a good technical answer before you deal with having to change people and change people's way of working into that new standard."
"You know, in terms of Industry 4.0 implementation, the biggest challenge you have is people do not know what they want or when to start".
"The biggest challenge we have right now is probably resource constraints, and that is across the board, and it is the availability of skilled resources.".
"And the challenge you will always get is why? Why would I change it? I am not going to get anything out of it.

Q8. *What tools of Industry 4.0 (e.g., cybersecurity, CPS, cloud computing, mobile technologies, machine to machine, 3D printing, also referred to as additive manufacturing, advanced robotics, big data/analytics, Internet of Things (IoT), RFID technologies, and cognitive computing, AI etc.) do you think might help the organisation/department?*

The interviewees discussed areas in which they felt Industry 4.0 could support or impact their daily tasks and regulatory compliance throughout the interview process. Many tools listed and discussed include Agile, SAP, RFID, Concur, eQMS, RIMs, visual scanners, and MES. They also include the continued use of cloud computing and big data analytics across all departments to help gather and analyse data to support real-time decision-making.

As with the motivating factors and benefits of Industry 4.0, interviewees agreed that the use of such technologies will help the organisation achieve improved compliance, reduction in human errors, efficiencies, standardised work, on-demand access to reliable data, quicker time to market and free up employees' time to work on other projects. It was also discussed that the use of autonomous technology could support the production process to determine if a product has been made to specification or not; it could provide more flexible and better controls on where product can and cannot ship. In addition, improving how regulatory controls are managed both at the manufacturing site versus the distribution centre and throughout the supply chain supports identification and traceability that allows the organisation to identify very quickly where the product is and if it has been used. Table 9 below are the comments from interviewees on the tools they think might help the organisation.

Table 9. Comments from interviewees on the tools they think might help the organisation.

"And do you know that would certainly help us, you know, even yesterday we had a conversation about ship holds and current shipments that are live and authorised.. Where the regulatory shipments list right now does not stop product shipping from a site, everything is hoarded in the DCs, and we are hoping that the ship list holds that. So, in reality, where it would be hugely beneficial is if we can push back to the sites and say, right, there is a trigger here within the system that says you can or cannot ship to that DC because it has been approved to go to that market or it is not approved for that market. So if the sites are not approved to supply product to that market, it cannot go anywhere.".
"So as much as we can manage our data without the subjectivity of a human, the better and when I talk about that data, I mean the binary data, is the product made with everything on the bottom, yes or no is the product made to this spec, yes or no, that is critical."
"We have also looked at optical scanners for label verification during production shipment and creation. So, using sensors to scan barcodes, package tracing for biologics, temperature, real-time, temperature, and excursions to alert it for stability."

Q9. *Has the implementation of Industry 4.0 positively or negatively impacted regulatory compliance within the organisation?*

All thirteen interviewees said that Industry 4.0 had a more *"positive"* than negative impact on regulatory compliance within the organisation. However, some comments were made by interviewees 6 and 9 that although they agreed that the impact was positive, the organisation needed to be *"wary"* and ensure that implementation was *"done right";* otherwise, there may be a negative impact. Table 10 below are the comments from interviewees on whether the implementation of Industry 4.0 positively or negatively impacts regulatory compliance.

Table 10. Comments from interviewees on whether the implementation of Industry 4.0 positively or negatively impacts regulatory compliance.

"it is definitely more positive. However, on the other hand, it cannot be more negative because it allows people to do things they were not able to do before."
"I think it definitely has a positive impact. There is no way I could see it will have a negative impact."
"Absolutely positive without question, it gives us quicker, faster access, better understanding, better management of our data, better communication with regulators and patients. Absolutely one of the biggest opportunities that we have had."
"it offers huge potential for Company X"
"I think it is very clear that this tool Veeva, that we have used has, you know, a positive impact."
"absolutely positive"

Interviewees when discussing how regulatory compliance was positively impacted used the following words "*control*", "*people*", "*data*", "*quicker*", "*faster*", "*access*", "*patient safety*", "*systems*" and "*time*". One interviewee stated, "*when it comes to regulatory compliance, as long as we are doing all our validations and everything correctly, it makes it much easier to respond to things promptly, which obviously helps improve our compliance, right? Everything returns to patient safety risk associated and being able to act timely should things go wrong. Something like industry 4.0 accelerates our ability to do that. So, from that perspective, it is always seen as something that has positively helped the organisation*.". Another provided an example of how implementing a global labelling solution (GLS) had reduced the number of labelling-related recalls " *GLS has reduced recalls since it has been put in place*",.

