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Publication Date	2022-02-17
Publication information	Trubetskaya, Anna, Manto, Declan, & McDermott, Olivia. (2022). A Review of Lean Adoption in the Irish MedTech Industry. Processes, 10(2), 391-396. doi:10.3390/pr10020391
Publisher	MDPI
Link to publisher's version	https://doi.org/10.3390/pr10020391
Item record	http://hdl.handle.net/10379/17257

Review

A Review of Lean Adoption in the Irish MedTech Industry

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Abstract: There have been many literature reviews carried out on Lean implementation in larger organisations with specific focus on the automobile industry. Lean implementation in the medical device industry has not been extensively investigated. Thus, this research endeavored to analyse the benefits of Lean, tools utilised and challenges and results of Lean implementation in Medtech companies. This article aims to bridge a gap in the literature by reviewing the literature that discusses Lean implementation in MedTech companies in Ireland with a perspective of identifying the benefits and challenges faced. The quantitative methodology allows us to review the comprehensive numbers and data which were collected from 20 Enterprise Ireland MedTech case studies. There are very few published case studies in the literature on Lean due to the highly regulated nature of MedTech sector and the vast array of medical devices, which are often under privacy and confidentiality constraints. The results showed that integration of Lean has brought benefits to companies by increasing productivity and product quality, optimised cost, and time. An inclusive discussion of Lean tools for Lean implementation within MedTech was established and suggestions for future research orientations are thus provided.

Keywords: Lean; medical device industry; Ireland; supply chain management

Citation: Trubetskaya, A.; Manto, D.; McDermott, O. A Review of Lean Adoption in the Irish MedTech Industry. *Processes* **2022**, *10*, 391. <https://doi.org/10.3390/pr10020391>

Academic Editor: Pietro Bartocci

Received: 1 February 2022

Accepted: 14 February 2022

Published: 17 February 2022

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1. Introduction

Various industries have seen, over recent decades, massive improvements to manufacturing processes due to the application of the Lean methodologies [1]. Heavily regulated industries such as medical technology (MedTech) and Pharmaceutical Manufacturing have been slow to adopt and implement Lean strategies [2]. In the medical device and pharmaceutical industries, which are highly regulated to assure patient and customer safety, continuous improvement programs can face many challenges [3]. Due to the regulated nature of the industries, medical device manufacturing focuses on quality, and for good reason, though this means little time is left to remove the sources of waste. It is critically important to have all released products be 100% compliant with all specifications and understand all factors which have a strong impact on the improvement of Lean strategies in MedTech to remain a competitive industry [4].

Ireland has gained tremendously from this high-growth industry and currently employs over 40,000 people within this sector [5]. Ireland has been identified as a desirable location for MedTech companies as 9 of the world's top 10 MedTech companies have located their manufacturing facilities here [6]. Ireland is seen as a high-cost manufacturing location mainly driven by high cost of labour, property, transportation, and utilities [7]. Despite all of this, Ireland is globally recognised as being competitive in a range of sectors including food, medical devices, pharma/biopharma, ICT, engineering, and green technologies [8]. Due to the thriving success of the MedTech industry, organisations in Ireland are increasingly transitioning to the adoption and deployment of Lean methodologies with the objective of driving new and innovative technology, delivering on new product development, and looking to improve operational efficiency and product quality [9]. The

MedTech companies based in Ireland are hugely reliant on large multinational enterprises and form part of a vast network of suppliers who provide products and services to these customers. Irish-owned companies in Ireland are considerably smaller in terms of scale and the higher proportion of exports is delivered by foreign enterprises, which requires the development of a supply chain network that is different from other EU countries. The MedTech network in Ireland very often uses the contract manufacturing business model, in which a medical device company outsources partial or entire manufacturing of their medical device or services to another company with specialised knowledge and technical expertise. The customer constantly demands excellent operational performance from MedTech. Therefore, the survival of MedTech in this competitive environment strongly depends on the continuous improvement of the operational performance [10]. The roots of continuous improvement methods such as Lean did not originate within the MedTech industry. The automotive industry is responsible for the birth of Lean production. Henry Ford revolutionised this industry by focusing on interchangeable parts and implementing the first moving assembly line. The primary goal of Lean is to eliminate or reduce waste, with waste being anything that adds no value in the eyes of customers. Womack et al. (1990) defined Lean thinking as “a way to do more with less and less human effort, less equipment, less time, and less space while coming closer to providing customers with what they want” [11]. Principles of Lean are adding value, creating flow, and establishing pull in pursuit of continuous improvement and putting the customer first [12,13]. Lean focuses on non-value-added waste elimination, including the seven waste types of transport, inventory, motion, waiting, over-production, over-processing, and defects, which is particularly vital in helping add value and improving flow in an operation [14]. The success of Lean integration strongly depends on the selection of tools. One of the Lean tools is a value stream map (VSM) that shows the steps of the workflow process and further can help to identify and eliminate the Non-Value Add (NVA) and reduce delays. This supports the quality improvement of product and services. Creating a continuous flow to the customer would play a significant role in optimising the process efficiency by enabling a continuous flow of the product and services [10]. Various other lean tools may include; Kaizen, which emphasises continuous improvements by focusing on the minor improvements; Just-in-time, which meets the customer demands that flow from the customer; SMED, which minimises the changeover time; Poka-Yoke, which issues alerts on failures and defects; Jidoka, which ceases the production or assembly line during defect; Gemba, seeing the problem at the source; and Kanban, which manages the inventory levels [15]. All of these tools would ensure that the Lean approach reduces the cycle time of the business process, improves the service delivery or product time, reduces the inventory levels and defect generation chances, and optimises resource utilisation.

