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Pharma industry 4.0 deployment and readiness: a case study within a manufacturer

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Abstract

Purpose – This study investigates the readiness for and understanding of Industry 4.0 in a pharmaceutical manufacturer.
Design/methodology/approach – Utilising qualitative interviews within a single-site case study in a pharmaceutical organisation, the understanding of Industry 4.0 and the challenges, benefits and critical success factors for Industry 4.0 readiness therein and applications of Industry 4.0 are assessed.
Findings – The research findings found that Industry 4.0 implementation has implications for regulatory compliance and enhancing operational excellence on the site. The Pharma site is embracing Industry 4.0 technologies, particularly for paperless systems and data collation and analytics, but the site is somewhat of a late adaptor of Industry 4.0 implementation and is on a path towards increased digitalisation.
Research limitations/implications – A limitation of the study is that it is a single-site case study, but the results can be generalisable in demonstrating how Industry 4.0 is being deployed and its challenges and benefits.
Originality/value – This study is unique and novel because to the authors knowledge, it is one of the first studies on Industry 4.0 readiness and status in an Irish Pharma site within a single pharmaceutical organisation. This study can be leveraged and benchmarked by all pharmaceutical organisations as it demonstrates the complexity of Industry 4.0 deployment from a highly regulated and complex pharmaceutical manufacturing and processing viewpoint.

Keywords Operations management, Technological innovation, Industry 4.0
Paper type Research paper

1. Introduction

The pharmaceutical industry continuously strives towards innovations that help humans live longer and better lives. It is a very competitive industry; therefore, it must keep up with

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new technologies and improvements (Byrne *et al.*, 2021). It is one of the largest sectors in the world, yet it is still expanding and has experienced significant growth in recent years (Mikulic, 2023). Organisations face bigger product demands as the world population ages (O'Mahony *et al.*, 2023). Companies must adjust their operations processes very quickly to keep up with demand, and the past few decades have seen a rapid change in manufacturing technology (Antony *et al.*, 2021c). However, the pharmaceutical industry is slow and cautious at implementing new technologies and making changes due to regulatory requirements, which require regulatory approval submissions and stringent review by regulatory authorities (Arden *et al.*, 2021; McDermott *et al.*, 2022a).

Simões *et al.* (2022) found in a qualitative study of Industry 4.0 technological readiness in the Pharma industry in Portugal that technology investment is still a gap in updating to Industry 4.0 and that knowledge gaps related to technology ability and employees' knowledge of the technologies are a concern. Wang and Chen (2021) found in a study of Chinese pharma Industry 4.0 readiness that the overall technological innovation efficiency of that industry was low in relation to Industry 4.0 technology. Reinhardt *et al.* (2020) studied the development of Industry 4.0 in the pharmaceutical sector in Ireland and the preparedness to adopt Industry 4.0 across the country. Although the study was significant, it was broad and holistically included the readiness of the pharmaceutical, biopharmaceutical, and medical devices sectors. While there are many studies on Industry 4.0 readiness, case studies related to the Pharma Industry and technology readiness, in particular, no site-specific readiness studies focus on all aspects of organisational and technological Industry 4.0 readiness, especially from a single site.

This study aims to establish awareness of the Industry 4.0 concept and assess the readiness for its adoption within a pharmaceutical site operating in Ireland. Ireland represents the global Pharma sector as Irish-based pharmaceutical companies supply the majority of Ireland's 2020 exports (€39bn) going to the US market and is estimated at over $80 billion (Government of Ireland, 2019; Irish Medtech Association, 2020). All ten global top ten pharmaceutical companies have manufacturing operations in Ireland (IDA, 2023). The novelty of this research is in demonstrating the readiness and journey of one particular Pharma company site and the knowledge of its employees when it comes to the adoption of Industry 4.0 and filling a gap in the literature (Ding, 2018; Inuwa *et al.*, 2022; Reinhardt *et al.*, 2020). By understanding the pathway involved in the Pharma industry in particular, then, the Pharma industry can leverage learnings for the study. Digitalisation and automation are now ensuring that Pharma companies reduce production mistakes in the future that could lead to potential safety issues or recalls, resulting in a decrease in financial and reputation damage (Kitson *et al.*, 2018). More importantly, digitalisation can be used to track medication, helping in preventing counterfeiting through the use of serialisation and can aid in achieving compliance with regulations (O'Mahony *et al.*, 2023, 2024).

Three research questions (RQ) will guide this study:

RQ1. What knowledge level and awareness of Pharma Industry 4.0 regarding the concept and its deployment within the case study site?

RQ2. How ready and progressed are the case study site for implementing Industry 4.0?

RQ3. Will Pharma Industry 4.0 affect the site's regulatory compliance and Operational Excellence status?

Section 3 outlines the research methodology, Section 4 the results, while Sections 5 and 6 outline the discussion and the conclusion.

2. Literature review

2.1 The evolution of Industry 4.0 in pharma

Arden *et al.* (2021) stress that the pharmaceutical industry is in the process of technological transition, with companies still operating in Industry 2.0 and 3.0 paradigm. Moreover, they also state that organisations present the "first to be second" approach, which means observing how the competitors deal with innovative technologies and how the regulators respond. In effect, they are "late adopters" who, as described by Antony *et al.* (2021d), adopt a "wait and see" approach and benchmark and learn from pioneering "early adopters" but they are not willing to be the first to implement the changes (Yan *et al.*, 2019).

To reach the stage of Industry 4.0, the industry went through a transformational process from Industry 1.0 to Industry 4.0. The transformation and the concept of Industry 4.0 have been extensively explored and spoken of throughout the years (Sony *et al.*, 2021a; Yan *et al.*, 2019; Leng *et al.*, 2021). Industry 4.0 aims to transform regular machines into self-aware and self-learning machines. Cohen *et al.* (2019) state that awareness is a central pillar of Industry 4.0 and name four types of machine awareness. Amongst others, there are components of Industry 4.0 such as cyber-physical systems, the smart factory, the Internet of Things and Internet of Services, Big Data and Analytics, autonomous robots, simulation, cybersecurity, cloud computing, additive manufacturing (AM) and artificial intelligence (AI) (McDermott *et al.*, 2023).

