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Application of Design for Lean Six Sigma to strategic space management

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Abstract

Purpose – This paper outlines how Design for Lean Six Sigma methods aided a medical device manufacturing company in developing a new strategic space management and approval process for its manufacturing site.

Design/methodology/approach – The project demonstrates the application of the Design for Lean Six Sigma and structured Define, Measure, Analyse, Design, and Verify methodology in designing and implementing a process that enables the case study manufacturing site to improve its space utilisation and free up space.

Findings – The project was validated in one manufacturing department, and the Design for Lean Six Sigma methodology resulted in creating 15% new space for that area, with opportunities identified to free up 44.7% of the total manufacturing floor space and realise over €2.2 million cost savings as well as start to manufacture new products launched.

Research limitations/implications – The manuscript highlights for the first time how the Design for Lean Six Sigma methodology can be utilised for space utilisation and can be leveraged by other manufacturers. The current study's limitations are that it is a single-site case study application. Future longitudinal case studies on Design for Lean Six Sigma application in more manufacturing space utilisation projects would be useful. This study has implications for identifying best practices for Design for Lean Six Sigma methodology application in the device industry, thus improving the state of the art for introducing new manufacturing lines.

Originality/value – This is the first published work to utilise Design for Lean Six Sigma methodology for space utilisation in a medical device company. This review will provide medical devices and other manufacturing organisations with recommendations on utilising Design for Lean Six Sigma and design for improved space utilisation to reduce costs.

Keywords Medical device, DFLSS, DMADV, Lean Six Sigma, Space management

Paper type Research paper

1. Introduction

Global market competition and fluctuating customer demands require manufacturing enterprises to focus on cost reduction and efficiency improvements to increase competitiveness and sustainability. The availability and management of space in manufacturing environments are key components of providing adequate capacity to meet customer demand and provide the manufacturing site with a competitive edge over its external

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and internal competitors (Green *et al.*, 2010). The primary function of a manufacturing entity is to build and supply products to the customer on behalf of the organisation. Therefore, strategic manufacturing layout and space decisions are considered one of the most important design decisions as part of business operation strategies and their proven repercussion on production systems' operation costs, efficiency and productivity (Pérez-Gosende *et al.*, 2021). The floor space available to manufacturing is also a resource that can help drive a successful manufacturing strategy. Lean Six Sigma (LSS) approaches have successfully developed and improved processes within the manufacturing sphere to improve quality and reduce waste (Antony *et al.*, 2021). Many studies have discussed the advantages of applying LSS to enhance space utilisation, reduce floor space and improve flow (McDermott *et al.*, 2022a; McDermott and Nelson, 2022; Trubetskaya *et al.*, 2022). Kovács (2020) conducted a study in a manufacturing facility that combined Lean methods and facility layout design to achieve efficiency improvements and cost reductions. Within this study, there were many benefits: minimised material workflow, travel distance of materials, material handling cost and space used for assembly; improved cycle time and reduced the number of workstations and operators, work-in-process and inventories, space used for assembly, material workflow, travel distance of materials, material handling costs, labour cost, component supply and improved product quality, transparency, standardisation and workplace ergonomics.

However, much literature discusses using the LSS DMAIC model to improve existing process and space utilisation problems. Define, Measure, Analyse, Design, and Verify (DMADV) is a data-driven quality strategy that focuses on the development of new products or services compared to existing ones (Burke and Silvestrini, 2017). The DMADV method or approach is often used when implementing new strategies because of its basis in data, its ability to identify success early and its method, which requires thorough analysis. Industrial facility layouts are defined as physically arranging the space and equipment within a manufacturing site. The manufacturer is trying to design a strategic layout for a medical device manufacturer where this research takes place. This layout will shape the production system to suitably and efficiently fulfil the organisation's strategic objectives and gain more space to start manufacturing other products from their parent company. In the case study organisation where this research takes place, it is proposed to utilise the DFLSS model of DMADV to design an improved layout in tangent with the start of the facility layout process. It is proposed that a DFLSS approach can be utilised to develop a strategic space management and approval process in a manufacturing site.

A new process will be developed to avoid repeat capital expenditures, prevent inefficiencies on layout relocations and increase site readiness for capacity increases and new product introductions. Using the DMADV methodology, the project will create a new space management process to utilise manufacturing floor space as a strategic weapon to gain a competitive advantage (Pérez-Gosende *et al.*, 2021). Thus, the research questions are as follows

RQ1. How can DMADV methods be applied to a manufacturing site layout design?