There are many Lean tools, which can be grouped into sections: waste minimisation, flow improvement tools, and new layouts. The selection of tools strongly depends on the desired improvements from basic work to entire line engineering and includes the following tools (Table 1).

Table 1. Lean tools (author constructed).

Lean Tools	Description
Waste minimisation tools	Many forms, e.g., inventory, waiting, over-processing
Value Stream Mapping	A map of the entire value chain, identifying all the activities involved in the product from start to finish
Value-added analysis	Identify value in the eyes of the customer and categorise into value added, non-value added, and non-value by required
5S house keeping	Tool to organise a workplace, establish standardised conditions, and maintain the discipline that is needed to do this job.
Flow improvement tools	Allowing customer to pull value when needed.
One-piece flow	Work-in-progress eliminated, allowing flow through the value chain.

Kanbans	Signal to internal processes to provide a product. Used with pull systems.
Pull production	Manufacture of product as customer wants it.
Total Productive Maintenance	Machinery performing with zero breakdowns and high quality.
Poka-yoke (error proofing)	A mistake-proofing procedure or device designed to prevent or detect errors.
Single Minute exchange of Dies (SMED)	A series of technologies to allow for rapid changeovers of production machinery.
Just in Time principles	Producing and delivering the right items in the right time in the right amounts
Layout improvements	Can range from basic work step improvements to entire line reengineering.
Flow charts	Graphical representation of process sequences.
Line balancing	Alignment of work steps aiming to minimise process delays and fluctuations with production levels.

Aside from the fact that Lean systems (LS) did not originate within the MedTech industry, this sector operates under a very stringent regulatory regime to ensure that its products are safe to use on their customers, many of whom are based in healthcare settings [16]. Globally regulatory bodies such as the European Medicine Agency (EMA) and the US Food and Drug Administration (FDA) amongst studies place stringent requirements on MedTech companies to ensure product safety in the design, manufacture, and use of medical devices. Depending on what countries a MedTech company exports to, the company may have to meet the regulatory requirements of several global jurisdictions. An Irish manufacturer exporting into the USA and Europe must adhere to both the FDA and EMA regulatory requirements. A robust and detailed Quality Management System (QMS) must be maintained within any company operating under these regulatory requirements. This is, of course, beneficial for a company to work towards these requirements and achieve the standards set out by global regulatory agencies. Adhering to regulations can create difficulties internally for a company trying to introduce new programs or methodologies such as Lean [17]. The focus on regulatory compliance makes it more difficult to make internal process changes once a product has already been approved for commercialisation, and as a result, creates obstacles in the implementation of Lean programmes within MedTech particularly in smaller and mid-sized companies (SME's) [18,19]. Larger MedTech companies tend to have more success in deploying such programs [20,21]. Case-study examples in this sector have been collected by Lean Business Ireland [22] and demonstrate that the common challenge companies face when trying to implement a Lean or Six Sigma strategy is with a constraint of resources. Naturally, larger companies are better positioned to overcome this obstacle, so it makes sense that these programmes have a higher probability of success within these organisations. Alternatively, SME companies choose to adopt Lean tools, which best fits the issues that need to be addressed and what needs to be improved within that company, i.e., productivity, quality, and process focus [18,21]. This approach can also yield successful outcomes but does not realise the full capabilities of Lean by only focusing on processes and output versus building a culture of continuous improvement within that organisation [23]. Due to ever-growing competition in today's manufacturing sector, many companies are using continuous improvement as a change management discipline to help their companies become more competitive [24]. These improvements are achieved by using the right tools and techniques targeted at identifying and removing waste and variation in business processes of all sizes [25]. The concept of continuous improvement comes under many different guises, most notably continuous improvement itself, but it also encompasses enterprise excellence and Lean manufacturing and Lean systems [26]. Much of the literature covers Lean implementations mainly in the manufacturing sector as the origins of Lean lie therein [18]. However, it is also evident that Lean can also bring significant benefits in transactional environments [27–29]. While much of the literature refers to Lean in large organisations and how it should be adapted to suit SMEs, there is limited research into deployment within the MedTech [18,19].