2.2 Implementation challenges and benefits of Industry 4.0

Implementation of Industry 4.0 comes with inevitable challenges and barriers like improvement of automation, improvement of processes, lack of digital skills, lack of strategy, lack of understanding, lack of system integration, problems with the return of investment, cybersecurity, high cost and time consumption, and interoperability (Ding, 2018; Vaidya *et al.*, 2018; Phuyal *et al.*, 2020). In contrast, there are many benefits of Industry 4.0 implementation. Such are the benefits of Industry 4.0 that there are many different paradigms or branches that have emerged such as Quality 4.0 (Zulfiqar *et al.*, 2023), Lean 4.0 (Foley *et al.*, 2022), Lean Six Sigma 4.0 (Antony *et al.*, 2023a, b), Lean Supply Chain 4.0 (McDermott *et al.*, 2023), and Healthcare 4.0 (Sony *et al.*, 2022) amongst others. There are several benefits of Industry 4.0 to quality management and quality product delivery, specifically related to improved data analytics, predictive maintenance, improved product traceability, and defect reduction via the elimination of the potential for manual error. Digitalisation enables the customisation of products to specific customer needs and has advanced customer satisfaction to new levels. From a Lean and Six Sigma viewpoint, Industry 4.0 is complementary to both Lean Six Sigma and Lean and has a synergistic relationship with both. Digitalisation aids the elimination of non-value added waste and the elimination of human error and can reduce administration and non-value added activity (Buer *et al.*, 2018). Within healthcare delivery enhanced digitalisation has led to increased design and development and sales of mobile health apps often referred to as the combining of production and service delivery or "servitisation" (Cobelli and Chiarini, 2020). The concept of servitisation means that an organisation is not just selling a product or a service, but a service and a product providing a combined solution. Within the supply chain Industry 4.0 impacts both LSS and the sustainable organisation (Skalli *et al.*, 2023). Industry 4.0 enables a more green and sustainable supply chain and also aids more sustainable processes as well as the circular economy through the use of Lean tools to eliminate environmental wastes (Duarte and McDermott, 2024; McDermott *et al.*, 2024). Conversely, in a study by Chiarini *et al.* (2020) of over 200 Italian manufacturers, it was found that the digitalisation technologies do not contribute to any significant improvement in environmental sustainability but that as previously mentioned, the technologies have "benefits for servitization, design-to-cost, supply chain integration and machinery-electronic equipment-and database integration, as well as Lean strategy are enabled through the adoption of Industry 4.0 technologies."

In a survey, Sony *et al.* (2021b) highlight benefits in manufacturing such as improvement of customer satisfaction and efficiency, ability to make data-based decisions, and improvement of effectiveness and agility. Another benefit Olsen and Tomlin (Lennon, Olsen and Tomlin, 2019) mentioned is that recalls will be handled extremely efficiently thanks to blockchain, which is particularly advantageous to the pharmaceutical industry (Yan *et al.*, 2019). Ding (2018) claims that Industry 4.0 technologies will help pharmaceutical organisations shift their reputation from heavily contaminating, high-waste energy-intensive users to smarter, more flexible, and sustainable thanks to the continuous production that reduces energy consumption, material utilisation, and greenhouse gas emission. Industry 4.0 aims to create technologies that will use and augment human intelligence (McDermott *et al.*, 2022c).

Furthermore, AI will be able to replace humans in tasks that are arduous, repetitive, and dangerous (Selenko and De Witte, 2021) or those that can be seen as mortifying and dehumanising. Manufacturing companies understand AI's potential, but no clear deployment is embedded within the industry (Escobar and Morales-Menendez, 2018). While Markarian (2018) argues that AI will be a challenge due to the constant changes as computers learn from scenarios leading to validation issues, with validation being a particular regulatory challenge and requirement in pharma and device industries (McDermott *et al.*, 2022a; McGrane *et al.*, 2022). Rüßmann *et al.* (2015) and Gyurjyan *et al.* (2017) state that demand for employees in the mechanical – engineering sector will rise. Skills required in the factories of the future will be different to the ones required presently for the activities such as quality inspections, assembly, or precision positioning will be done by robots (Stăncioiu, 2017). Rüßmann *et al.* (2015) state that Additive Manufacturing (AM), such as 3D printing, will be used broadly to produce small batches of tailored products as the demand for high-individualized products is increasing (Barreto *et al.*, 2017).

Lennon Olsen and Tomlin (2019) note that 3D printing will face challenges as different materials require different AM technologies. AM product cycle time is slower, but the material waste is lower. They also state that advanced robotics (AR) – a system for humans and robots working alongside each other is still not ready and safe, but advances in sensor technology are promising. However, robotics are expensive and require a team of specialists to install, calibrate, and programming. Industry 4.0 has been much reinvented or relabelled as Pharma 4.0 (Yan *et al.*, 2019), and one element of Industry 4.0 embraced by the Pharma industry has been additive manufacturing. 3D printing can allow Pharma manufacturers to control dosage manufacturing regarding material utilized, build plans, and aid preclinical development and clinical trials up to and including hospital site care (Reinhardt *et al.*, 2020).

Organisations must identify their goals for Industry 4.0 and be realistic (Foley *et al.*, 2022). An example of this is the self-check study conducted within seven manufacturing companies by Machado *et al.* (2019), in which they conclude that by focusing mainly on technology, companies forget to start at the right point and have a strategic plan. Companies must also be aware of cybersecurity risks to be prepared for the full implementation of Industry 4.0.

To implement improvements and changes, top management must show their commitment, provide directions, and allow time and resources (Antony *et al.*, 2023b). No big change is possible without it, and anything that does happen without it will not be permanent (Dale *et al.*, 2021). When it comes to managerial skills after their survey, Grzybowska and Łupicka (2017) claim that to cope with the new challenges of Industry 4.0, the three most important managerial competencies are: decision-making, problem-solving, and conflict-solving. Pharma organisations are large enterprises and do not suffer from the readiness challenges seen in smaller and medium enterprises, such as a lack of government supports and funding available to finance digitalisation programmes (McDermott and Nelson, 2022).

2.3 Industry 4.0 and its effect on pharma regulatory compliance and operational excellence

Industry 4.0 has been stated as having a synergistic and complementary relationship with Operational Excellence methodologies (Antony *et al.*, 2023a, b). Conversely, compliance with regulatory body requirements and different regulatory jurisdictions has been shown to stifle Operational Excellence (McDermott *et al.*, 2022a; McGrane *et al.*, 2022). However, Industry 4.0 is an enabler for both Operational Excellence methods and for improving compliance with regulations by enhancing the manufacturing of highly regulated products and aiding compliance with regulations (Foley *et al.*, 2022; McDermott *et al.*, 2022c). For example, Industry 4.0 adoption in Pharma can help drug development and clinical research and aid the completion of market launch and approval using AI and Embedded tools and devices (ETD's) for applications in clinical research (Hariry *et al.*, 2022). Leng *et al.* (2021) claim that blockchain is the new Industry 4.0 tool that can tackle cybersecurity issues such as cyber-attacks, traceability of operations, information vulnerability, advanced viruses on control systems, device fabricating or false authentication.