RQ2. What are the benefits of implementing a DMADV design?

Section 2 outlines the literature review, while Section 3 discuss the methodology taken to review the literature, section 4 outlines the results from reviewing the literature and sections 5 and 6 discuss and concludethe results, respectively.

2. Literature review

The importance of the manufacturing strategy as a function within organisations has been highlighted for decades Dangayach and Deshmukh (2006). Manufacturing is a strategic competitive factor by which companies can differentiate themselves, and it is no longer enough to manage and adapt manufacturing using short-term goals (Harmon *et al.*, 2010). Therefore, manufacturing and facility line layout and the facility are considered one of the most important operations design decisions (Ghassemi Tari *et al.*, 2018). Gupta *et al.* (2018) also highlight the importance of formulating a manufacturing strategy to gain a competitive advantage. Competitive advantage in the literature is written in the traditional sense - making products cheaper and faster or as Harmon *et al.* (2017) puts it, competitive advantage is the edge of firms over their competitors. It can manifest in higher sales margins or the ability to retain customers and firms most clearly understand their competitive advantage and exploit it to create a distinct image.

The treatment of manufacturing floor space as a source for competitive advantage links in with the resource-based view of competition. Conner (1991) argues that acquiring, developing and controlling scarce resources and deploying them strategically to achieve goals has solid grounding economically. It is more profitable to focus on developing, protecting and leveraging a firm's unique operational resources and advantages to change competition rules (Gagnon, 1999). As an expensive and scarce resource, manufacturing floor space is an important factor in manufacturing. The experience in manufacturing operations to use lean six sigma tools to improve issues with current processes and make products faster and cheaper (Garza-Reyes *et al.*, 2012) has developed a knowledge base of how these tools can be used for continuous improvement. Hamel and Prahalad (1990) built upon this by pointing out the importance of linking core competencies and the competitiveness of an organisation where operations management would not just structure processes but would have detailed knowledge of its resources, look after them and use them intelligently to enhance competitiveness.

Traditional LSS continuous improvement projects follow the Six Sigma DMAIC (Define, Measure, Analyse, Improve, Control) methodology, which has been applied since the 1980s as a recognised data-driven scientific method for solving complex business problems (Trubetskaya and Mullers, 2021). The DMAIC methodology has been built on established scientific, engineering and quality improvement techniques pioneered throughout the past few decades (McDermott and Antony, 2021). A more recent Six Sigma methodology known as 'design for Six Sigma' or DFSS was introduced in the late 1990s to support the design of new products, processes, and services (Huang *et al.*, 2010).

Among the ten reasons for improvement projects to fail that was put together by Antony and Gupta (2019) is a selection of methodology and associated tools that are faulty. Gijo *et al.* (2021) pointed out that the understanding of different DFSS methodologies, such as DMADV (Define, Measure, Analyse, Design, Verify) or DMAIC (Define, Measure, Analyse, Improve, Control), among many other proposed methodologies and customising it based on the organisational needs will reinforce the productivity and performance. DMADV methodology is more suitable for creating new processes, whereas DMAIC is suitable for solving problems within existing processes (Cudney and Agustiady, 2017). When the product or service under consideration is under major design change requirements or still at the initial stages of development, DMADV is the five steps that are used (Salah *et al.*, 2010). Within each of the five steps, various statistical and lean tools are selected as appropriate (Womack *et al.*, 1990). However, some authors have proposed an 8-step DFLSS toll gate process as the best practice (Chatterjee and Green, 2007). Initially, DMADV was utilised for product design (Chandan *et al.*, 2022) and is well established in services design in some cases using Identify, Design, Optimize, Validate (IDOV) (Furterer, 2016). Design for Lean Six Sigma (DFLSS) has been described as an outgrowth of the DFSS and Lean Six Sigma approaches but with the principles of Lean incorporated to aid waste reduction, improve flow and reduce non-value add (Thomas and Singh, 2006). Antony (2012) has discussed the need as firms to improve their processes and move towards Six Sigma to redesign their products, process and services to "design out" defects and design-in quality. Organisations working at three or four Sigma commonly spend between 25 and 40% of their incomes fixing issues (Gaikwad *et al.*, 2022), and DFLSS offers a method of reducing these costs while designing “right first time”. Thus utilising the voice of the customer (VoC) can enable the design of processes and products incorporating customers, stakeholders and all relevant opinions (Ko and Hunt, 2008). The advantages acquired from the use of the DFLSS approach are increased comprehension of customers, assumptions and their needs identified with products, processes or service attributes, as well as enhanced quality to manage risks in the design process for products, processes or services with reduced post introduction cost such as warranty about products and rework about processes (Antony, 2002).