The MedTech sector is generally perceived as averse to risk and change [30,31]. In their paper on MedTech design process improvement, Boylan et al. [32] also discussed their objective of improving the process without invoking extra regulatory approval and oversight. Regulatory compliance is perceived to be a barrier that stifles innovation and continuous improvement within the industry, significantly limiting the scope for design changes and innovation and especially changes once launched [33,34]. Parallels can be drawn with other heavily regulated manufacturing industries, such as aerospace and pharmaceutical drugs [35]. A focus on regulatory compliance and quality management is often cited as an impediment to Lean and other continuous improvement tools in the Medical Device industry [36]. Even in organisations where continuous improvement systems are deployed, they remain secondary to the dominant regulatory quality system, e.g., ISO 13485:2016 [18]. When comparing the international standard for Quality Management System ISO 9001:2015 with the corresponding equivalent standard for the medical device industry, ISO 13485:2016, the section on continuous improvement is a noteworthy omission from the medical device standard in an otherwise harmonised pair of standards [37]. There is greater scope to make changes to non-manufacturing processes and transactional processes in a medical device organisation, such as changes to the New Product Introduction (NPI) process, administrative, warehousing, and logistics.

The success of Lean in Irish MedTech is well documented, with many companies receiving prestigious accolades in this area and transforming Ireland into a globally recognised hub of excellence [22]. The uptake of organisational excellence and process improvement methodologies has been accelerated by the greater scrutiny from regulatory bodies and agencies in different global jurisdictions to demonstrate the cost/benefits of medical device products [36]. However, global regulatory authorities' evolving marketing and regulatory requirements necessitate constant monitoring of each regulatory jurisdiction by manufacturers [38]. Fear of upsetting regulatory authorities also can lead to a fear of implementing process changes least compliance be affected. However, there is potential to use Lean Systems in the Irish MedTech industry as Lean has been shown to drive improvements to both cost and lead times [39].

The previous studies have shown the potential of operational excellence tools to launch new medical devices and technologies at a faster pace by integrating the knowledge on Lean Systems in MedTech [40,41]. To the authors' knowledge, this review article is the first work that discusses the application of lean in transactional and service processes of the Irish MedTech.

The research objectives for this research are to study Lean deployment and implementation in Irish Medtech. The researchers also seek to ascertain the reasons for implementation, understand what type of Lean tools are most utilised and if different to other industries, and what benefits and results are observed. As previously mentioned there is a dearth of literature related to Lean deployment in Irish Medtech and in Medtech in general [18,19,32,36].

This work aims to show the enormous potential for improvement to both cost and lead times through the literature review around Lean deployment and the factors that can influence successful deployment within the MedTech. Section 2 outlines the research methodology, while Section 3 elucidates on the results. Finally, Sections 4 and 5 contains the discussion of the results and conclusion.

2. Review Methodology

2.1. Methods

This section describes the research approach followed in this study. Secondary research was utilised to review the quantitative and qualitative results of case studies with the main aim to assess the impact Lean deployment has had within the Irish MedTech sector, including benefits and challenges which the organisations faced. The results of case studies conducted in 19 medical device organisations in Ireland, involving MedTech

employees from private sectors in a period of 6 years were reviewed. The available lean tools were discussed, then the importance of a company size for the selection of Lean strategies, and lean tools used specifically in the MedTech organisations including challenges and benefits of tools' use. In this review article, the published case studies were reviewed, and the results were related to the recent literature on the digital transformation in MedTech followed by discussion and conclusion sections.

2.2. Case Studies

An exploratory study of literature and a documented case study database was carried out to conduct the current research work. The government of many countries worldwide are encouraging and helping small- and medium-scale industries understand and implement lean systems by preparing an accessible database of Lean consultants, providing financial assistance for training by professionals, and establishing professional associations [42,43]. This approach has been well documented through case studies provided by Lean Business Ireland via structured interviews and quantitative data gathered by participants [22] that there is growing uptake of Lean from MedTech companies who have had little exposure or experience with this philosophy. Multiple case studies published by Enterprise Ireland on Lean deployment initiatives in 19 MedTech companies were studied. These case studies were made up of structured interview commentary and quantitative data collection from participants in the Enterprise Ireland Lean program. The reasons for the Lean deployment, the benefits of the Lean deployment, and the results and challenges to Lean deployment were all studied, and the types of Lean tools used. The case studies reviewed were selected based on company size directly linked to different companies in MedTech in different locations across Ireland, as shown in Table 2.

Table 2. Lean Case Study Organisations reviewed from the Irish MedTech Industry (location and size) (author constructed).

