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Implementation of a Lean 4.0 Project to reduce non-value add waste in a Medical Device company.

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Abstract: The fourth industrial revolution, also referred to as Industry 4.0, has resulted in many changes within the manufacturing industry. The purpose of the study is to demonstrate how an Industry 4.0 project was scoped and deployed utilising Lean tools to reduce non-value add wastes and aid regulatory compliance. A case study research approach was utilised to demonstrate how a Lean Industry 4.0 project was implemented in a Medtech company to enhance Lean processes while increasing digitalisation. This research demonstrates that Industry 4.0 can enhance Lean, improve flow, reduce nonvalue add waste and facilitate product lifecycle regulatory compliance to reduce defects, enhance quality, improve cycle time, and minimise reworks and over-processing. Lean and Industry 4.0 combined offer many benefits to the MedTech Industry. This research will support organisations in demonstrating how digital technologies can synergistically affect Lean processes, positively impact product lifecycle regulatory compliance, and support the industry in building a business case for future implementation of Industry 4.0 technologies.

Keywords: Industry 4.0, Medical Device, Medtech, Regulatory compliance, Engineering Change Management, Product Lifecycle Management, Regulatory 4.0. , Lean 4.0

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1. Introduction

The Medical Device Industry is one of the largest growing industries in the world. This growth is driven by ageing populations, advancing technologies and new innovations to meet clinical needs [1]. In order to reduce costs, improve manufacturing productivity and reduce cycle times, the Medtech industry, along with other industries, has embraced Lean[2]. However, with the advent of Industry 4.0 and increased digitalisation, the MedTech industry can improve efficiencies, reduce operational costs, and support organisational decisions through big data analytics [3,4]. Some studies have investigated Lean 4.0 -the combination of Lean and Industry 4.0 and concluded that there is a synergistic effect between Lean and Industry 4.0 [2,5]. A recent Boston Consulting Group (BCG) study showed that states have a multiplier effect when lean and Industry 4.0 are combined. The study found that Lean can reduce operational costs by 15-20%, and digitalisation can reduce costs by 10-15% but combine both, and you get up to 40% cost reduction [6].

The impact of digital technologies impact on product lifecycle regulatory compliance has also not been widely researched. Product lifecycle regulatory compliance or regulatory compliance is how Medical device manufacturers comply with the different statutory, mandatory, and voluntary regulatory requirements to ensure their organisations deliver a safe and effective product and meets various regulatory jurisdictions' specific regulatory requirements [7,8]. Increasingly changing regulations in Europe related to medical devices and other jurisdictions and keeping compliant with technological advances have increased regulatory compliance complexity [9].

There have been few practical case studies of a Lean Industry 4.0 application [10], and neither one specifically focused on Medtech organisation nor Lean Industry 4.0's impact on regulatory compliance [11,12]. This study will utilise a case study of a multinational medical device manufacturer with several global sites. This research aims to investigate the impact of Lean practices combined with Industry 4.0 on regulatory compliance and enhancing Lean processes within the MedTech Industry using the case study organisation as a reference. This research will address the following research questions:

RQ1: What impact can Lean 4.0 have on a Medical Device manufacturer's Total Product Lifecycle and Regulatory Compliance?

RQ2: How can Industry 4.0 enhance and enable Lean in a Medical Device manufacturer?

Section 2 reviews the published literature that is currently available on Lean Industry 4.0 in Medtech and how Lean and digitalisation can support regulatory compliance. Section 3 discusses the research methodology, while Section 4 documents the findings and results. Finally, the discussion and conclusion are outlined in Sections 5 and 6.

2. Literature Review

Lean 4.0

According to Antony et al [11, 12] in studies on Lean and Six Sigma combined with Industry 4.0, Lean 4.0 has emerged as a topic of researcher interest only from 2017 onwards. A systematic literature review found that Lean and Industry 4.0 (or Lean 4.0) combined, while still a nascent area, had many symbiotic and synergistic needs for each other [13,14]. Traditional manufacturing evolving into digitalisation with Industry 4.0 technologies has resulted in Lean becoming digitally enabled**[15]**. Integrating Industry 4.0 with Lean can enhance cost-competitiveness [16] and can generate reduced waste [17]. Several Lean concepts can be improved by integrating I4.0 technologies [13]. I4.0 can increase data availability which will enable Lean and aid in measuring, monitoring, and improving key performance indicators (KPI's) in organisations [18]. Thus the synergistic effect between Lean and Industry 4.0 in Lean processes by improving flows and reducing bottlenecks [19].