3. Methodology

The project was initiated to create a space management and approval process for a medical device manufacturing site. The framework adopted for the project is the DFLSS methodology of DMADV. As the company has begun its lean transformation in recent years, there was a familiarity with DMAIC (Define, Measure, Analyse, Improve, Control) that had the project team initially favouring the DMAIC approach. However, as there is currently no defined process for managing manufacturing space in the company, the project team moved to the DMADV approach, as summarised in Table 1.

3.1 Define

At the project’s concept stage, a Gemba walk of the manufacturing areas of the site was conducted by the site leadership to observe what floor space challenges and opportunities existed. Following this, discussions were held, and affinity diagrams were used to organise the ideas. A SIPOC chart was used to determine and visualise the new process’s suppliers, inputs, outputs and customers. The SIPOC also helps the project team determine the level of

Stage	Tool	Output
Define	Gemba walk	Physically observe the potential of the manufacturing space
	Brainstorming and affinity diagram	Develop ideas ad group them together
	SIPOC	Provides a clear picture of the inputs and outputs for the process
	Project charter	Details the scope, goals, resources and deliverables for the project
Measure	Critical to quality tree	Used to translate the business needs into qualifiable outputs of the new process
	Data collection plan	This will be used to measure the current use of the manufacturing space
Analyse	Pareto chart	This will be used to analyse the current use of the manufacturing space
	Ishikawa cause and effect	Used in reverse to brainstorm ideas to reach the requirements of the process
Design	Process mapping	Design the new space management and approval process
	Gantt chart	Used to plan implementation
Verify	Pilot run	Validate that new process design meets runs smoothly and meets target outputs
	Change management	Manage resistance to new process and ensure that it is meeting its target outputs
	Control plan	Schedule ongoing review of process to ensure that it is meeting its target outputs
	Gemba	Used to physically observe the new process has the desired impact in the manufacturing area

Table 1.
The tools used in the project

resources (either capital or human) to develop the new process and ensure that these are implemented for the project.

The output from these brainstorming sessions provided the team with a project charter, which set the objectives, scope, specific project benefits, financials, deliverables, key metrics during the project and a communications plan. In addition, the project team, their roles and key responsibilities were also defined in the project charter.

3.2 Measure

During the Measure stage, the project team built upon the outputs of the future process and gathered information on the requirements of the business. This information was gathered by meeting with the customer (site leadership). Generally, the voice of the customer is based on how they experience a service or product, and the information can be vague and difficult to measure. On this basis, the voice of the customer was transformed into critical to quality (CTQ) parameters to ensure that the customer's requirements are quantified and, therefore, measurable. A CTQ Tree was used to create specific and measurable outputs from general and hard-to-measure characteristics to transform the customer's needs into quantifiable and measurable characteristics. A data collection plan was also developed. The purpose of the data was to provide detailed information on the current use of manufacturing space within site.

3.3 Analyse

Pareto charts were developed using the data from the measure phase. This provided a foundation for the team to analyse the current floor space use within the factory. The team used an Ishikawa Cause and Effect diagram to brainstorm ideas on how any new process would meet the CTQs of the new process. During this phase, the team also began sketching high-level draft process maps to develop the concepts of how each of the CTQs would be met.

3.4 Design

During the design phase, the team constructed a map of a process that would meet the CTQs. The mapping process began at a high level and more detail was added to reach the optimal process. Following this, a Gantt chart was again used to develop a plan for verifying and implementation.

3.5 Verify

The new process was verified by simulating a product transfer project and then used while introducing a continuous flow line in an existing area. Following the verification of the process, the standard was documented and published. A change management and communication plan were initiated to ensure that all personnel understood the process and their role in it. A control plan was also developed to ensure the process continued functioning as designed post-implementation. Gemba walks of the manufacturing floor will also be used to ensure that floor space management meets the documented standards.