Case Study Organisation	Organisation Size	Location
#1	Medium (50–250 Employees)	Southeast
#2	Small (10–50 Employees)	Southeast
#3	Small (10–50 Employees)	Southeast
#4	Large (250+ Employees)	Southwest
#5	Large (250+ Employees)	East
#6	Small (10–50 Employees)	Southwest
#7	Small (10–50 Employees)	Northeast
#8	Large (250+ Employees)	West
#9	Large (250+ Employees)	Southeast
#10	Large (250+ Employees)	Mid-West
#11	Small (10–50 Employees)	Southwest
#12	Large (250+ Employees)	Mid-West
#13	Medium (50–250 Employees)	Midlands
#14	Small (10–50 Employees)	Mid-West
#15	Large (250+ Employees)	Southeast
#16	Large (250+ Employees)	Southwest
#17	Large (250+ Employees)	Mid-West
#18	Large (250+ Employees)	Mid-West
#19	Large (250+ Employees)	Southwest

2.3. Company Size

87 MedTech companies are operating in Ireland as of 2020 [43,44]. Within this study, of the 19 MedTech companies reviewed, 58% (11) were large enterprises (LEs), 32% (6) were small enterprises (SEs), and 10% (2) were medium enterprises (MEs). Generally, in

the literature, it is recognised that LEs have more success with Lean implementation due to having more extensive resources at their disposal [45,46]. Extensive research carried out by Eatock et al. [47] demonstrates that changes to a product type or technology within the MedTech industry can impact the level of success and Lean strategies deployed. This, coupled with company size from a micro-sized to a large company, also pivots the approach towards specific methodologies versus others [48]. The types of medical devices being manufactured, and their classification must also be considered as it drives many pre- and post-market regulatory requirements. The higher the classification of a device, the higher the risk of the device in use and, therefore, the more significant the safety and regulatory controls required of the manufacturer and within the manufacturing processes. In the USA, for example, Class I devices are deemed to be low risk and are subject to minor regulatory controls, e.g., dental floss is classified as a Class I device [49]. The MedTech companies involved in this study ranged from manufacturers of Class I, the lowest risk classification devices, to Class III, the highest risk, with some making several types of devices. This means that there may be several manufacturing “factories” within one manufacturing factory.

3. Results

3.1. Reasons for Undertaking a Lean Initiative

With the ever-growing competition in today’s manufacturing sector, many MedTech companies are using continuous improvement as a change management discipline to help them become more competitive. These improvements are achieved by using the application of tools and techniques targeted at the identification and removal of waste and variation in all business processes. The main reason that companies implement continuous improvement is to improve their performance, increase their profitability and create a competitive advantage [50]. These efforts can seek ‘incremental’ improvement over various period of time or ‘breakthrough’ improvement all at once. The concept of continuous improvement comes in many different guises, most notably continuous improvement itself but it also encompasses enterprise excellence, lean manufacturing, and lean systems aiming to improve competitiveness and performance of an enterprise [4].

Within the case study, MedTech organisations who participated in the Lean Ireland program funded by Enterprise Ireland listed their critical reasons for starting on a Lean journey or continuing an existing one as outlined in Table 3, with many themes being listed more than once. Nearly all of the reasons given by the MedTech organisations were along with the themes of improving production line layout and flow, improving work-in-progress (WIP), standardising processes, improving productivity, and improving quality. Reducing waste and cost savings were also cited by almost all the MedTech case study organisations. Some of the reasons stated directly for implementing Lean were “*The main objective is cost; current cost exceeds the budgeted cost*” and “*maintaining our ability to meet customer demand*” as well as to “*to enhance a Problem-Solving Culture*”. These results align with benefits of continuous improvement were observed across other industrial sectors such as automobile and pharmaceutical manufacturing [51].

Table 3. Key reasons for Lean initiative deployment in Irish MedTech organisations (author constructed).

Key Reasons	Detailed Explanation
Improve layout and flow	Just-in-time that meets the customer demands that flow from the customer
Supply Chain Enhancement	Active supplier involvement and management
Reduce Waste	Reduce non-value adding process steps, often mentioned in the literature as the 8 forms of waste
Improve Productivity	Productivity boost through operations strategy and network optimisation
Expedite Operations	Expedite the time to market of medical devices

Improve Quality	A strong focus on quality and eliminating causes of defects by participation in improvement initiatives and problem solving
Standardise Processes	Standardisation and '6S' practices, resulting in continuous improvement
Improve Competitiveness	Improvement of performance in competitive priorities such as quality, reliability, and speed
Work-in-Progress Reduction	Reduce unnecessary early start in a push-pull and pure push system