Foley *et al.* (2022) discussed the importance of data analytical tools and other Industry 4.0 technologies, including Agile, SAP, RFID, Concur, eQMS, Regulatory Information management systems (RIMs), visual scanners, and MES, as well as the continued use of cloud computing and big data analytics across all manufacturing support departments to help gather and analyse data to support real-time decision-making. In particular, RIMs provide secure access to real-time regulatory data and visibility across global regions, supporting regulated industries in achieving regulatory compliance throughout a product's life cycle (Kovács, 2020). 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 (McDermott *et al.*, 2022c).

3. Methodology

This study is a qualitative research study completed within a case study organisation – a pharmaceutical company in Ireland. Qualitative research aims to thoroughly understand the problem (Chenail, 2011). The research uses interviews to gather the necessary information for this research. Interviews were selected as a method for this study as it gives the possibility to extensively investigate the subject (Altheide and Johnson, 1994). The open questions allow us to explore topics in-depth and gain more lengthy answers (Frey and Oishi, 1995). Convenience sampling was used to select the interviewees as the interviewees were easily accessible to the researcher (Guest *et al.*, 2006). Consideration was also given to who could provide the best insight and information on the topic of Industry 4.0, and thus a cross-functional set of interviews was chosen (Creswell and Cresswell, 2003). The data for this paper was collected during a mix of online interviews via Microsoft Teams and face-to-face interviews (Salmons, 2011). The participants were informed about the purpose of the study before they agreed to be involved, and the study's ethics were discussed and shared, and an ethics form was signed; anonymity was also promised (Israel and Hay, 2006). Questions were focused on gathering information concerning the adoption of Industry 4.0, its challenges, opportunities, disadvantages, motivating factors, tools, and overall understanding of the concept of Industry 4.0 and were derived from a literature study.

Thirteen participants agreed to take part in the study from various functions such as Quality, Automation, Regulatory, Engineering, Information Technology (IT), Continuous Improvement (CI) and Human Resources (HR) with representatives from various strategic and senior management positions of directors, senior managers, managers, and senior global manager. Of the 13 participants interviewed, coming from the aforementioned cross-functional areas within the Pharma organisation enabled the collection of a wide array of

varying viewpoints depending on how Industry 4.0 was affecting them or involving them in their day-to-day work lives. After 13 interviews, the data was deemed saturated, as no new themes were emerging (Guest *et al.*, 2006). Table 1 represents the questions each interviewee has been asked and their alignment with the RQs. The questions were developed based on the literature reviewed related to Industry 4.0 in general and the pharmaceutical industry in particular.

After gathering the data, analysis commenced utilising ATLAS.ti 23 ^{TM} and trends and themes among the interviewees were analysed. Coding and memoing were utilized to analyse themes (Cascio *et al.*, 2019). Three researchers coded the data, and interrater reliability was measured at 0.9, which confirmed there was no bias and consensus among the raters.

4. Results

All 10 questions were answered extensively, and the participants voiced their opinions and shared their knowledge and thoughts related to the research questions.

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

The opening question was asked to ascertain the interviewees' understanding of the concept of Industry 4.0 and the different levels of it. Depending on their role within the organisation's structure and functional responsibilities, answers varied from general to very informed. The

No.	Question	Research question	Literature source
Q1	How would you describe Industry 4.0 or Pharma 4.0 in layperson's terms?	RQ1	Antony *et al.* (2021a), Chiarini (2021)
Q2	Do you currently have any Pharma Industry 4.0-type projects within the organisation/department/function you work in or with?	RQ2	Gyurjyan *et al.* (2017), Yan *et al.* (2019)
Q3	What are the motivating factors for implementing Industry 4.0 within the Pharma organisation/department/functional area?	RQ1	Reinhardt *et al.* (2020), Yan *et al.* (2019)
Q4	What factors must be considered for the organisation to embrace and adopt Pharma Industry 4.0?	RQ1	Agostini and Nosella (2019), O'Mahony *et al.* (2024)
Q5	What impact will implementing Industry 4.0 have/will have on your site's regulatory compliance?	RQ3	Foley *et al.* (2022), McDermott *et al.* (2022c)
Q6	What are the benefits and opportunities of implementing Industry 4.0, particularly in a Pharma organisation?	RQ1	Sony *et al.* (2021b)
Q7	What are the challenges, disadvantages or barriers when implementing Industry 4.0? Are there any of these specific to Pharma?	RQ2	Machado *et al.* (2019), McDermott *et al.* (2022a)
Q8	What tools of Industry 4.0 might help the specific organisation/function/department that you reside in or are responsible for?	RQ2	Chiarini (2021), Leng *et al.* (2021), Antony *et al.* (2021b)
Q9	Do you have a Lean or Operational Excellence Programme? If so, for how long?	RQ3	Argiyantari *et al.* (2020), Byrne *et al.* (2021), McDermott *et al.* (2022a)
Q10	Do you think Industry 4.0 will aid your Lean Programme?	RQ3	Antony *et al.* (2023a), Foley *et al.* (2022), Kamble *et al.* (2020)

Source(s): Authors' own work

Table 1.
Interview questions

word used most was *"data"*, as 10 participants used it to explain their understanding of the topic. One participant stated, *"what we use here is 'fit for future' or 'fuel for growth'"* (P1). Other phrases used for describing the Industry 4.0 concept were *"interconnectivity"* (P2), *"better decisions"* (P3), *"faster decisions"* (P4), *"evolution"* (P5), *"streamline"* (P6), *"new technology"* (P7), *"informed decisions"* (P9) and *"automation"* (P11). Figure 1 represents the word cloud related to the responses to Question 1.

One interviewee mentioned the fact that Industry 4.0 helps to *"identify opportunities to move forward"* (P10), and another spoke about *"removing the complexity"* (P12) and *"how we do more with less"* (P13).

Q2. Do you currently have Pharma Industry 4.0-type projects within the organisation/ functional area?

Participants were aware of the projects happening across the site, and some interviewees were heavily involved in the project management and implementation. The one mentioned the most was the Electronic Batch Record (EBR); 7 of the 13 participants mentioned it as an example.