4. Results

4.1 Define

Having realised the need for a unified space management and approval process, the operations director assembled a project team. The core of the project team included the Facilities Manager, Production Manager, Engineering Manager, Quality Manager, R&D Lead and QE Manager. In addition, this researcher (Manufacturing Supervisor) was appointed to guide the team through each project stage. A project charter, which defined the project's scope, was determined and agreed upon with the operations director.

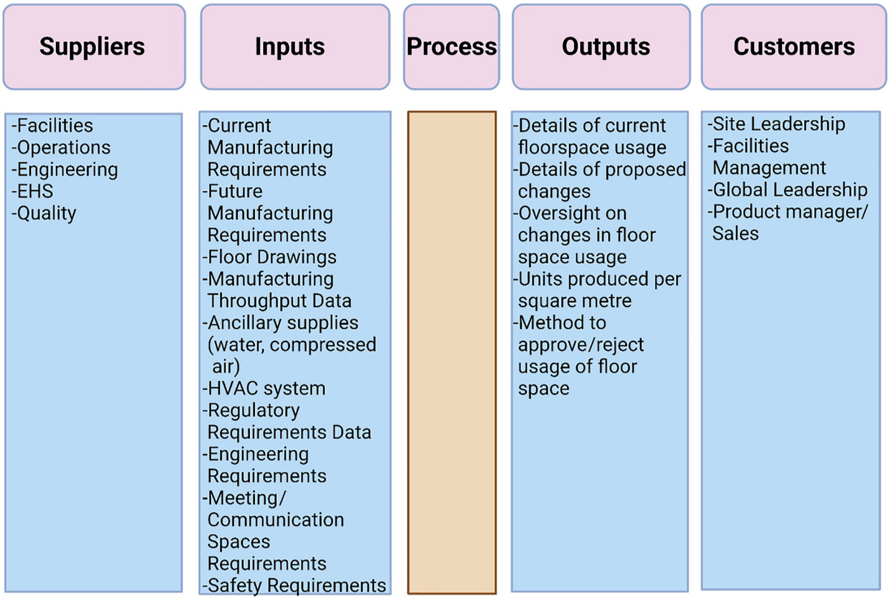
The initiative's define phase included brainstorming and using a SIPOC diagram, as shown in Figure 1. The brainstorming discussions, aided by using affinity diagrams, were held with site leadership and operations managers, and the team found that space was utilised in different ways by different departments, depending on how that department's managers saw to use it. Space was usually used in an ad-hoc manner, often reacting to requirements and available space was often commandeered, whether it was part of that manufacturing unit (MU). Resistance to the appropriateness of such space utilisation was often shut down with the 'business needs' card. It became clear that such methods of acquiring or utilising manufacturing space did not suit the customer's requirement, i.e. site leadership.

Following these initial meetings, the team worked with stakeholders to understand what context a strategic space management process would exist. Using a SIPOC map (Suppliers, Inputs, Processes, Outputs, Customers) facilitated the construction of what resources were required for the process and the expected outputs. Having completed a SIPOC, the project team then highlighted areas that would provide data as a baseline for current performance.

4.2 Measure

Within the measure phase, the needs of the business (voice of the customer) identified in the project team's engagement with the stakeholders were mapped to a CTQ template, as shown in Figure 2. This enabled the team to develop metrics that captured the customer's voice and provided measurable targets for the new process.

The CTQ tool assisted the team in understanding the needs of the business and transformed these needs into specific and measurable criteria. The project team found that understanding the drivers of the needs provided more insight into the customer's requirements, which led to better servicing of those needs. For example, in the CTQ, a need to know what type of floor space is available may not always be clear and could have led the team down many different paths.



Suppliers	Inputs	Process	Outputs	Customers
-Facilities -Operations -Engineering -EHS -Quality	-Current Manufacturing Requirements -Future Manufacturing Requirements -Floor Drawings -Manufacturing Throughput Data -Ancillary supplies (water, compressed air) -HVAC system -Regulatory Requirements Data -Engineering Requirements -Meeting/ Communication Spaces Requirements -Safety Requirements		-Details of current floorspace usage -Details of proposed changes -Oversight on changes in floor space usage -Units produced per square metre -Method to approve/reject usage of floor space	-Site Leadership -Facilities Management -Global Leadership -Product manager/ Sales