Lean strategies enable the MedTech companies to develop and deliver high-quality products and services faster and with less waste. Lean thinking can be effective in any industry, i.e., automobile, pharmaceutical, etc. However, MedTech companies can obtain significant competitive advantages in the areas of development, production, and supply chain through the implementation of Lean deployment strategies. The key reasons for Lean initiatives deployment in MedTech is to “*improve productivity, expedite manufacturing operation*” by bringing the product on the market rapidly and making the products “*competitive*”. Toyota’s lean product development process can provide a MedTech company with the ability to beat its competitors to market with products that better meet the needs of its customers. If a medical device manufacturer can shorten its internal production lead times, two key benefits will result, such as more investment into development or into acquisitions and possibility to mass customisation. Lean strategies can help a medical device company to improve “*supply chain management*”. Most medical device companies are not vertically integrated, but lean supply chain methodologies can be used to shorten supply chain lead times and ensure better quality. The utilisation of lean strategies will also result in development of more reliable and “*higher-quality products* as well as its delivery/lead-time and cost. Instead of increasing the number of inspection stations, a lean medical device manufacturer would utilise true root cause analysis problem-solving to eliminate the causes of defects. With the increased demand of medical devices in the COVID-19 crisis, it is especially important to ensure timely delivery, customer satisfaction and minimisation of delays. A “*continuous flow*” with no interruptions, no batches and inventories, and no queues and wasted motions is a key reason to integrate Lean tools in the MedTech. In a continuous flow layout, workers perform much more value-adding work and can more easily see the results of this work, which provide them with a sense of accomplishment and satisfaction from the work. Concurrently, “*work-in-progress*” should be minimised to keep the production cycle optimal with respect to the quality, cost, and productivity. By the development of key Lean parameters, MedTech companies will be able to standardise processes and services in the complex and vast network of suppliers and customers.

3.2. Lean Tools and Principles Utilised by Irish MedTech Organisations

The Lean tools and principles which were cited as utilised in each of the Irish MedTech organisations who participated in the case studies are shown in Table 4. Visual Management and Non-Value Add (NVA) waste analysis, 5S, Value Stream Mapping (VSM) and introduction of Key performance indicators (KPIs) were the most commonly utilised tools. It should be noted that depending on the organisation’s size, there was a difference in the level, usage, and application of Lean tools. There was more utilisation of several Lean tools in the LEs as compared to the smaller ME and SE organisations. The smaller and medium-sized enterprises utilised one or two main Lean tools, whereas the larger ones utilised more of a suite of Lean methods. KPIs, visual management, and visual management boards were applied consistently throughout all participating organisations, as they are foundational lean tools. Tortorella and Fettermann [52] discussed the importance of evaluating the deviations registered in the visual management and KPI production boards in driving actions that were not implemented in the daily routine whenever needed, registering comments and observations, and observing problems and improvements in the production flow.

Table 4. Lean Tools and Principles deployed within Irish MedTech.

Case Study Organisation	Lean Tools/Principles Deployed
#1	KPI's, 5S, Kanban, Visual Management
#2	KPIs
#3	Process Mapping
#4	Visual Management
#5	Process Mapping, NVA Analysis
#6	OEE analysis
#7	5S, Visual Management
#8	Process Standardisation, NVA Analysis
#9	Defect reduction, NVA Analysis, Kaizen, VSM
#10	POC VSM, Yamazumi Charts
#11	Brainstorming, Affinity Diagrams, FMEA, Visual Management
#12	KPIs, Visual Management
#13	Standardised work, SMED, 5S
#14	Visual Management Boards, DFSS, 5S, NVA Analysis
#15	VSM, Process Mapping, Kaizens, DMAIC, A3 Problem solving
#16	VSM, Kaizens, KPIs, Gemba
#17	KPIs, Visual Management
#18	Standardised Process
#19	5S, Kanban, SMED, Standard Work, TPM, A3 Problem solving

There are other less-popular tools mentioned in the Lean literature that includes: 5 Whys; Small Lot Sizing and Single Minute Exchange of Die; Level scheduling; and Kaizen [8]. These tools are seen to be less popular among SME companies due to their complexity and high cost [53–55]. Despite this fact, there is very little in the literature that discusses the justification or motivation for the selection of specific Lean tools in SMEs and larger MedTech enterprises.

3.3. Challenges to Lean Deployment within Irish MedTech

Achanga et al. [54] suggested that the implementation of LM, as with any other productivity improvement initiative, is believed to harbour enormous difficulties and challenges. Challenges were highlighted regarding Lean deployment by the case study of MedTech organisations. The key challenges identified centred around “*lack of resources for Lean projects and deployment*”, “*lack of Lean knowledge*”, “*Lack of training*”, “*trying to create a culture for change and CI in the organisation*” and “*lack of alignment of metrics with strategic objectives*”. The organisations involved did not expand as elaborately and in as much detail on the type of challenges as they had in Lean deployment compared to the detail given on other areas of the Lean deployments. Extensive research carried out by Albliwi et al. [55] shows that a lack of financial or physical resources has been cited as a critical failure factor for Lean deployment, as was poor organisational capability. Resistance to change is a standard feature found in most companies when trying to change their methods, and smaller, under-resourced organisations struggle more to try and overcome this challenge [56].

Poor organisational readiness and lack of management commitment for Lean transformation has also been seen as the main obstacle to Lean success [55]. As it is part of a broader cultural change, the involvement and commitment of intermediate leaders and senior managers are fundamental for Lean efficacy [57]. As management approached Enterprise Ireland for support with their Lean deployment programs, lack of commitment and support was not a factor in this study. However, it is unknown as to the levels of support and momentum sustaining the Lean initiative by management teams once initial

training and Lean consultants sponsored by Enterprise Ireland had moved on to other organisations. Shrimali and Soni [58] proposed that an effective method to break down this barrier is to establish workshops, presentations, and belt programs within the company. They also suggest that the training should be structured in a way that is relevant to employees' jobs. Another option to improve the Lean culture in MedTech organisations is to combine Lean techniques with Sigma Six strategies [1]. This could provide a more integrated and coherent approach to reduce cost, make deliveries on-time, and minimise both inventory and cycle time [59,60].