Within a Lean value stream, integration of Industry 4.0 technologies benefits the Lean approach by combining the simplicity and efficiency of Lean with the agility of the I4.0 technologies[17]. Antony et al. [11] argued a bidirectional relationship between Lean and Industry 4.0. Some studies have argued that while Lean is an enabler for I4.0 or a pre-requisite for its introduction, there still needs to be more studies and guidance on its integration [13, 20].

How is Lean & Industry 4.0 impacting Medtech Regulatory Compliance?

The Medtech sector is by its very nature highly regulated with many different regulatory requirements globally, from the European Medical Device Regulation (MDR) and In vitro diagnostic medical devices Regulation (IVDR) to the American Food & Drug Administration (FDA)'s Code of Federal Regulations (CFR) in the United States of America (USA), the Pharmaceutical and Medical Device Act (PMD Act) in Japan, the Regulation on the Supervision and Administration of Medical Devices, Order 739 in China, and the Therapeutic Goods (Medical Devices) Regulations 2002 in Australia, to name just a few. Global Regulations set out the regulatory requirements, including pre and post-market requirements, to ensure that medical devices are produced which are safe and effective [21].

Many Medical device companies have deployed Lean, with one recent study by McDermott et al. [2] on the Irish Medtech sector highlighting that over 95% of Irish Medtech companies had a Lean program. Lean in the medical device industry, as with other industries, has enabled waste reduction, particularly non-value add activity and improved process flow [22]. However, medical device regulatory compliance involves manual tracking and surveillance of multiple databases, leading to over-processing.

While Industry 4.0, Quality 4.0, Supply Chain 4.0 and even Healthcare 4.0 are studied in academic literature, Regulatory 4.0 or Industry 4.0's impact on regulatory affairs digitalisation is not a term that has been widely used[23,24,25]. In particular, the Quality (QA) function is more advanced on its digital transformation path than the Quality Assurance & Regulatory Affairs (QARA) partner function Regulatory Affairs (RA) [26]. Industry 4.0, in particular, can support Regulatory compliance using tools such as Regulatory information management systems (RIMs) [27]. RIMs provide secure access to real-time regulatory data and visibility across regions. A challenge for device manufacturers is to remain current with global regulations and changes in achieving regulatory compliance throughout a product's life cycle [28]. IMs aid the RA function in quicker regulatory submission times and product registrations, resulting in faster access to markets in the organisation across global sites.

RA functions must access several regulatory databases; for example, the European database on medical devices(EUDAMED) is used to access medical device-related data to understand how a device is performing in the market, its risks and benefits, and if post-market surveillance corrective actions are required based information that has been inputted into the system on individual devices as required by the European Union Medical Device Regulations (EU-MDR). To adhere to the MDR, manufacturers must register devices, sites, unique device identification (UDI), notified bodies information and

certificates, clinical investigation results data, device performance studies, vigilance and post-market surveillance (PMS) information [29].

Many Regulatory functions utilise Excel for tracking and trending, which is not Lean. Regulatory intelligence can be obtained and managed using digital technology, removing data inventory, defects or errors, waiting, delays and over-processing [30]. Several types of information must be tracked, including Regulatory Impact Assessments (RIAs), change notifications (CN), licenses, submissions, and device registrations [31]. Industry 4.0 technologies can help aid RIMs to be more efficient and Leaner. The digitalisation of an organisation's regulatory data is key in supporting RA moving forward on its Lean journey. Digitalisation of RIMs will drive flow, reduction of non-value add activities, and ensure standardised, efficient systems. Industry 4.0 digitisation ensures RA functions know when regulators have made changes to guidance documents, standards and regulations, reducing the non-value add waste of checking global regulatory websites to keep abreast of the latest changes and other systems that can manage regulatory information [22]. It is key that manufacturers of aware of changes to standards or regulations as they occur, as they need to demonstrate regulatory compliance and have access to the latest revisions in a more automated manner [32]. Much of an RA professional's time is spent waiting and searching for regulatory information in a non-value add manner.

Within the medical device regulatory world, several global jurisdictions have put in place legislation to protect patient data, enhance cybersecurity in relation to smart devices, and implement standards and guidance documents that can support their implementation [33]. Industry 4.0 can aid device manufacturers' data security, implementation of digital signatures, transaction time stamping and data encryption, which enhance traceability and increase cybersecurity [33]. However, there are many regulators and standards organisations, such as the International Organization for Standardization (ISO), American National Standards Institute (ANSI), European Committee for Standardization (CEN), the American Society for Testing and Materials (ASTM) and European Telecommunications Standards Institute (ETSI); there must be a more effective technological method of keeping abreast of all relevant regulatory requirements [34, 35].