EBR is a paperless system that replaces all paper documents with an electronic system. Regulators required that Pharma manufacturers maintain a master batch record (MBR) prescribing the planned manufacture of a product. For each batch that follows the MBR, an electronic batch record (eBR) is produced rather than a traditional paper record (Federal Drug Administration, 2023). The EBR is implemented to prevent human mistakes and simplify the operators' jobs. One participant *said, "That is where we are replacing all the batch records of paper documents with an electronic system. Thus, that, I guess, is part of a technology journey that we are on. It might not be Industry 4.0, but we can eventually connect the EBR to MERP* [Materials Enterprise Resource Planning]. *So, this will simplify goods issues and receipt transactions back and forth. However, we are not connecting the two yet; although it has the capability, we keep the scope pretty narrow because it is a big project. However, when we have it in place, it allows us to expand it to MERP"* (P4).

Four participants mentioned Overall Equipment Effectiveness (OEE), which helps measure equipment effectiveness and performance, identify real-time issues, and populate dashboards. One interviewee described the benefits of OEE tracking and monitoring: *"OEE is your performance, availability and quality metric, and it determines the performance of a line and will help you, kind of, determine what reasons it has stopped. So, if it is down for maintenance or it is down for a breakdown, or if it is down for, I do not know, maybe people going on breaks or something like that, then that is another good way of integrating a real-time platform with all that data. So that is being currently rolled out as well."*(P6).

Figure 1.
Word cloud

Source(s): Authors' own

Another Industry 4.0 project being depleted is Open System Interconnection – Plant Information (OSI – PI), which six people mentioned. One interviewee described the project as *"OSI-PI is an enabler for digital uplift, bringing data up from the shop floor into a system where it can be viewed, understood, and driven into something transformational. So once the data is there, it can be used to trend display either in live web host displays or to generate reports that get emailed or printed. This brings us to the advanced part of Industry 4.0, which is more autonomous systems where they make decisions to increase throughput, quality, et cetera, et cetera. So, we are in the early phase of the implementation of OSIPI, but that system allows us to bring us to the full evolution of industry 4.0"* (P12).

The FDA promote the Process Analytical Technology or PAT framework to encourage the voluntary development and implementation of innovative pharmaceutical development, manufacturing and quality assurance (Center for Drug Evaluation and Research, 2020). To this end, Pharma manufacturers have adopted machine learning (ML) with analytical sensor systems and artificial neural networks (ANNs) for process monitoring and control purposes in upstream and downstream manufacturing steps and direct compression of tablets (Nagy *et al.*, 2022). One interviewee talked about a manufacturing project on the direct compression of tablets (e.g. how Aspirin can be manufactured), stating, *"So with direct compression, you will not granulate. You will simply mix and compress so granulation will be complete, you know, eliminated, and this is where Industry 4.0 technology will be playing a big picture in this in our site going forward"* (P9).

Another interviewee spoke about Power BI, an interactive data visualisation software product developed by Microsoft with a primary focus on business intelligence, saying: *"we now have a Power BI which is complete digitalization in line with Industry 4.0. Basically, what happens in operations, for example, if you are in packaging, at each shift, the packaging f*ront Line Leader *updates what we have made. It automatically transfers into that Power BI report, which helps you analyze your performances"* (P11). Another software system, Solvace, described as Operational Excellence in real-time, was mentioned as it enables improving decision-making processes with real-time data. It enables the organisation to gather metrics, display data and attach pictures for clear understanding. One participant explained it: *"Solvace is more of a display system. So, we collate our data under EHS, quality, and customer service. It is a dashboard that collates the data for us. We have moved from a manual board on the wall to a digital display"* (P8).

Other manufacturing type enhancements were the potential use of Automated Guided Vehicles (AGV) and Autonomous Mobile Robots (AMR), with one interviewee stating, *"we are now just about to launch into an automated guided vehicle program for movement of materials from warehouse"* (P9).

Overall, the site does not have a plan everyone would know about. One interviewee stated, *"So I think if you were to ask me do we have an Industry 4.0 delivery road map that we are following, I would say the answer is probably no!. But ask me if we on that journey and doing "pockets" of it? Yes, we are!. I think we recognize that it is a gap. There is a new automation manager, and I would expect now that he is in his role it there will be momentum this year" (*P4) while another confirmed the status quo stating, *"We are still developing our road map"* (P1) and one more saying, *"we are actively meeting on digitalization and Industry 4.0 and looking for ideas and new initiatives that we can use"* (P3).

Q3. What are the motivating factors for adopting Industry 4.0 within the organisation/department/functional area?

The participants had similar perceptions of the motivating factors highlighting the *"simplification", "visibility", "traceability", transparency", "efficiency", "compliance", productivity", "informed decisions", "manufacturing the product right first time", "shortening the lead times"*.

One interviewee also mentioned competitiveness as a motivating factor stating, *"It is about being ahead of the curve of all the time, and also it is a mechanism for making sure that you are latching on to something which keeps you from going out of date, you know, and becoming a dinosaur. Because many manufacturing factories fall prey to this, where we will keep on running"* (P4). Another interviewee stated that one of the purposes of implementing Industry 4.0 would be *"to improve our regulatory compliance from the data integrity point of view and an ALCOA* [Attributable, Legible, Contemporaneous, Original, Accurate an FDA data integrity and compliance standard] *point of view"* (P5). Table 2 presents other statements made by the interviewees.

Q4. What factors would need to be considered for the organisation to embrace and adopt Pharma Industry 4.0 within the Pharma organisation/ department/functional area?

Many factors were spoken of. Seven interviewees were concerned about people's capability as the factory *"was built to be manual"* (P1) over 30 years ago, and that is how it is being operated to date in many areas. For instance, one of the participants said, *"You know, in terms of our technicians, like as we upgrade our lines, it becomes less something that you fix with a spanner and more something that you fix with a laptop. So, it is a whole skill of the people,"* while others similarly stated, *"So your stakeholders are important, and you need to consider your stakeholders and see where their mind is at in terms of progress and the use of digital software and tools", "You know it is not something that traditionally we would have had through our college programs even though now it is starting, right. So, you need to, I suppose, have a want and a desire to use that technology and have people capable of using it you now"* (P11).

Another factor that was spoken of was the equipment being old; *"so you need to have an IT infrastructure capable of supporting these larger and larger volumes of data", and* "[you need] *that level of automation in your current manufacturing environment*" which raised the questions like *"Is your company set up for it? Have you the network setup for it?"* The last factor that six interviewees highlighted was the cost and the return on investment.

Q5. Do you think the implementation of Industry 4.0 will have or had a positive or negative impact on regulatory compliance?