Figure 1.
SIPOC

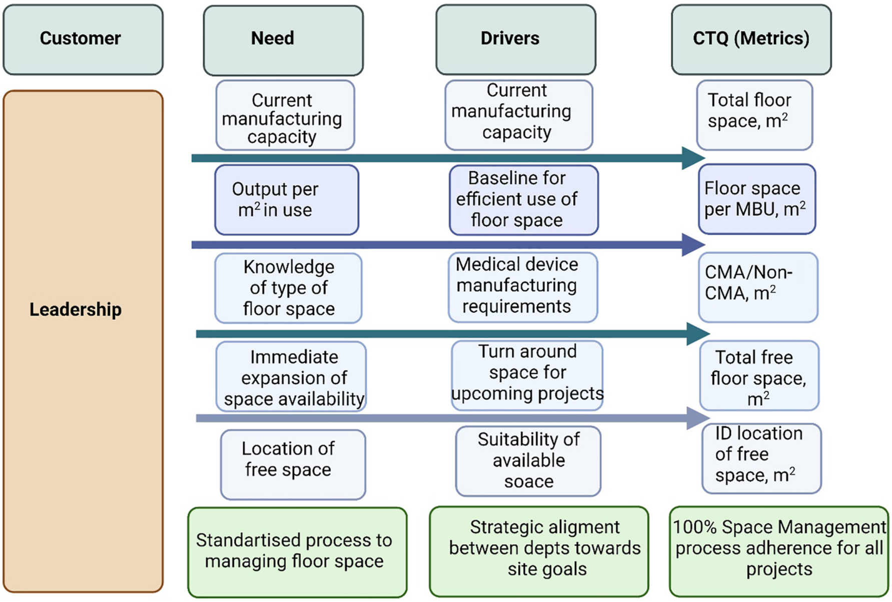


Figure 2.
CTQ template

However, understanding that some products require processing in class 8 clean rooms and others does not drive the need to understand whether the site has available space for either type. Of the six CTQ (Critical to Quality) metrics, the first five are the data points that the new process requires to set out a baseline for the new process. They are the total manufacturing space (m^2), the space currently used by each MU, clean room or non-clean room space, the free space currently available and the location of that free space.

The team put together a data collection plan to gather the required data, as shown in Table 2. Guiding the team in creating the collection plan to meet the requirements of the CTQ output was the simple principle of What? Who? Where? When? & How?

Table 2.
Data collection plan with results

MU	CMA1	CMA2	CMA3	CMA4	Received	Shipped	Total, m^2	m^2 CMA	m^2 non-CMA
Urology	605	28	0	0	125	89	847	605	242
Plastic	496	18	0	0	113	89	716	496	220
Stents	0	15	354	0	87	89	545	369	176
Self-expanding stent	0	6	378	0	93	89	566	384	182
Area X	0	5	280	0	101	89	475	285	190
Ultrasound needle	4	4	168	0	50	89	315	176	139
Area B	0	14	0	823	35	89	961	837	124
m^2 used by area	1,105	90	1,180	823	604	623		3,152	1,273
m^2 non-used by area	155	18	0	0	44	0			
Total m^2 by area	1,260	108	1,180	823	648	623			

Using the existing drawings, the team worked with operations personnel to highlight differences between the site drawings and the actual usage of floor space. This activity included several visits to each area, and the team often found space for overflow storage of items that may not have been there on the previous occasion. The existing layout of each manufacturing area was captured, and the floor space usage was measured. The drawings were also used to colour workspaces by the MU that was using them at the time.

Figure 3 below shows how CMA3 had several MUs intersecting in some areas, but it also showed how the MU in the middle of the floor (yellow marked) retained workbenches for future use. This aligned with the issue highlighted in the original engagements with stakeholders about how space was utilised differently depending on the area and manager.

In the areas outside the manufacturing suites, it was found that the Receiving and IQC (Incoming Quality Control) areas did not have details on the space utilised by each MU for the materials for that MU. It was a case of use that was available. The team worked with the local area owners to measure the specific space usage by materials for each MU. In the shipping area, it was not easy to accurately measure the floor space usage as products from all MUs flowed through this area. The team decided to divide the floor space equally for each MU. The storage and processing space used in IQC, Receiving and Shipping for each MU was measured and included in the Pareto chart.

The data collection activity found that 4,425 m^2 of manufacturing space was in use and that 217 m^2 was not in use. Therefore, based on the productivity of each MU at the time of the data collection, the team were able to carry out a calculation of the output per m^2 for each MU, as shown in Figure 4.