Challenges to Lean Industry 4.0 deployment

Implementing Lean 4.0 is impacted by many factors, including management support, organisational vision and investment [36]. The difficulty in implementing Industry 4.0 systems can be off-putting due to the technology complexity and resources involved, as well as the time required [37]. In particular, for the medical device industry, new European medical device regulations have provided severe resource challenges in preparing for more stringent regulatory requirements [38]. While this EU-MDR is not precluding Industry 4.0 deployment, it has stifled the MedTech Industry from implementing it [39]. System changes

in device manufacturers need regulatory authority approvals [40]. These regulatory approvals consume time and resources [2]. Many studies have highlighted the importance of management support and leadership commitment in both Lean and Industry 4.0 deployment **[41,42]**. However, given the costly nature of digitalisation, it is very important that the right technology is chosen and understood and the cost benefits analysed **[43, 44]**. In addition, the technology chosen needs to be aligned with the organisation's strategic vision so that the technology can be integrated across the organisation and multisite functions **[45]**. The timing of when Industry 4.0 is adopted can also affect organisations. According to Antony, Sony, and McDermott [43], late adopters benefit from cost reductions in technology and can benchmark tried and tested solutions, while early adopters pay more but can achieve market share through increased competitive advantages. Table 1 summarises the Lean 4.0 opportunities from the literature.

Table 1 Lean Industry 4.0- Opportunities and Challenges

Technology	Opportunities	Challenges
Cybersecurity	Reduced waste	Creating automated
Cloud Computing	Improved flow	waste
Mobile Technologies	Available data	Resources
Machine to Machine	Accurate data	Resistance to change
3D Printing	Data Analytics	Timing of adoption
Advanced Robotics	Quicker decisions	Data security
Big Data / Analytics	Flexibility	Data protection
Internet of Things	Connectivity	Change Management
RFID Technologies	Reduced errors	Lack of digital data
Cognitive Computing	New markets	Costly
	New products	Time-consuming
	New customers	Location
	New regulations	Management support
	New standards	Alignment with strategy
	Flexible working	Choosing the right tech-
	Faster	nology

	Cheaper Innovation Increased productivity Revenue growth Predictive maintenance Regulatory Compliance	Cost-benefit analysis Lack of communication of strategy

3. Methodology

This research aims to demonstrate through a case study on a Lean Industry 4.0 project that digitisation positively affects both Lean processes and regulatory compliance. The case study approach allows the researcher to focus on just one instance rather than multiple instances, supporting an in-depth review that can provide insight that may not be visible using multiple cases. A case study can also help the reader better understand the researched topic [46]. This study uses a single case to support the research. The case study will concentrate on one of the organisation's Industry 4.0 projects currently in implementation. Using a case study is a means by which the researcher can explore the subject in-depth, understanding how and why the subject is being implemented and how it is received by the organisation [47]. Data for the case study will be gathered using local documents and having Microsoft Teams meetings with the case study organisations project lead to understand how the project is progressing through implementation, what challenges there are and why this particular Industry 4.0 project was chosen.

This research focuses solely on Company X, a medium-sized MedTech company in the early stages of its digital transformation. The case study will review and demonstrate how regulatory compliance has been impacted through detailed planning and execution of one of the organisation's Industry 4.0-type projects.

Company X has over 23,000 products in its portfolio, employs over 14,000 people globally, generates just under $3 billion dollars in revenue and has over 120,000 customers. Company X products are used in over 24,000 surgical procedures in the United States, and its products are used in Intensive Care Units (ICU), Cardiology, Radiologists, Vascular Surgeons, and Emergency Responders. Therefore, Company X must continue to deliver products that meet customer and regulatory requirements. With the organisation's growth, its use of digital technology has also expanded. Due to how Company X has grown, through acquisition, multiple management systems manage its data, including product data, complaints, records, documentation, and the supply chain. Multiple systems have led to complex, difficult-to-manage processes, inefficiencies, a lack of global processes and interconnectivity between IT systems, non-conformances and recalls. Because of these issues, Company X is currently working on having one platform, system, and data source across all sites to enhance its production, reporting capabilities and compliance. While company X has had a mature Lean program for many years, it is considered a late adopter in terms of its Industry 4.0 deployment. Antony et al. [43] defined late adopters of Industry 4.0 as those organisations which delay the

implementation of enhanced technology and adopt a more cautious approach to investing in such technologies.

The project this case study will focus on is internally referred to as "Project Impact". Project Impact is the organisation's Enterprise Change Management (ECM) program. ECM is the cornerstone program that will support the organisation's roadmap for the rollout of future Industry 4.0 initiatives. The project is a strategic initiative that aims to deliver a best-in-class ECM process for Company X's product data. Managing change in organisations is a laborious task that consumes value-added time in various segments of the product lifecycle, including design and development, production, delivery, and product disposition [48]. ECM and Product lifecycle management play an important role in minimising the time required for managing engineering changes [49].