All participants agreed that the implementation of Industry 4.0 would have a positive impact on regulatory compliance thanks to *"using less human interaction"* (P2) and the fact that *"Industry 4.0 drives data integrity"* (P4) and *"It gives regulators confidence that you are following a defined criterion"* (P5). It was also pointed out that *"the regulators are looking for large sites like* [us] *to move more into the computer and digital space rather than remaining in the paper-based system where there is a lot more data integrity traps, gaps, etcetera*" (P6) with 4 of the interviewees (P2, 4, 6 and 9) praising the EBR saying *"I mean it is got built-in fail saves*

"So, if you look at the electronic batch records, it is updated as you go, and so, there is no signing, and then from a quality point of view, everything is green (on the screen). You know no further actions are required; it is green. It is just reviewing the greens. Moreover, if there are no reds in it, you just press approve and off it goes. So, it cuts out a large number of days in terms of reviewing documentation."(P3)

"I said it again, and I will say it until I am, I suppose, retired. It is a simplification. So, it is how do we remove complexity? How do we make it easier to do our jobs? So, like that simple example of complaints and data and pulling data seven days to manipulate data, we have a system. And, if we worked that system properly, it could take us less than an hour to do the same job. That is some difference. So instead of manipulating data for seven days, you have a person working on the improvement for seven days, and actually, you will start to see the cogs turned then. So that is what drives me."(P10)

Table 2. Motivating factors for Industry 4.0 deployment

Source(s): Authors' own work

like. (. . .) You cannot skip steps", "operator error will be reduced". One interviewee stated that regulators are already *"hiring in that knowledge".* Another one stated that *"we should get excited about the potential of never needing to be audited again, right. (. . .) Imagine the auditors being able to access that* [data] *remotely."* However, two interviewees have voiced their concerns stating that *"the more information that's there, the more damning if something goes wrong. The more information is there to damn you as well,"* and *"the only concern I would have on it, and I have seen it before, is that the regulators, the more you give them, the more they want"* (P13). Table 3 expands on the statements on the impact of Industry 4.0 on Regulatory compliance.

Q6. What do you see as the benefits and opportunities of implementing Pharma Industry 4.0?

What most of the participants view as a benefit is the *"increased productivity", "visibility", "interconnectivity", "better decisions", "reliability", "consistency", "financial benefit", "ease of access to data", "less waste", "removal of the complexity", "speed", "data at your fingertips", "less opportunity for error", "cost reduction", "compliance" and "traceability".* One interviewee stated, *"So I think one of the key benefits is* to *get rid of all these duplicate versions of data. Have one single source of the truth"* (P8), with another one saying, *"If we can visualize and understand with data what our process fail looks like. (. . .) If we could understand where our pain points are then that could be a huge benefit"* (P9).

Moreover, one interviewee shined a light on why the company made a big improvement a few years prior by saying, *"So at a meeting a few years ago MERP had come in for* [company name] *at the time the [company name] CEO was at a meeting and that CEO for was able to pull up exactly how much product they had and where he had it in the world. And the CEO for [company name] was asked the same question, and it took him three weeks to get the documentation/data. So, that is why he implemented MERP. So, you have greater visibility."* Table 4 presents more statements on benefits and opportunities.

"If you are talking about a Regulatory Compliance impact perspective, that does not come into the equation. None of what we are doing will impact any of that. You are making the product so that it is less likely to have a quality impact. I suppose one of the key things that can be said about Industry 4.0, I suppose, is that you reduce the amount of risks by taking out human error. So, by automating these processes and having these systems talk to each other over the network as opposed to having people manually enter values, you reduce the risk of error. So, on reflection, this improvement positively impacts compliance." (P1)

"From the perspective of the Pharma or heavily regulated industries, the big challenge would be the speed at which you can roll Industry 4.0 out. Because any change you make to a system would have to be validated, or you have to ensure that you are not impacting a validated system when rolling it out." (P5)

"I think EBR is maybe an example of where we put in a system to try and help improve compliance. So today, as you know, right, you get a batch manufacturing record where you have all the paper, and you know, you follow the paper in sequence, and you fill it out as you go. Now if somebody chooses to, they do not need to be contemporaneous in how they fill it out. Everybody should be Attributable, Legible, Contemporaneous, Original and Accurate (ALCOA) compliant. But in reality, when you finish the paper document, nobody knows the sequence you filled it out in. When you put in an EBR, EBR steps you down in a sequence. So, it will say do this, and then you do that, and then it will say do this, or it will say do a group of things. And so, from an ALCOA point of view, it helps" (P7)

"But the regulators have already embraced Industry 4.0, and even that is reflected in the training of and the types of personnel that they are hiring. They are hiring in the knowledge that we are in an Industry 4.0 environment. Thus, with them, they are coming to audit us, and some of those auditors are even well ahead of us in their knowledge. Moreover, we are worried about what are they asking.So, this is not a new adventure; some industries are much further ahead than others. We in this company are behind the curve and must catch up." (P11)

Source(s): Authors' own work

Table 3. Impact of Industry 4.0 on regulatory compliance

"We have people that are managing Excel spreadsheets and stuff like that we do not need them doing. The data is there in the system. We just do not know how to mind it back out."(P1)
And I think that is where Quality and Regulatory will shift to a new paradigm, not being reactive in quality, saying, OK, we ran the batch, but we had an issue. It is kind of turning it around and saying, OK, what can we forecast now based on the results we see from this run ?Is there anything across that trend pattern we can see? We can't do that at the moment. We can, but it means bringing all that data and putting it somewhere in Excel or something like that. We are going to have this online at our fingertips."(P2)
"The data can only improve the decision-making. And it should allow decisions to be made quicker. So, you know, systems can analyze data quicker than humans. You know, I think we should make better decisions in a timely fashion and be more pre-empt failures before they occur."(P4)
"So, the benefit is the speed and the data at your fingertips. Reviewing the trend that the system is telling me as opposed to putting the trend together and working on the improvement, working with the people, working on the process, and not sitting at your table doing up trends and pulling data and pulling your hair out. So, lots of benefits."(P11)
"Like you know, we always do, you know, raw material testing when it comes on site like that. I probably take a good bet that the supplier has also done his, you know, ID[identification]*testing and everything else and stuff like that. So why can't we use their data to remove that step from our process? And your point is correct, how does granulate from supplier A, how does that perform in our granulators and the rest of our equipment compared to supplier B and things like that, right."* (P8)
Source(s): Authors' own work

Table 4.
Benefits and opportunities of Industry 4.0

Q7. What are the challenges, disadvantages or barriers when implementing Industry 4.0? Are any of these specific to a Pharma-type organisation?