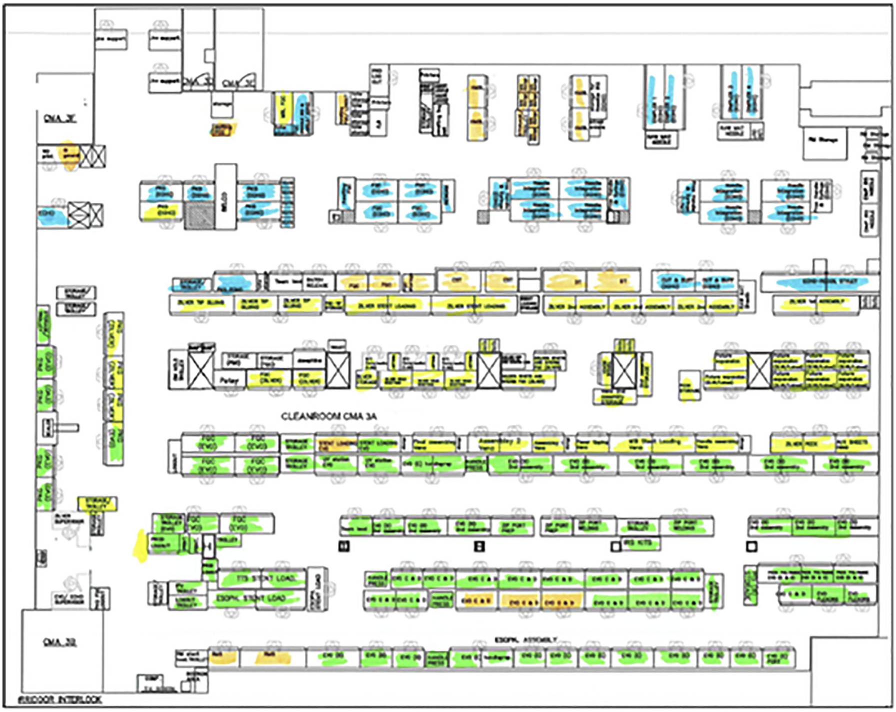


Figure 3.
CMA3 floor drawing

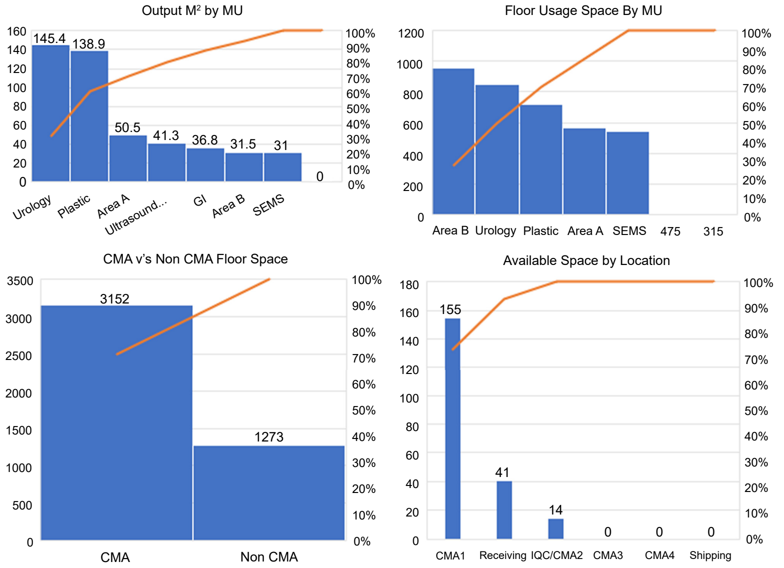


Figure 4.
Output of the available space and potential space usage

Figure 4 above shows the floor space currently in use by each MU. Area B uses the largest floor space at 961 m^2, and GI uses the least floor space at 315 m^2 and illustrates that CMA (Controlled Manufacturing Area) was measured at 3,152 m^2 and Non-CMA floor space was measured at 1,273 m^2. As requested by site leadership, the data collection results also indicate the location of available space, as shown in Figure 4 and the location's name indicates the type of floor space available.

4.3 Analyse

Applying the lean six sigma principles has proven beneficial in identifying how the lack of a space management process has impacted the floor layout by making the issue more visible. Next, the team set about using an Ishikawa diagram to brainstorm how the process would meet the requirements of the business, as shown below in Figure 5.