4. Results

What were Industry 4.0 tools implemented?

The ECM program focuses on two key elements, Product Lifecycle Management (PLM) and Master Data Management (MDM). PLM is the process of managing the entire lifecycle of a product from inception, through engineering design and manufacture, to service and disposal of manufactured products and product end of life. ("Product Life Cycle Management System for the PLM Process") PLM is the business activity that effectively manages and supports Company X products throughout their lifecycle; refer to Figure 1 for an overview of PLM. The new PLM will use Oracle Agile, cloud-based software that will manage the following electronically: the Design History File, Registrations, Device Master Record, Change Process and Sustaining.

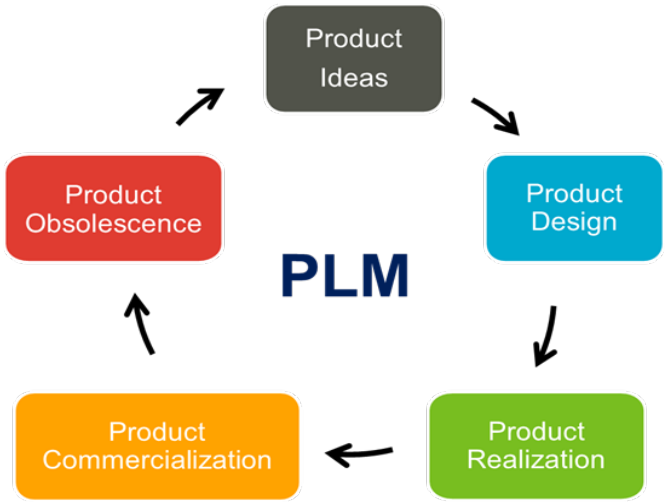

Figure 1: PLM Structure

PLM impacts all aspects of Company X's business, including people, culture, technology, and process, as seen in Figure 1 above.

MDM is a combination of systems and processes that link, manage and process key product data. MDM is a comprehensive method enabling an enterprise to link all its critical data to one file, called a master file or golden record. Refer to below Figure 2 for an overview of MDM. MDM uses Systems Applications and Products (SAP) Master Data Governance (MDG) software that will be the following for Company X's master data: a data hub, a golden Record, a Gatekeeper, and a workflow, which automates and defines data ownership.

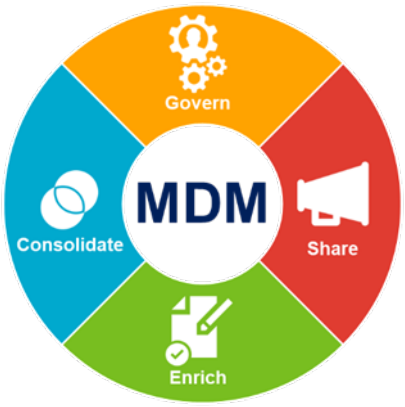

Figure 2: MDM Structure

MDM will provide Company X employees with clear roles and responsibilities; it will deliver end-to-end metrics so that decisions can be made based on accurate data; it will simplify the current complex processes using technology and implementing one global system. The interface between PLM and MDM is a Business-to-Business (B2B) interface; MDG, in turn, consolidates and shares data with SAP. Two systems were chosen as both provide different functionalities. PLM will be used for managing product design and engineering specifications, change control, product lifecycle, workflow and task management, registrations, training, and document management. MDM will be the central repository for consolidated and clean data containing rules for integration and synchronisation of data that will be shared across both systems through workflow and task management using an interface.

As well as the two systems, another important element of Project Impact is Organisational Change Management (OCM) which is key in any project but even more so when implementing such a transformational change across the organisation. Anticipating and managing changes to people and process is critical to mitigating risk and enabling success [50]. Effective change management is more than training and communications; it also includes having and sharing the organisation's vision, having leadership support, bringing people on the journey as it happens, encouraging and enabling behavioural change, managing stakeholders, and continuously analysing and assessing on a daily, weekly, monthly, annual basis how the goals and objectives of the project and the team are progressing. Having a governance model in place to help and support the team in their decision-making gives the team the autonomy it needs to be successful and deliver per the agreed-upon timelines. Having the support of the Steering Committee, Project Leaders and Project Team helps to ensure that decisions are made in a timely manner so that timelines are not impacted. It is about managing the change so that the people, processes, and technology are aligned, which ensures a successful outcome, benefiting all involved.