The COVID-19 crisis have caused radical changes in the tools and production processes of medical devices and services used by people. The novel production methods and lifestyles are in process to be formed by transforming the communication tools and production systems used. Increasingly sophisticated and complex products, combined with more stringent regulatory requirement require the MedTech companies to embrace digitalisation to remain competitive. Industry 4.0 focuses on improving process efficiency to deliver high-quality products at lower costs. The Industry 4.0 platform can strongly influence productivity through increased automation, more intelligent control of planning, logistics, maintenance and purchasing, optimised supply chains, improved traceability, and establishment of new delivery platforms [61]. Thus, the data collection and integration into Industry 4.0 platform, communication, and education of MedTech companies will boost lean systems framework [62].

3.4. Results of Lean Deployments

In terms of the results of Lean deployment in the case study organisations, there were several quantitative and qualitative benefits put forward by participant MedTech organisations. In terms of quantitative benefits, improved productivity, reduced waste, cost reduction, improved quality, and elimination of customer complaints were all listed. However, from an organisational point of view, several other resulting benefits were verbalised, including increased employee engagement, improved organisational culture for problem-solving, education in Lean and continuous improvement, improved team engagement and alignment with strategic objectives, to name but a few. Extensive research carried out by Eatock et al. [47] demonstrates that changes to a product type or technology within the MedTech industry can impact the level of success and Lean strategies deployed. This, coupled with company size from a micro-sized company to a large company, also pivots the approach towards specific methodologies versus others [48]. The main results from case studies are summarised in Table 5.

Table 5. Results of Lean Deployments in Irish MedTech case study organisations.

Case Study Organisation	Results of Lean Deployment
#1	<i>The warehouse capacity was increased by 27% completely alleviating the bottleneck. Warehouse capacity now visible and in real-time.</i>
#2	<i>We devised an operational dashboard, identified targets and metrics to show what successful outcomes would look like. We increased Gross Profit by 200% during a 6-month period.</i>
#3	<i>Engagement with the concept of Lean resulted in improved staff morale, increased engagement within the team, and an overall better understanding of how day-to-day activity can help to achieve the overall business objectives and vision.</i>
#4	<i>10% Productivity Improvement</i>
#5	<i>Improved culture</i>
#6	<i>Increased productivity by 20 units per week on one line that yielded an extra gross contribution of EUR 63,000 per annum for the company.</i>
#8	<ul style="list-style-type: none"> • <i>Process stabilisation 10–15% year on year productivity improvement in Key Value Streams.</i> • <i>10–20% reduction in scrap within key value streams.</i> • <i>Organisational structure development.</i> • <i>Cultural change and employee engagement.</i>
#9	<ul style="list-style-type: none"> • <i>Batch review and release time has reduced by over a third</i>

	<ul style="list-style-type: none"> • Elimination of non-value-add activities in the collection, transcription and checking of a large number of data points for each batch of product
#11	A key result was the development and operation of Lean production scheduling visual boards as the basis for New Products being introduced to a developing production system.
#12	Improvement areas identified that were addressed resulted in cost reductions of EUR 120,000 per year; and the dashboard is now playing a key role in measuring the effectiveness of future improvement projects
#13	Result—9% increase in overall output and revenue saving of EUR 160,000 per annum
#14	Elimination of waste (defects) from volume production lines, elimination of customer complaints. Huge shift in culture especially at associate level—empowered to do their job better Eliminated Non-Value-Add activities such as manual collection, collating data in Excel, producing reports etc. ROI in Excess of 200% within 12 months
#16	Overall Increased Efficiency 7% Increased Output 5% Scrap reduction across the value stream <40% Reduction in WIP Increased Equipment Utilisation—from 80%–85% Increased Schedule Attainment—from 90%–96%
#18	<ul style="list-style-type: none"> • Made visible the invisible—COPQ was 4x larger than original estimates • Enabled COPQ reduction activity in excess of EUR 10 million
#19	<ul style="list-style-type: none"> • Company embraced A3 as problem solving methodology. • Trained all 130 staff in how to use A3.