Eight out of thirteen participants mentioned *"cost"* as the main barrier. Other statements included *"downtime"*, *"business case"*, *"resistance to change"*, *"fear of change among employees"*, *"mindset"*, "*scepticism about new toys*", *"culture"*, and the fact that "*people do not like change"*, and *"people are frightened of change"*. One person spoke about change stating, *"Working with your people and getting them on board. And it is the whole change element. Some people don't like change, and it takes a bit of time to work with them and work through it"* (P2).

One interviewee used a description, *"So people do not know what they do not know"* (P1) regarding the challenge of knowledge and data collection, while others asked the questions *", Do you know your process? And what do you need? What data is available, how it flows, the timelines of it, etcetera."* (P3). Another interviewee said, *"So it is like if we're running 24/7, when are you supposed to implement these updates, you know. So that is one of the big challenges here, it is downtime."* (P13).

Many interviewees also highlighted *obsolescence: "So many of our systems are quite old. So, they cannot currently connect to anything else. So, they will require system upgrades"* (P7), *"So, if you are in an aged facility, your old IT infrastructure may not be capable anymore. It is not just that shop floor level, which is all the systems after that, the hierarchy, the architecture may need to change"* (P10). Table 5 presents more statements on challenges, disadvantages and barriers.

Q8. What tools of Industry 4.0 do you think might help the organisation/department/functional area that you are involved in or responsible for?

Cybersecurity was the tool that was mentioned the most, as six people used it in their statements. Much work is happening around the subject and the security system on site. Four participants mentioned mobile technologies, with one stating that they already use them on-site. Three interviewees also spoke of cloud computing. Digital twins were mentioned by one interviewee stating, *"I think, you know, application of digital twins is*

"So, we have people who understand the business but maybe do not understand the technology that could improve the business. And then similarly, we have some very good technical people, but maybe do not understand the business, so." (P1)
"Because quite often we end up with staff who are not, you know, technology literate as they should be as we emerge in a manufacturing world which is getting highly, highly, highly automated, and extremely efficient. Then if our people are not being educated to follow that, it is very hard for us to ever be competitive in the future because we will be way out of date." (P4)
You know we are quite weak in the area of technology. We do not have a strong technology infrastructure, as you probably observe yourself. It is very weak that needs an awful lot of work. So I think we would have to define a standard to meet even before looking at Industry 4.0. Before we start, because we are not even at the right, the basic level, you know, in terms of our capability. So, I think we need to do an enabling work to get us there, and then you can say: OK, from there, now we can leap off. So that would be it." (P12)
"I think across the board that should be the case that the systems we put in need to enable compliance by default. As opposed to the other way around, that we put in systems and then we have to make the systems complicated because we need them to be compliant" (P9)
Source(s): Authors' own work

Table 5. Challenges, disadvantages and barriers to Industry 4.0 comments

something that we need to sort of embrace more than we do. It's like can we understand our processes? Can we twin our processes? And you know, how can we drive an improvement with a twin rather than trying out on the real thing" (P5). Other tools mentioned were big data and the internet of Things (IoT), with two contradicting opinions on it; *"data analytics and IoT, they are things that I think we can leverage off "* (P3) and *"Internet of Things and RFID – they do not apply really"* (P5).

There was some misunderstanding regarding 3D printing usage as some of the interviewees stated that it does not apply on-site; *"3D I think it would be good, but our machines are so old it would be difficult"* (P1), another interviewee stated "t*hat we do not use it, but we could. 3D printing is something that's in place in* [company name]*, but not in our site. And there is an opportunity there for us"* (P3). Another interviewee stated that we already use *"3D printing - they are using that at the moment in engineering for spare parts. So, they are looking at the options to print seals and certain things like gears and stuff from 3D printing, which works well. I have not had many dealings with it, but I have heard about it, and this is supposed to be cool."* (P6).

Another tool that interviewees had contradicting opinions on was Artificial Intelligence (AI), with one person saying, *"AI - not really, I suppose we could use … you would need cognitive computing and AI in somewhere like* Stryker [medical device company name]*, where you are making a really small sensitive medical device. However, here, not so much"* (P3), as opposed to another interviewee stating, *"I will say artificial intelligence will be a big, big tool for us on-site"* (P8).

The last one participant had different opinions on Advanced Robotics (Cobots). In comparison, some participants said, *"Advanced Robotics. Yes, I think there could be something in that. So not necessarily advanced robotics but robotics, using cobots could be very useful in this type of manufacturing organization here"* (P2) *"Robotics, yes. We have case packers, robotics at the end of our lines, etc. But as you know, Automated Guided Vehicles (AGV) is also a form of robotics, right? You know, where we have these things, transporting materials, etcetera, around the organization. So, I am going to say there are probably other areas like that, that, in future, could be big drivers for the organization reducing kind of non-value add activities or, you know, where we can get more focus on delivering the products, etc., and things like that"* (P7), two other interviewees stated, *"Advanced robotics – It does not apply here really, like cobots"* (P1) and *"We looked at cobots but could not make a business case for them"* (P3).

Furthermore, one of the participants said, *"The other important thing is having some sort of end state in mind about where we are going. Because the challenge with a lot of the Industry 4.0 programs is that we just keep adding one on. We add one on, we add another one on, and we do not stand back and understand what this end-state ecosystem will look like. How are these different solutions going to talk to each other, going to communicate"* (P11), which was confirmed by a statement of another one: *"If you do not control what you are doing, what you are rolling out, you end up creating so much complexity that is not adding the value anymore, it is just making things more complicated"* (P12).

Q9. Do you have a Lean Program? If so, for how long?

There was a clear understanding of the Lean program being present on-site. However, each interviewee was asked how long the Lean program was in place as it was not as embedded or deployed in some functional support areas as in others. Every interviewee was aware of the new relaunch of the Lean program recently in the organisation. Some interviewee has discussed the history of lean on-site and its previous incarnations. Table 6 describes more statements regarding Lean on site.

One participant talked about Lean in detail: *"Lean aids quality. It should not be an add-on to your everyday. Lean needs to be a way of working so anyone in any job, whether I am making the coffee in the canteen and I need to be able to use Lean principles to do it the most efficient way I can do it to save time for me, to save time for people and just have the less complicated job. So, Industry 4.0 can remove the complexities. But nobody or nothing can remove all complexities of this site. There are 934 people on this site, and every single person needs to have the mindset that we can all do that. And it is the only way we will make a huge change, not by just implementing Industry 4.0"* (P3). Lastly, another interviewee voiced their concern about their Lean program stating, *"What it (the program) does not do very well is it does not integrate digital into (Lean) it very well. Lean is very, very people-centric"* (P12).