To deliver such a project, the team worked on obtaining buy-in from the Senior Leadership Team, which enabled them to build the team required to plan and execute the deliverables. The team includes a Steering Committee, Program Leadership/Advisors, and Project Management Office (PMO) Leadership who offer knowledge and support to each workstream, including PLM, MDM, Transformational Change, and IT. In addition, each workstream is supported by a core team and extended teams across the organisation.

Why implement Industry 4.0 tools?

The reasons for embarking on this transformational journey include product quality and compliance, recall reduction, revenue growth, improved time to market, operational efficiency, re-registration cost savings, effort during quality and regulatory audits, cycle time reduction for product management, and cost of goods sold (COGS) reduction, including scrap reduction and acceleration of cost improvement projects (CIPS). The team first built a strong business case to obtain Senior Leadership buy-in and support to support this project. The business case included reasons and examples of why and what could be achieved through implementing the PLM and MDM technologies and what the benefits are including customer, internal and financial benefits. Table 2 gives an example of the importance of these technologies from a customer and internal point of view, including the issue, risk, and impact. Having an effective PLM/MDM prevents the type of error and consequences.

Table 2: Example of Internal and Customer Impact scenario that PLM/MDM can prevent

Customer Story
Product: A medical device kit designed to support the most urgent clinical needs of the critical care patient.
Issue: Incorrect component listed on Bill of Materials (BOM)
Risk: The issue could have resulted in patient irritation during kit use, thereby complicating an already compromised patient during use.
Impact: Recall, Regulatory non-compliance, Business Impact

Internal Impact Story
Site to Site (Transfer issue)
Issue: Component manufactured in a new facility not cleared for release in EMEA by a regulatory agency. Insufficient controls for containment between regulatory plans, change control process, and product release at finished goods, semi-finished or component level.
Risk: Finished goods/components were distributed without required regulatory clearance
Impact: Possible Recall, Regulatory non-compliance, Business Impact

The Teams vision enables Company X's accelerated growth by driving excellence in managing product creation and change through a unified global process. Thus the ECM will support the organisation's vision by standardising and deploying a global PLM

process to reduce the risk of quality-related issues and introduce an MDM system for the management of product-related data for consistency and accuracy.

Other non-value add wastes specifically related to compliance identified by Company X as part of project brainstorming sessions and Value Stream Mapping (VSM) demonstrated the need to implement such technologies. The challenges included safety risks, quality risks, compliance risks, recall risks, impact on brand equity, highly manual work, and increased costs:

- Product changes implemented without adequate review/approval
- Lack of verification of requirements to ensure the design meets the intended functionality
- Discrepancies between product specifications, BOM, and commercial labels
- Manufacturing processes not updated in coordination with product design updates
- Inaccurate and non-compliant label information being released
- Poor management of global label variations (language, metadata)

In addition to the above challenges, Company X has many disparate processes to manage product master data and document changes across the organisation. These result in very complicated workflows that can be challenging to manage and control, resulting in manual processes with many resources required to maintain them. Value Steam Mapping was utilised to map the current process and identify all non-value add (NVA) wastes [51]. Figures 3 and 4 demonstrate schematics based on the high-level VSMs before and after implementation of the Industry 4.0 project (Note: a schematic has been included rather than the original VSMs for legibility purposes). The new system creates pull and flow, adds value and can aid continuous improvement. The new system is more "Lean" and has a less complicated process resulting in reduced overprocessing and more streamlined processes for change management and master data maintenance.