Q10. *Are you planning on implementing any Regulatory Intelligence tools or RIMs? If so, why do you need to do this, and what benefits can be achieved from this implementation? What might the potential benefits be from implementing such a system within the organisation?*

This question was aimed specifically at the Quality & Regulatory Affairs function, to which all interviewees answered "Yes". Company X is currently in the planning stages

of identifying suitable RIMs that can deliver what the organisation needs. This RIM requirement is an automated system that will support the RA function, ensuring that products meet the many global regulatory requirements, support the registration process and control of shipments, ensuring only products that are registered and meet the regulatory requirements can ship. The ever-changing regulatory frameworks drive the need for RIMs throughout the world where Company X sells products and supports compliance. As discussed with One interviewee, the RIMs, like the ECM program, will be the foundation for digital transformation within the RA group. Once implemented, the RIMs will be used to control shipments, ensuring only a product that is approved ships and also to monitor changes to regulatory requirements so that changes can be assessed in real-time and action when required taken to maintain market access. As discussed with One interviewee, the first part of the project will be to identify the system, and like project XXX, a business case must be made to obtain the required buy-in and financial support. Table 11 below are the comments from interviewees on the implementation and benefits of having RIMs.

Table 11. Comments from interviewees on the implementation and benefits of having RIMs.

"The RIMs project will essentially move in the direction and be a foundation for Industry 4.0 and for RA. The main elements of it as a tool that allows us to control our ship tables, and we want to automate this process as much as possible, but it will only be as good as the data that contains information about regulatory approvals globally. Regulatory approvals are not given forever, and they depend on a lot of things; RA and Regulations evolve. Moreover, we are looking for an automated way of looking at those changes that would influence whether we can or cannot ship product into a particular region".
"So, it's an automated regulatory intelligence tool that basically monitors changes in the regulatory requirements around the world and helps us decide whether they are applicable or not to our portfolio. to a large extent; it will happen in the background and allow us to identify where there may be an impact to existing registrations or to the new products entering the marketing."
"The Unique Device Identifier (UDI) will give us much greater control over our products because UDI allows you to monitor the product throughout its lifecycle, including all the actors and touch points with the product, and I think having this information automated and having it available to us allowing us to search at the product and whatever happened with it will be invaluable for traceability of the products on the market. This obviously translates into safety when you have a safety issue or a product quality-related issue; you are quickly able to identify where those products are, whether they have been utilised already, what is happening with them and whether you can pull them off the market and also you can differentiate between good products and bad products. Hence, there are multiple benefits of having that system automated. So, the main two benefits are reduction in workload and resources and the reduction in potential errors".

5. Discussion

5.1. Theme 1: Industry 4.0–Understanding of the Concept

This question provided insight into industry leaders' knowledge and understanding of what Industry 4.0 is. Collectively the interviewee's explanation of Industry 4.0 was generally aligned with the articles reviewed as part of the literature review [2,60]. However, not all interviewees had a full understanding of the concept of Industry 4.0, which is having systems in place that are connected so that organisations have full visibility of what is happening in real-time within their facilities [61,62]. For example, 8 out of 13 interviewees mentioned the word "digital" in their response to this question; however, only 4 mentioned the word "connect" in some form. Some interviewees did appear more knowledgeable depending on their level within the organisation, their function, and their experience in other companies. For example, interviewees from I.T and Operations were more familiar with the concept of smart factories and the overall concept of Industry 4.0, some of which came from previous experience working in companies where digital technologies such as digital twins were being used. One interviewee stated, "*it is just embracing the whole digital revolution and applying that to the way we go about running our manufacturing plants, our supply chains from a smart factory perspective*". Executive leadership (VP and above) understood the concept of connectivity and having connected systems, not just stand-alone systems that worked in silos. If leaders within the industry lack the full understanding

and concept of Industry 4.0, how can they implement the technologies and use them to their full advantage [63]. Thus this case study emphasises in line with the literature the importance of leadership understanding of the technology and leadership support.