The results presented in Table 4 indicated that the dominant objectives for Lean Deployment in the MedTech companies are reduction of waste and cost, increase of productivity on the production floor and improvement of organisational culture. The case studies show that Lean Deployment is predominantly introduced successfully in large corporations, however this concept should work in any size business. This is due to the nature of Lean systems that depends upon characteristics inherent to any business, not on the size of the business itself. Of course, SMEs have constraints that limit their ability to initiate a large-scale Lean Deployment, such as the finances and resources to train staff and implement Lean support structures across the full organisation, but there are ways to overcome these limitations. The financial and cultural transformation benefits that stem from Lean Deployment should propagate more quickly through a SME due to its small size. Focusing the Lean tools at any properly scoped project should deliver savings to the bottom line while achieving breakthrough change. In case study 14, driving cost and waste out of the business is seen as a critical part of the business and using Lean systems should help achieve this. In case study 16, there are 9 criteria which is more difficult to achieve, but the integration of Industry 4.0 platform could support the MedTech company in this transition. Using Lean Deployment fits the enterprise excellence strategy which is to continually improve processes and empower everyone to solve problems. The high-performance culture pillar is about growing and developing people to achieve superior results, innovation, and speed. It is also about finding creative ways to do things better and faster, whereas voice of the customer is about delivering what the customer wants. The Lean Deployment across the MedTech site can support all these strategic plans.

4. Discussion

The MedTech industry in Ireland spans the entire country and brings a rich and large number of companies which are based in Cork, Galway, Dublin, and Limerick. Such a growing industry also brings with it a diverse range of company types, sizes and products and services that they offer. The most noticeable differences of MedTech sector to other industries is based on the burden of regulatory requirement which companies must follow and a vast of products and services which MedTech companies offer. The various sizes of MedTech companies and complex network of supplier and manufacturing plants are the

main contributing factors in the Lean Deployment. The Lean tools used by Irish MedTech companies are summarised as a part of the Toyota production system in Figure 1.

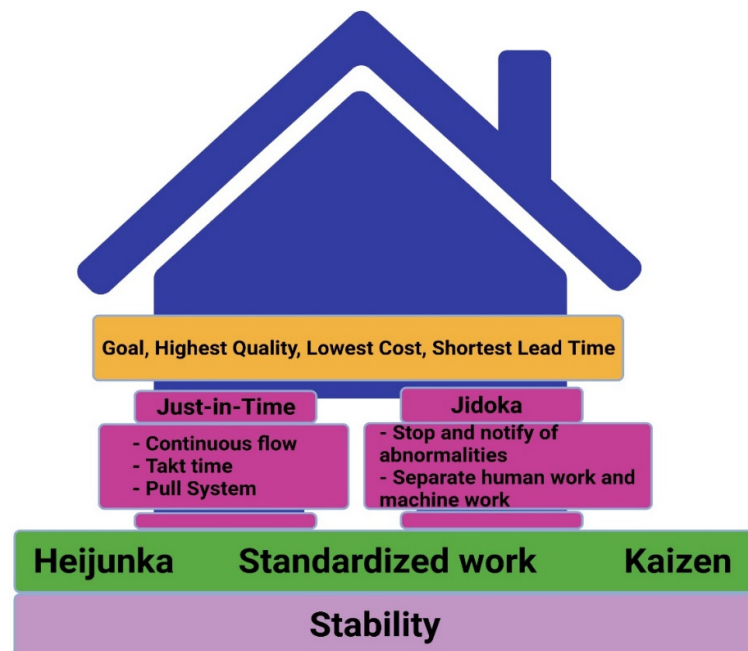


Figure 1. Toyota production system (TPS) of MedTech companies.

The goal of the Toyota production system is to obtain products of the highest quality in the shortest lead time and at low cost. SME companies will use only some of the Lean tools due to the limitation of resources and finances. However, the results of this review indicated that the integration of Lean tools depends on both production system goals and organisational culture. Lean is embraced despite the strict regulatory regime surrounding the MedTech industry. Just-in-Time and Jidoka concepts have been successfully used in large MedTech companies, but several case studies also showed promises to deploy all mentioned Lean tools to continuously improve organisational culture and manufacturing.

The results and changes highlighted from Lean deployment were generally more to do with standardised work, improved line layout and elimination of non-value-add steps. The Lean tools used in the MedTech sector are not different from other industries.

There are many tools which can be grouped into sections: waste minimisation tools, flow improvement tools and new layout tools. The selection of tools strongly depends on the desired improvements from basic work to entire line. Moreover, none of these changes utilising basic Lean tools such as 5S, standardised work, process mapping, Kaizen, and NVA analysis would require substantial manufacturing changes or process and equipment validations.

The changes mentioned above would be basic and would not affect product functionality and safety and thus require notifications and submissions to the regulatory authorities. The majority of the changes to layout, standardised work, implementing visual management, problem-solving, and KPIs had more of an effect on employee morale, team engagement, training, and enabling problem-solving and generating a culture of continuous improvement (CI). Compliance with the approved QMS was also unlikely to be affected, nor would the original regulatory authority approvals. Another important result in this review is related to the opportunity to deploy similar Lean tools in MedTech organisations of various sizes. While there were more SMEs than LEs and SEs in this study, there seemed to be common benefits, results, tool usage, and reasons for deploying across all the organisational sizes. However, the Lean tool suite was a broader deployment

within the participating LE organisations, which is understandable given their more significant share of resources. As Enterprise Ireland aided these organisations with supporting Lean deployment, it was not surprising to see more SMEs involved as many larger Irish LE MedTech organisations with US-based parent companies already have their own Lean initiatives and did not require Enterprise Ireland support.