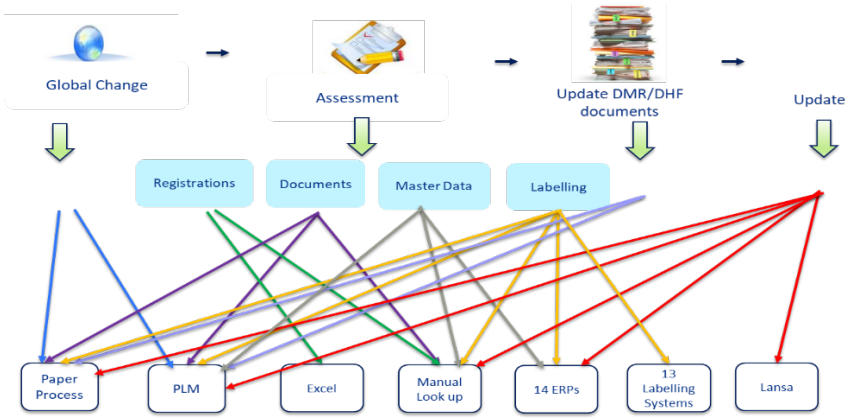

Figure 3: High-Level VSM before implementation

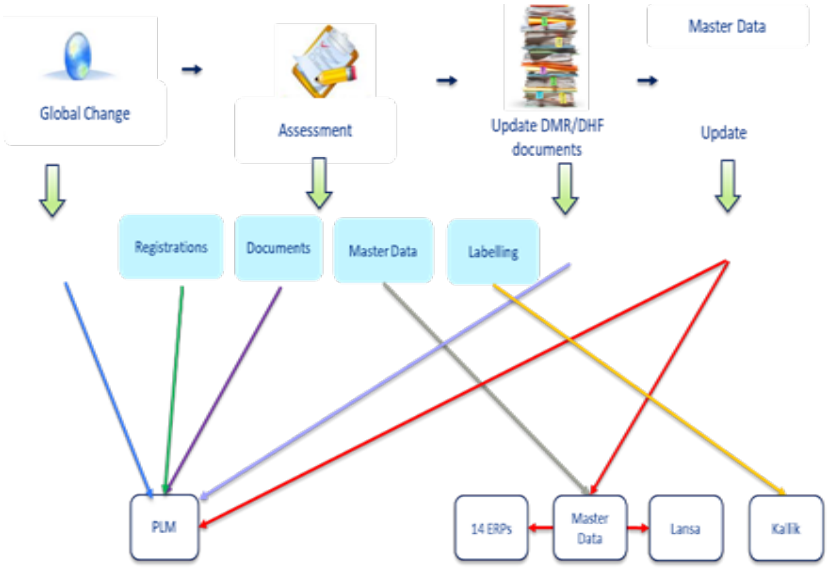

Figure 4: High-Level Future VSM After Implementation

Benefits

In addition to the above, table 3 below lists the additional benefits that were gained post-full implementation of PLM and MDM.

Table 3: Benefits of the Lean 4.0 project

Benefits	**Lean Non-value Add Waste Reduction**
Reduction in Recalls	Defects/Transport/Over-processing
Reduced effort for compliance audits (internal and external)	Over-processing/Waiting/Over-production
Cycle Time Reduction	Waiting
Reduction in re-registration efforts	Over-processing
Reduction in Scrap	Defects/Over-processing
New Product Introductions (NPI) are delivered to the customer faster	Waiting/Over-processing
Better access and visibility to manage change internally leads to a streamlined, efficient process.	Over-processing/Waiting/Defects

Scalable process to assist how Company X grow in the integration of future Mergers and Acquisitions (M&A)	Waiting/Transport/Inventory
Harmonised processes, data standards and direct access to a source of true information	Defects/Over-processing/Inventory
Centralised, digital design documentation	Over-processing/Inventory/Defects/Waiting
Globally consistent Change Management process	Waiting/Inventory/Defects/Over-processing/Over-production
Product management from conception to termination	All 7 wastes
Correct decision ownership	Under-utilisation of employee skillset
Process and data ownership defined with end-to-end metrics	Under-utilisation of employee skillsets
Aligning documentation	Inventory/Defects/Over-processing
70% Reduction in user interfaces	Over-processing/Inventory/Defects/ Over-production/ Waiting

The benefits directly impact the people, processes, and systems at Company X. Many of the benefits will have a positive impact on regulatory compliance, ensuring that Company X products, processes, and services deliver a product that is safe and effective, meets customer requirements and expectations and meets regulatory requirements by delivering a harmonised global change management process with access to accurate and reliable master data.

Detailed Examples of ECM Impact on Regulatory compliance

The following section takes a more in-depth look at some of the benefits associated with implementing ECM and how they will positively impact regulatory compliance. One common element across all areas of the ECM is the reduction of non-value add wastes in terms of man hours and human interaction across each process. Reducing the number of people involved in any process reduces the number of opportunities for human error. Human error is one of the main sources of non-conformances across Company X; therefore, reducing human interaction directly impacts regulatory compliance by reducing non-conformances and defects.

Reduction in non-conformance investigations and Recalls related to ECM

Based on initial figures, 15% of Non-Conformance Reports (NCRs) were due to ECM activities (17 out of 110). Implementing an ECM program will reduce the number of ECM-related NCRs, positively impacting regulatory compliance and patient safety. Less NCRs result in fewer recalls and reduced effort in processing both NCRs and recalls

freeing the ECM team up to work on other tasks, such as continuous improvement projects. ECM will deliver a 50% improvement in the number of ECM-related NCRs and recalls. Refer to Table 4 below for improvements relating to NCRs / recalls.