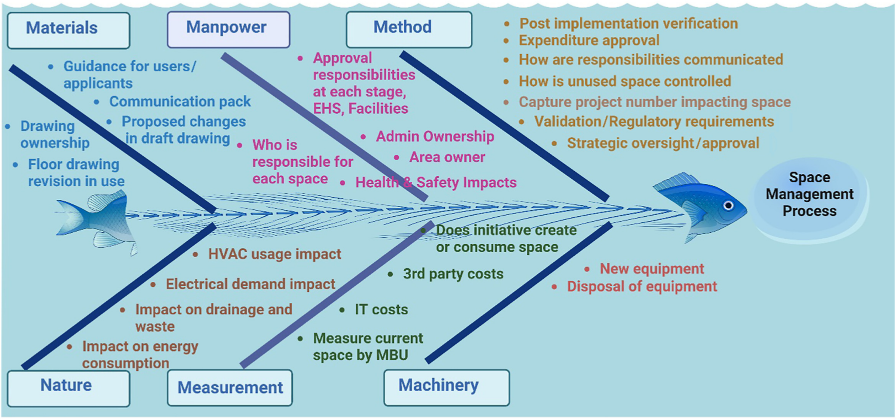


Figure 5.
Ishikawa diagram

Utilising the outputs from the SIPOC and CTQ exercises, the team brainstormed several areas requiring mandatory information inputs for any person or department undertaking an activity that impacted the manufacturing floor space. For example, what impacted the floor drawing ID and its revision? This would highlight if there were other changes planned for that floor space. An important data point would be whether the project engaged in the new process would be consuming or creating space and the drivers behind these changes. In addition, it would be important to understand if any changes were aligned with the overall strategy for the manufacturing site. The number of departments specified in the Ishikawa diagram also highlighted the need for early collaboration between all impacted departments. The final consideration in the brainstorming was which department would own the process. Would it be facilities, as they are usually responsible for the drawings, or would it be line support, who are usually the users of the manufacturing floor drawings? The number of potential variables that could feed into any project that impacts floor space highlighted to the team that any new process would need a guidance template so that project leads could easily follow that process.

4.4 Design

Using the information from the brainstorming sessions, the team worked on developing a strategic space planning and approval process that would include the criteria from the analysis and meet the needs of the business, as shown in Figure 6. Recognising the importance of early collaboration to the success of any project, the team set out a process that requires impacts to be shared with stakeholders early in the process before other expensive activities, such as costings and regulatory approvals, are sought. In addition, how floor space is impacted must be detailed and highlighted in future state visualisations of the floor plans.

One of the CTQs set out by the site leadership is that there would be adherence to a 100% strategic space planning process for all projects. Therefore the team designed the new process as a precursor that leads into the Project Management Cycle process for business or continuous improvement projects (CIP or BIP).