The organisation, as seen as part of the study, has a strategic vision; however, not all digital technologies were part of this as discussed as part of the interview process. A strategic vision is a CSF for Industry 4.0 [64,65]. For example, the Veeva project was part of this vision and comments were made during the interviews that some sites were trying to implement their processes locally when global systems that are connected is really what is required.

5.2. Theme 2: Industry 4.0–State of Implementation

Under this theme, Industry 4.0–State of Implementation, the responses to questions 2, 4, and 5 will be analysed and discussed. These questions were chosen as they provide information on the different digital technologies being considered or implemented within the case study organisation, their readiness, and the critical success factors for implementing Industry 4.0.

From the findings and results analysed, 8 out of 10 departments had already implemented or are working on implementing some Industry 4.0 type projects. However, some projects were stand-alone, implemented in silos, and did not connect to other systems within the organisation, lending to questioning if they truly were Industry 4.0. Many studies have discussed the importance of "joined-up thinking" and selecting the right tools for digitalisation to ensure the right technologies are deployed that do not negatively impact other areas. Unfortunately, some projects implemented did not meet this alignment and cohesiveness stressed by the literature [4,13,66]. During the interviews, interviewees spoke about organisational readiness being strongly influenced by the proper infrastructure to support the technologies. Without the proper infrastructure implementing Industry 4.0 can become challenging [67,68].

Although on its journey, the case study organisation is considered a late adopter and is in the early stages of Industry 4.0 implementation. The case study organisation is implementing a global change management process that is considered the organisation's foundation for many of the other Industry 4.0 technologies being planned and reviewed for implementation in the future. It is a journey that organisations must consider if they want to stay competitive [27]. The case study organisation has made the decision in line with the reasons cited by many in the literature because of their desire for increased competitiveness. To support these new systems and in order to be ready for them, having a robust infrastructure is vital. This infrastructure needs to have appropriate security levels to support the business and prevent the technologies used from cyber-attacks protecting its data to ensure regulatory compliance is maintained is very important [4,25]. This was pointed out by several interviewees who indicated this was a key element to being Industry 4.0 ready. In terms of infrastructure readiness the case study organisation can be considered vigilant and cognizant of the security levels required and scope these requirements when selecting infrastructure.

An organisation's readiness and ability to change can impact its Industry 4.0 journey. If change within an organisation is met with challenges, implementing new technologies that will change how people work will not be easy [69]. However, the case study organisation have a clear strategy, aligning several stakeholder functions and a clear deployment plan thus adding readiness and improving communications for change. Organisational change management (OCM) is important so that the people involved are educated about what is happening and why; communication should also include the impact of the change so that people embrace it rather than fear it [45].

5.3. Theme 3: Industry 4.0–Reasons for Implementation

8 out of 13 interviewees mentioned the word efficient, efficiency or efficiencies during their interviews. However, only 5 out of 13 mentioned compliance; therefore, efficiency is more motivating than compliance. Others spoke about how there were both internal and external motivating factors. External factors are regulators and regulations and these were

a motivating factor for implementation. This finding is not surprising given that much of the literature discusses the impact of Industry 4.0 on productivity and efficiency and there is very little awareness nor practical case studies on Industry 4.0 benefits to Regulatory compliance [3,4]. The motivating factors discussed as part of question 3 align with what Industry 4.0 technologies can deliver according ot the literature [5]. Industry 4.0 technologies provide access to big data, big data analytics, and connected systems through the IoT, cloud computing and CPS, providing access to real-time data and system connectivity and resulting in more efficient and compliant processes [23].