Table 4 Reduction in NCRs and Recalls related to ECM

Recall Product Cost

Recall Cost Impact	$5M
% Related to PM	55%
% Improvement with ECM	50% or $1.38M
Value Realisation	$830,000 (60%)

*Risk Factor of 40% factored in

NCR Efficiencies

# NCR's Annually (average)	110
# Linked to ECM	17
Average Cost to support each NCR	$120,000
Total Cost of Support	$2M
% Improvement with ECM	50% or $1M
Value Realisation	$600,000 (60%)

*Risk Factor of 40% factored in

Reduced effort for Quality Audits

The introduction of an ECM program means having all product and master data available electronically. Having data that is readily available and easily accessed during audits/inspections reduces the number of people involved in pulling data manually and having to copy or scan documents to provide to an auditor/inspector. In addition, it ensures that documents, when requested, are available to the auditor/inspector promptly and without undue delay> This is particularly useful where there are many actors within an organisation working across many different time zones which are required to support audits and inspections across multiple sites depending on their actor statuses such as manufacturer, sub-contract manufacturer, component supplier, importer, distributor, authorised representative or specification developer. As a result, ECM will deliver a 20% improvement in the effort it takes to manage a quality audit/inspection. Refer to Table 5 below for improvements relating to quality audits/inspections.

Table 5: Reduced effort for Quality Audits

Reduced Efforts for Quality Audits

# of audits	42 External

	300 Internal
Resources	15 people over 3 days
Total Effort	123120 hours
% Improvement with ECM	20%
Average Labour Rate	$37.13 per hour
Total Cost	$910,000
Cost Avoidance	$550,000 (60%)

*Risk Factor of 40% factored in

Total Current Effort	123, 120 man hours
20% Inefficiency due to lack of ECM	24,624 man hours
Post-ECM deployment Effort (hours)	11650
% man hour reduction	60%

* Risk factor of 40%

Reduction in re-registration efforts

As stated above, introducing an ECM program means having all product and master data available electronically. Having data that is readily available and easily accessed supports the registration process. When it is time to re-register products, rather than reaching out to different business units that must pull documents manually, scan them and arrange them for submission, ECM will support this process and make it easier and less time-consuming. As a result, ECM will deliver a 20% improvement in the effort it takes re-register the product. Refer to Table 6 below for improvements relating to re-registration.

Table 6: Reduction in re-registration efforts (Source: Project Impact Lead)

Reduction in re-registration efforts

Annual # of registrations	616
Re-Registration Effort	10.5 days/registration
Average Time to Support Each registration	51,744 hours
Average Labour Rate	$37.13
Total Cost of Re-Registration	$1.92 M

% Improvement with ECM	20%
Total benefits (millions)	$380,000
Cost Avoidance	$230,000 (60%)

*Risk Factor of 40% factored in

Total Current effort for Re-Registrations	51,7444 man hours
% Improvement due to ECM (20%)	10,349 man hours
Post ECM Deployment Effort	4,140 man hours
Man hour reduction	6,209 man hours
% man hour reduction	60%

*Risk Factor of 40% factored in

Cycle Time Reduction

Implementing an ECM will deliver a 48% reduction in the cycle time. Reducing cycle time means faster time to market, so customers and patients will have access to devices. Refer to Table 7 below for improvements relating to cycle time.

Table 7: Cycle Time Reduction (Source: Project Impact Lead)

Cycle Time Reduction

Total # of changes	11,344
# of changes requiring rework	10% or 1,134

Average Approval & Creation Time

Approval	2 hours
Creation	3.04 hours
Total	5.04 hours

Enterprise # of changes	7631
Average hours spent per change	16.03 hours
% improvement by PLM	48%
Total No of hours	58,715 hours

Total current effort	64,432 man hours
% man hour reduction	38,659 man hours (60%)

*Risk Factor of 40% factored in

Faster Time to Market

Based on the project's complexity, the time to market based on the implementation of ECM differs from between 5% and 15% improvement in the time it takes to get a device to market post-implementation. Having products on the market faster means customers can access life-changing and life-saving devices quicker, as seen below in Table 8.

Table 8: Faster Time to Market Benefits

Device Product Complexity	*Average Time to Market (months)*	*% Improvement by ECM*	*Adjusted time to market (months)*	*Saving in Months*
High	27	15%	22.95	4.05
Medium	16	10%	14.40	1.60
Low	9	5%	8.55	0.45

The case study was performed on Company X, a medium-sized medical technologies (MedTech) manufacturer that provides medical devices and technologies globally. Company X has grown through acquisition resulting in its many management systems. The case study provides an overview of Company X's history, which includes why the organisation has started implementing some Industry 4.0 tools to aid its Lean processes. These include simplifying processes, improving Lean flow, realising efficiencies, and reducing the number of errors and recalls across the organisation through implementing a global system for managing changes and product data. In addition, as a case study, company X provides examples of how Lean Industry 4.0 tools have a more positive than negative impact on regulatory compliance.