Q10. Do you think Industry 4.0 will aid your Lean Program?

The participants were unanimous about the positive outcome or influence of Industry 4.0 on the Lean program saying *"absolutely", "no doubts whatsoever", "100% will aid", "I would see Industry 4.0 being a big piece of that", "they would go hand in hand"* (P1 to 13). There was no hesitance when the question was asked. There were clear indications as to what approach the organisation should take to ensure the site can benefit from it and not squander the effort. These comments are outlined in Table 7.

"Yes, we have a Lean program. It was called the XPS, the X [company name] production system. It has now called [company name] Performance System. And it is adopted by Toyota and different industries across the pharmaceutical world. So, we had a study about 10 years ago and came up with the [company name] production system. And we have evolved. And it is a way of looking at our waste and identifying opportunities to drive performance. One important application has been waste elimination and lean-ing our changeovers through observation and analysis and SMED [single Minute Exchange of Die] *activities"* (P5)
"So yes, we do have a Lean program. We started our Lean program somewhere around 2000. It started at that time as an operational excellence program where we trained people, and it was an external consortium that we brought in to train people. We created Black Belts; we created Master Black Belts, and they were trained in Lean and Six Sigma. And then, eventually, we simplified it into XPS. And it was based on Lean, Zero defects, zero waste, and zero accidents. And now again, we are more moving towards more Lean and the XPS because that is what our industry needs" (P6)
"Certainly, we do. I am trying to think how long have we been looking at Lean. We have had it in some form, I would say, for 15 to 20 years at least" (P7)

Table 6.
Statements on lean program deployment

Source(s): Authors' own work

We went to a company in Prague when I was at [previous position]. *And this company was a lean company that married digital solutions to lean. So, their idea was that you must be Lean first. So, you Lean your process first, and then you digitize it. Too many salesmen will come to you and say, 'I have a solution. Put this in place, and your process will be lean.' You have to use, you know, tools like value stream mapping* [VSM] *and all of the other lean tools to make your process lean. And then, you put a digital solution on top. Otherwise, you have got an inefficient digital solution because all you are doing is digitizing the waste that already exists today. I think Industry 4.0 will help the Lean program. But we need to be lean before we digitize this kind of mantra, yeah"* (P9)
"It is just very important to me that we do not consider all of the Industry 4.0 toys, and we do not just think, 'Oh, we just need those toys to make us lean, we need those toys to give us data integrity.' That is not really how we want to work at all. We do want to take ourselves forward and get to the point of machine learning, AI. We do not need AI across all of our lines. We don't need machine learning on all of our vision systems. I worked for another company before I joined here, and the site drive was, 'this is going to be the factory of the future. So, we're going to have all of these toys.' That was the driver. And it is very, very hard work if you are just trying to fit toys (sic . . . technologies) in. If you're just fitting them, then you've completely missed the point of the technology. It is really important to start that digital journey, but it is important to start for the right reasons so that cultural transformation happens" (P7)
"I would say that a lot of what Industry 4.0 does is it drives the Lean programs to some extent. You know, I mean, you do not need to have technology in a Lean program. But I think the implementation of some technologies assist the lean program" (P2)
"The whole Lean program and, I suppose, business process transformation go hand in hand with any transformation. Be it digital transformation or process transformation, or anything like that. My experience from outside this organization is that sites or organizations that have just brought the technology in either have not involved their Lean team or have not looked to change their process and have struggled to adopt the technologies. So, I love this question; it is an important factor for me to adopt Lean first" (P3)
Source(s): Authors' own work

Table 7.
Impact of Industry 4.0 on lean and operational excellence

5. Discussion

The research was specific to the readiness for Pharma Industry 4.0 and how it is being deployed in a case study pharmaceutical manufacturer.

In terms of RQ1 assessing the knowledge level for and awareness of Pharma Industry 4.0 in terms of the concept and its deployment within the case study site, overall knowledge and awareness were strong across all participating functions. The responses to Questions 1, 3, 4 and 6 aligned with RQ1 and demonstrated a high level of knowledge and awareness of the purpose of the Industry 4.0 projects in the case study organisation and an understanding of ongoing projects. As the interviewees were from various departments and had diverse backgrounds, the researcher could collate unique points of view and assorted levels of knowledge about the concept of Industry 4.0. However, despite having a good knowledge of ongoing projects related to Industry 4.0, some participants did not know what Industry 4.0 was or what it stood for when initially asked to participate in the research. A lack of understanding of what Industry 4.0 or what digitisation is and how it aligns with an organisation is a recognised struggle faced by many organisations (Grzybowska and Łupicka, 2017). The knowledge of the definition was not prominent even if the participant was involved in a project that fell under the umbrella of Industry 4.0. Many studies have highlighted that employee involvement and communication are key to driving a digitalisation strategy, and this organisation's employees are aligned with the *strategy* (albeit it perhaps not a well-defined one) and what the projects being deployed will do for them (Antony *et al.*, 2023b). An overwhelming number of participants identified or associated Industry 4.0 with data. During the interviews, all participants reiterated their confidence that data was a big part of that concept. It is believed that data, when collected and used properly, will have a major impact on the organisation's decisions and the way those decisions are made, including the pace (Antony *et al.*, 2021a, b, c, d; McDermott *et al.*, 2022c). Moreover, data will help build trends and dashboards and make it possible to go back and

check it anytime. Much of the literature related to Quality 4.0 and the quality benefits of digitalisation have discussed how more detailed and better data can aid in the role of a quality manager and in improving root cause and corrective actions (Antony *et al.*, 2021a, b, c, d, 2023a, b). Most interviewees associate Industry 4.0 with new technologies that will inevitably arrive on-site and their subsequent interconnectivity, which is seen as a significant contributory factor to the development of Industry 4.0.

RQ2 was to investigate how ready and progressed the case study site was for Pharma Industry 4.0. Several projects were implemented and underway in digitalisation, but none of the respondents cited having a clear strategy or what was referred to as "*joined up thinking*". The interviewees have mentioned many times that the site was behind others both in their own multinational corporation and being behind previous sites that they have worked with, and it will take years to catch up. Antony *et al.* (2021a, b, c, d) discussed the concept of "early versus late adopters" of Industry 4.0. Many interviewees in this study felt that they were later in their adoption of Industry 4.0 than other Pharma organisations but that they were further along than non-Pharma organisations. This sentiment echoed Antony *et al.*'s study about later adopters adopting a "wait and see" approach before adopting new technologies. Many interviewees mentioned that the equipment is composed of old standalone pieces and systems. Therefore, it will be difficult to connect them, and some may need major upgrades. These upgrades will cost time and money, and it can be difficult to gain management approval for the investment. Integrating older and legacy systems and managing the transition can be another obstacle when introducing new technologies (Chiarini, 2021). Participants pointed out that most of the workplaces run 24/7 and complained that they are not given time for the upgrades. Studies on the critical success factors for implementing Industry 4.0 have cited that lack of investment in new technology, allocation of appropriate resources, and time for project deployment has affected Industry 4.0 success in an organisation (Sony *et al.*, 2021a). Other studies have cited waiting approval for management funding of these programs as taking months and years in some cases (Foley *et al.*, 2022; McDermott *et al.*, 2022c).