5.4. Theme 4: Industry 4.0–Benefits and Opportunities

As part of the analysis and discussion under this theme, Industry 4.0–Benefits and Opportunities, the responses to questions 6, 8 and 10 will be analysed and discussed.

The benefits and opportunities discussed were similar to the reasons for implementation as discussed above under theme 3 and included *"efficiencies"*, *"control"*, and *"compliance"*. Other benefits included *"the patient"* and *"people"*. As the organisation under study is a medical device manufacturer, it is not surprising that the patient is featured more as a benefit and opportunity than in the reasons for implementation. Many studies have discussed how Industry 4.0 is transforming Healthcare with improved diagnostic devices, smart and wearable devices and enhanced surgical equipment [4].

5 out of 13 interviewees referred to the patient and how the implementation of Industry 4.0 technologies could positively impact and benefit the patient. The benefits for the patient were put down to the systems improving how quickly devices made it to the market or in cases where product quality issues were identified; it was how quickly they could be traced and removed more than the use of SaMD. Questions 8 and 10 focused on the different tools and technologies being considered or implemented and their impact on the organisation, which include *"time"*, *"people"*, *"data"*, *"control"*, *"compliance"*, and *"transparency"*. The responses to both questions were aligned with the responses to question 6 but also gave an insight into the technologies that have been or are being implemented within the organisation, such as Concur, XXX Connect, SAP, Agile, MES, OCR, and Veeva. Others are in the planning phases, such as eQMS and RIMs. All the technologies are cloud-based, allowing the organisation to store, manage and access data in real-time, providing many if not all of the benefits discussed above [70].

5.5. Theme 5: Industry 4.0–Challenges and Barriers

As part of the analysis and discussion under this Theme, Industry 4.0–Reasons for implementation, the responses to question 7 will be analysed and discussed. After analysing question 7, three main challenges or barriers stood out: investment, people, and technology.

Obtaining investment was one of the biggest challenges for the case study Industry 4.0 plan. The investment includes time, money and resources, so having support from Senior Leadership across the organisation is a major element of implementing Industry 4.0 successfully [71]. The literature also emphasises the case study organisations experience that highlights the importance of designing a justification and a case needs to be drawn up which clearly outlines how the goal will be achieved and who is required to support it [13,66]. Senior leadership support and financial backing helped the case study organisation build a global strategy around digital transformation and a roadmap detailing how and when those technologies will be implemented to support the business and its employees supporting the literature [4–6,72]. People were another challenge highlighted. Gaining employees support and communication of the digital strategy is important to ensure the digitalisation journey is embraced and accepted [4,25]. Industry 4.0 has social (human-related) and technical (non-human) components coming together to pursue a common goal in a socio-technical system [73]. Therefore, employees are as critical as technology for the success of Industry 4.0 deployment [74]. Upskilling employees skillsets to support digital transformation and changing technologies must be planned for to ensure organisational readiness [75].

Technology was another one of the challenges where case study organisation was not considered to be at the forefront of Industry 4.0. The company is not advanced in its technologies and is considered a late adopter [71]. One interviewee stated, *"Company XXX, in general, is not a very digitalised company"*. However, as a late adopter the organisation may enjoy the advantage in terms of improved business models. The late adopters usually face less uncertainty in successful implementations as by the time they adopt, knowledge of implementation frameworks or certifying agencies will be more expert in implementing Industry 4.0 [6,76].