5.0 Discussion

This research met its objectives to define the impact can Lean 4.0 can have on the Total Product Lifecycle and Regulatory Compliance in a Medical Device manufacturer (RQ1) and to demonstrate how Industry 4.0 enhance and enable Lean (RQ2).

Lean processes, combined with Industry 4.0 technology as an enable, can aid in regulatory compliance by optimising processes, reducing non-value add work and over-processing, and enabling ease of vigilance and aces to regulatory information. Improved Industry 4.0 technology can aid process flow and prevent errors that can result in missed compliance deadlines and eros that could result in recalls. Lean 4.0 is an enabler for enhanced Lean processes and reducing manual tasks *[11,17]*. The synergistic effects between the two concepts ensure a more successful and symbiotic relationship and implementation of Lean 4.0 *[44]*.

Many studies on Lean, Industry 4.0, and Lean 4.0 combined discussed the benefits of an enhanced product and process quality, improved compliance, faster time to market and product cycle times, improved profits and revenue and increased market share [12,23,41]. In addition, there have been improvements in the case study organisation in the following areas.

- Product Quality and Compliance

Recall reduction: Patient safety and shrinkage in costs related to recalls caused by product management issues.

Effort for Quality Audits: Reduction in man hours related to searching and finding necessary data from across Company X sites and providing documents more efficiently and timely during audits.

- Time to Market

Acceleration of initial launch: Products made available to the end user quicker and increased revenue achieved based on an acceleration of average time to market

- Cost of goods sold reduction

Scrap reduction: Minimising scrap cost related to preventable issues based on accurate product definition.

Acceleration of Cost Improvement programs (CIPs): Accelerated time to adoption of cost improvement projects leading to increased cost-saving duration

- Operational Efficiencies

Cycle Time reduction: Streamline change approval process to eliminate non-value add activities

Effort for re-registrations: Cutback on required man hours per registration based on ease of visibility to data

Other benefits included brand equity, faster integration of Mergers and acquisitions (M&A), procurement efficiencies and inventory optimisation. To achieve these benefits, Company X chose two well-established technologies, Agile for PLM and SAP for MDM. Choosing the right technology and understanding how it can be integrated into an organisation is a critical success factor for Industry 4.0 *[52]*. These technologies are the foundation for the organisation's digital transformation journey. These technologies will provide the organisation with the infrastructure needed to execute the organisation's Strategic Vision and what is also considered the organisation's Industry 4.0 roadmap. A strategic plan and map for Industry 4.0 implementation is key to the success of the imitative *[53]*.

From the project's initiation, Company X's leadership team were fully invested, involved and supportive of the strategic plan for Industry 4.0 deployment. While it took some time to gain approval from the Senior Leadership Team (just under 2 years), significant investment was approved by the organisation in terms of resources, both people and finances. Many Industry 4.0 projects can fail without this level of management support and involvement to understand the alignment of digitalisation with strategy *[54]*. The project team had to provide the Senior Leadership Team with the evidence they needed in terms of benefits and return on investment before committing to the project. Detailed cost-benefit analysis and understanding of the need for such technology are key to the success of such deployments *[24]*.

Another key aspect of the project was driving change within the organisation and the requirement for effective communication and training. People need to understand what is being changed and why it is being changed so they can buy into and support the project *[4]*.

Digital transformation involves significant effort, time, and money [55]. However, the benefits the project could bring to make the organisation more Lean and enhance its regulatory compliance, the project needed Senior Leadership to buy in given its significance and for it to be successful and deliver the benefits to the organisation. The data presented in this case study demonstrates how Industry 4.0 and Lean combined can have a synergistic effect.

6. Conclusions

The research met its research objectives to demonstrate that Lean and Industry 4.0 can improve and enhance Lean processes, reduce waste and improve productivity and quality while enhancing digitalisation. Integrating Lean and Industry 4.0 can enhance regulatory compliance to ensure that organisations adhering to global regulations and legislation can deliver safe and effective products. A limitation of this research was that it was a single case study. Using similar or different-sized companies (small or large) would have provided another perspective on how and why other companies are implementing Lean 4.0 and at what stage they are in their journey so that a comparison could be made. The case study organisation used was only in the early implementation of its strategic plan for digitalisation to enhance Lean. Therefore while it is possible to review the first stages of the project's success, further research could focus on the ongoing deployment across company X. Further research should be taken post-implementation to gain more long-term data on the digital technologies implemented, their effects on Lean, and their impact on regulatory compliance. In addition, future studies should consider including other MedTech companies to make a comparison.

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