The abundance of products in the MedTech creates complexity as patterns of demand shift, companies need to consider where their future growth is likely to come from and adjust their suppliers' network according using selected Lean tools. MedTech companies are highly regulated where changes in legislations occur frequently and thus, requiring fast respond from the industry. Concurrently, quality and cost of products must be maintained to be optimal. The combination of customer's demand and MedTech product properties must be balanced to avoid risks. Managing risk is an essential enterprise requirement across industrial sectors [63]. From the perspective of well-established governance within companies, the ability to understand, define, assess, and implement preventive measures to avoid the risk is a main driver in the risk-management framework [64]. The relationship between the processes of risk identification, evaluation, and management formulates the risk management framework. There might be a number of significant risk-related challenges to the MedTech project. When a new technology is being introduced, from a regulatory compliance perspective a risk assessment must be performed to ensure there will be no risk to the patient and healthcare staff. It will additionally require support and approval from the senior management. There can be also a business risk that is associated with the potential inability to meet forecasted customer demand. New digital tools for the handling of risks related to MedTech supply-demand management could potentially reduce pressure on both government authorities and businesses concurrently, preventing financial challenges and environmental damages and promoting a mindset change at the corporate and individual levels [65]. Industry 4.0 consists of advanced manufacturing and information technologies for the fulfilment of the customised requirement and minimise risks in MedTech companies [66]. These technologies provide wireless connectivity in the MedTech manufacturing and service sector to enhance automation. The previous study on the integration of digital technologies in the MedTech industry identified five main surveyed barriers, which were 'Manufacturing Process', 'Medical and Professional', 'Medical Device Reimbursement', 'Material Issues', and 'Staff Training' [67]. These barriers must be addressed during workshops and trainings to attempt four opportunity areas—material science, technology, business models, regulations and quality management—where digital technologies can be integrated. Further investigations and new case studies around these four opportunities will disclose the practice-technology relationship and unlock the potential of Industry 4.0 use in the MedTech. This will benefit to the potential of engagement of new entrants to the MedTech industry, incumbent firms, health care system, and patients in Europe.

5. Conclusions

The novelty of this review article relies on the fact that the Lean tools utilised in the MedTech companies did not show significant differences to other industrial sectors. This is novel, as there has been a dearth of studies on Lean in the Medical device sector and this study adds to the state of the art. Moreover, due to the fact that the sector is highly regulated, which makes change difficult, this study proves that Lean can be deployed successfully in this sector.

Despite continuous improvement initiatives being more difficult in MedTech due to the vast number of available products and the heavily regulated nature of the MedTech sector, a number of Lean tools in combination with the improvement of organisational culture can be used. Larger MedTech companies are better equipped to plan and forecast the level of expertise, market demand, training and specific tools required by staff to continuously improve manufacturing. Small and medium-size MedTech companies were seen in the literature as organisations which integrate a specific set of Lean tools in

dependency on the strategic business plan. This review showed that companies of various sizes must align metrics with strategic objectives prior their selection of specific Lean tools. The complexity of the supply–manufacture–customer network in Ireland creates additional challenges to the integration of Lean tools in MedTech. The implication for practitioners in this paper is related to the active integration of digital tools such as Industry 4.0 to make the selection of Lean tools and strategies automatic based on the experiences of various MedTech companies in Ireland. The further penetration of digital tools into MedTech will benefit quality, cost, organisational culture, and the environment. This review identified a lack of studies related to consideration of sustainability in MedTech manufacturing. The comparison of Lean deployment in Ireland with other EU countries is another limitation that can be further investigated.

Author Contributions: Conceptualization, A.T., O.M.; methodology, A.T., O.M.; software, A.T.; validation, O.M.; formal analysis, A.T., O.M.; investigation, O.M.; resources, D.M.; data curation, D.M., A.T., O.M.; writing—original draft preparation, A.T., O.M., D.M.; writing—review and editing, O.M.; visualization, A.T., O.M.; supervision, A.T., O.M.; project administration, D.M.; funding acquisition, O.M. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

Abbreviations

CI	Continuous Improvement
COPQ	Cost of Poor Quality
DFSS	Design for Sigma Six
DMAIC	Define, Measure, Analyse, Improve, Control
EMA	European Medicine Agency
FDA	Food and Drug Administration
FMEA	Failure Modes and Effects Analysis
ICT	Information Communication Technology
KPI	Key Performance Indicator
LS	Lean Systems
MedTech	Medical Technology
NPI	New Product Introduction
NVA	Non-Value Add
OEE	Overall Equipment Effectiveness
POC	Proof of Concept
QMS	Quality Management System
SME	Small and Mid-sized Enterprises
SMED	Single Minute Exchange of Die
TPM	Total Productive Maintenance
TPS	Toyota Production System
VM	Visual Management
VSM	Value Stream Mapping
WIP	Work-In-Progress

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