5.6. Theme 6: Industry 4.0–Impact on Regulatory Compliance

The thirteen interviewees all agreed that Industry 4.0 technologies, once implemented correctly, have a more positive than negative impact on regulatory compliance. This view aligns with literature particularly around Quality 4.0 in relation to the impact of digitalisation on regulatory compliance [4,13,77]. A McKinsey report in 2021 outlined the benefits and application of technology in setting a strong compliance foundation [76]. This organisation under study has observed more positive than negative benefits in compliance from Industry 4.0. Industry 4.0 can help augment human intelligence, increase the speed and quality of decision-making, and improve transparency, traceability, and auditability [77,78] which can only aid regulatory compliance. Even though all interviewees said the implementation of industry 4.0 technologies positively impacted regulatory compliance, they also discussed some of the challenges and how having the correct balance between humans and technology is important in the medical device industry [72]. The multiway flow of information in all stages of the product life cycle, further enables improved quality of design, quality of conformance and quality of performance [78]. However, it should be noted that regulatory compliance can negatively impact Industry 4.0 as regulations require validations, documentation and compliance requirements with new technology [79].

5.7. Recommendations from the Research

The case study emphasises the importance of Industry 4.0 for process optimisation; improving productivity and enhancing quality. However, the study also demonstrates the importance of involving Regulatory functions in decisions around selecting of Industry 4.0 technology as the technology may enhance, improve or ease regulatory compliance type tasks. Especially in highly regulated industries such as Pharma and Medtech, making strategic Industry 4.0 deployment decisions can remove a lot of the manual tracking, paperwork, manual tasks and non-value add waste that is involved in regulatory compliance. The importance of Industry 4.0 in aiding regulatory intelligence and the overall compliance to the product lifecycle has been proven. Wei et al. [79] discussed the importance of bearing in mind regulatory requirements during a digital transformation, such as the need for process requalification, validation, and documentation, which can influence the velocity of the transformation. Such regulatory barriers must be taken into account when deploying Industry 4.0 in a Medtech environment.

5.8. Limitations of the Study & Future Research

There are limitations to this research. The case study demonstrates that implementing digital technologies can positively impact regulatory compliance. However, the case study organisation has limited the generalisation as it is one single case study focused on one medium-sized MedTech company. Several recommendations for future studies or projects can address these limitations. This research focuses solely on Company X, a medium-sized MedTech company in the early stages of its digital transformation. Using similar or different-sized companies (small or large) would have provided another perspective on how and why other companies are implementing Industry 4.0 and at what stage they are in their journey so that a comparison could be made. The opportunity for further research is to research post implementation of ongoing digitisation projects in the organisation's roadmap to gain more data on the actual benefits realised and what impact those benefits

had on product lifecycle regulatory compliance. There is also an opportunity to expand the research to include more Medtech organisations to make a comparative analysis. Such research will support organisations in demonstrating how digital technologies can positively impact product lifecycle regulatory compliance and support the business case for their implementation.

6. Conclusions

Industry 4.0 is the digitised revolution changing how products, processes and services are delivered. Industry 4.0 is about digital transformation and digital technologies such as cloud computing, big data, big data analytics, cyber-physical systems, system integration, cybersecurity, 3D printing and the IoT to change how the MedTech industry does business. Industry 4.0 technologies have been used within the MedTech industry for many years; however, some organisations are further along than others regarding their implementation and use. The use of digital technology supports an organisation in delivering efficient and effective processes, products, and services for its customers and, as demonstrated through this study, can have a positive impact on regulatory compliance.

The authors recommend that the Regulatory Affairs function be involved more in Industry 4.0 deployment strategy in order to ensure technology selected enhances and optimises regulatory compliance and benefits it. Furthermore, the impact of regulations in terms of validation, process requalification and documentation on Industry 4.0 implementation timelines must not be underestimated.

The literature review, and interviews completed for this study demonstrate that Industry 4.0 impacts product lifecycle regulatory compliance. The literature review demonstrates that Industry 4.0 is having an impact on product lifecycle regulatory compliance. The interviews in case study organisation provided the benefits that can be achieved by implementing digital technologies, which included a reduction in the number of recalls, re-registration efforts, reduced effort for quality audits, cycle-time reduction, and faster time to market, which together can have a positive impact on regulatory compliance. Finally, there was consensus across all those interviewed that Industry 4.0 is having a more positive than negative impact on regulatory compliance.

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