One of the most spoken-about aspects regarding Industry 4.0 was the EBR. Many in the Pharma site know of this project and see it as one of the first steps into the plants future digitalisation. Replacing paper documents with electronic ones is an organisational priority that is being seen as an opportunity to prevent errors. OEE reporting and tracking enhancements via data analytics and dashboards was another well-known project to aid productivity and OEE improvements. The access to data at one's fingertips is a strategic direction the organisation is moving forward in via the use of big data and data analytics. Lack of data, the wrong data, difficult to analyse data, non-real-time data availability and no visibility to data is a key benefit that Industry 4.0 delivers (Antony *et al.*, 2023a, b).

Participants spoke about the many motivating factors and the new technology associated with data, simplification and traceability (Antony *et al.*, 2021b). Moreover, the interviewees emphasized the improvement in the decision-making processes as data delivers facts, trends, dashboards and all sorts of visuals and will enable the site to be proactive rather than reactive.

The third RQ was to investigate the effect of Pharma Industry 4.0 on the case study organisations' regulatory compliance in different global regulatory and legal jurisdictions and its effect on enhancing site Operational Excellence. Regarding the regulatory compliance benefits of Industry 4.0, there was a consensus that the digitalisation projects would error-proof many manufacturing process elements and, in effect, remove human error. As previously mentioned Foley *et al.* (2022) found similar results when they implemented a site-wide digitalisation project in an Irish Medtech organisation and reduced defects as well as being able to error proof their regulatory processes. Some of the projects mentioned by the responders were seen to have enabled better data collection, traceability and accuracy, thus

enhancing records collection for regulatory and quality purposes. Many interviewees stressed the importance of the new technologies from the regulatory perspective as the regulators are legislating and looking for the Pharma industry to move forward with the times. It was mentioned that the future entails digital and remote audits rather than physical ones. Global regulatory authorities including the American FDA are promoting a strategy of remote audits, increased digitalisation in manufacturing processes and improved operational excellence via digitalisation (CDRH, 2020; Center for Device Regulations, 2022; FDA CDRH, 2017; McDermott *et al.*, 2022b).

There was a mixed response in terms of Operational Excellence effects from Industry 4.0 in the case study site. Some interviewees felt the organisation has a strong Lean program, having first deployed LSS nearly 20 years ago. However, the interviewees did feel that if an organisation does not have a foundation in Lean or Lean processes, Industry 4.0 projects implementation is futile. Implementing Industry 4.0 will not aid "Leanness" if "Leanness" were not already there and would only digitise or perhaps automate the waste. There was no doubt that the implementation of Industry 4.0 would support the lean program and that they would collaborate and complement each other. These views are very much in line with studies by Antony *et al.* (2023a), Buer *et al.* (2018) and Kamble *et al.* (2020) that Lean has a synergy to Industry 4.0. The example of the Site Improvement Plan (SIP) (or site Lean program) that is currently taking place was mentioned, which aids in simplification of the processes while removing the complexity. This project was deemed an example of how the EBR project with the SIP project would facilitate removing non-value adding steps that align with lean principles. Overall the interviewees found digitalisation and going "paperless" was positive for the environment and sustainability practices which echoes many similar case studies in the literature on digitalisation (Belhadi *et al.*, 2021; Duarte and McDermott, 2024). However, this opinion contradicted the Chiarini *et al.* (2020) study of digitalisation in Italian manufacturers where they didn't find a huge environmental benefit from digitalisation programs.

In summary, this research clearly demonstrates that the case study Pharma site has started to change very recently compared to other organisations in terms of Industry 4.0 deployment and is perceived as perhaps a late adopter behind other sites. However, there was a positive side to this in that taking the "*first to be second*" approach mentioned in the introduction enabled the site to benchmark and learn from others. As highlighted by Antony *et al.* (2021a, b, c, d), this will prevent the site from making the mistakes others have faced through early adoption of technologies and has enabled a preparedness for Industry 4.0 within the Pharma site. The site has operated in the Industry 2.0 and 3.0 paradigm for decades. This meant hundreds of signatures, tonnes of paperwork, and hundreds of thousands of boxes to be archived offsite but are now utilising paperless systems, data visualisation boards, and embracing new technologies to move into Industry 4.0.

6. Conclusion

This study demonstrated the knowledge of Pharma Industry 4.0, the readiness for it, the current state of adoption of Industry 4.0, as well as the benefits and critical success factors for its implementation. In terms of the effect of Industry 4.0 on operational excellence and regulatory compliance, digitalisation was seen as positive. However, in terms of operational excellence, an organisation should be Lean first before it is digitalised.

This study is limited because it is a single-site case study, and the generalisation of the findings may be questioned. However, as this site is a large enterprise and representative of the large Pharma industry of global multinationals in Ireland, this study has global applicability and value.

This study has both practical and theoretical implications; it gives an insight into the organisational specific challenges and journey to Industry 4.0 deployment within a single multinational manufacturers site enabling benchmarking of the study and practical insights for those hoping to adopt these technologies.

From a theoretical viewpoint, this study adds to the literature on how digitalisation can impact Pharma in particular. While there are individual case studies of digitalisation technologies in Pharma, this study looks at the digitalisation strategy and readiness of the organisation as a whole.

Also from a social implications viewpoint, the study demonstrates the value of how enhanced digitalisation can improve a site's productivity quality and traceability, thus ensuring jobs are safe and the public is provided with safe products. Thus, as one of the first studies specific to Industry 4.0 readiness within the Irish Pharma industry, the study has implications for pharma sites to benchmark lessons learned from this case study.

Future research would be to carry out a more longitudinal study on this site to assess its Industry 4.0 program and its success or failure in the deployment of Industry 4.0. Also, further multi-site case studies within the case study organisational sites and across other organisations would provide a useful understanding of Industry 4.0, particularly the pharmaceutical industry.

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