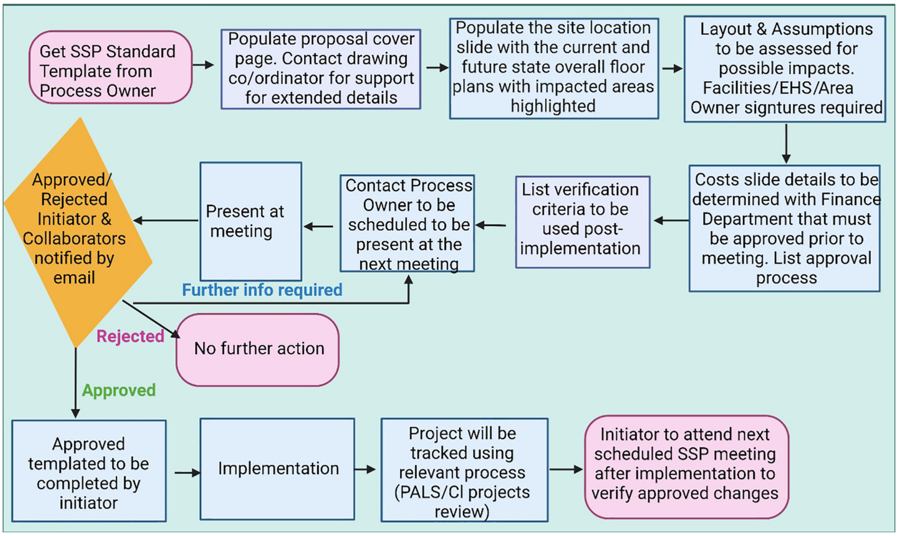


Figure 6.
Space management and approval process

To plan the project's next phase, the team put together a Gantt chart, as shown in Figure 7. This provided a high-level view of the next steps and the timeline of each step. These steps included building the Strategic Space Process template to guide users. Once in place, the new process, with the aid of the SSP template pack, was simulated. Following a successful simulation, the business policy document was finalised and released, and the company's project management process was updated to check for adherence to the space management and approval process. The team also planned to complete and roll out the communication and training plan in two weeks. Finally, the team planned to conduct an after-action review to take learnings from the entire process, as shown in Figure 7.

4.5 Verify

The initial plan was to simulate the strategic space management process using a previous product transfer and manufacturing line re-layout that had occurred earlier in the year. The lead for that product transfer was brought on board, taken through the requirements of the process and tasked with trialling the process. The result of this activity found that while the project was planned in great technical detail, there was a gap in the level of collaboration with the area owners across shifts. Upper management levels were aware of the changes, but manufacturing supervisors and team leads were not included. The exercise also reinforced the findings from the measure phase that there were gaps between the actual floor space usage and the drawings when the project was implemented. The project lead gave feedback that this led to a significant quantity of frustration and conflict in the days just after the floor relay out as the manufacturing team members raised issues about how their work area was laid out compared to its previous actual layout. A workshop was also conducted with several experienced project leads, and it simulated the process for a new product introduction for 2023. This activity found that the new strategic space planning and approval process worked well and was easy to follow. The team set about developing a change management plan. A training and communication plan was put together. This training plan did include how to use the strategic space plan and the why. It gave a background to the importance of manufacturing floor space, its costs, particularly in controlled cleanrooms, and how creating more free space can increase the capacity and competitiveness of the manufacturing site in Ireland. The communications also targeted all manufacturing team members on-site rather than just the leadership groups of each department. This was a deliberate measure, as the

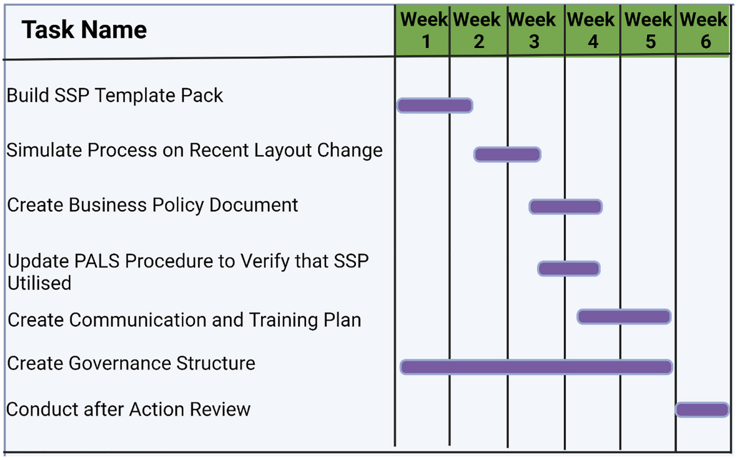


Figure 7.
Implementation plan

day-to-day users of the manufacturing spaces were in the best position to ensure that each section of the floor was utilised as planned and to bring about engagement for future improvements.

Several controls were put in place to maintain the gains made from implementing the new process. These controls included the development of the policy document and practical and tangible means for all personnel to ensure adherence to the space management process. The freed space was segregated from use, and signage was put in place to identify the owner of the space and the project that made it available. The weekly 6S audits were updated to ensure that free space was segregated and its ownership and purpose identified. Unauthorised incursions on the free space were to be highlighted, and the 6S audit score was impacted only more in the safety section. The Gemba walks conducted by senior management increased in frequency from monthly in each area to weekly and senior leaders from departments such as Engineering, Facilities and Quality began to participate in the Gemba walks. The schedule for the Gemba walks was updated to include a physical review of all free sections of floor space and to ensure that adherence was maintained.

The new Strategic Space Management and Approval process were validated in practical terms in June 2022 when a redesign of the Plastic Stents manufacturing areas in CMA1 was completed. This was the first project to utilise the Strategic Space Management and Approval process. The result of the redesign led to a reduction of the floor space used by the various sections of the Plastic Stents MU from 716 m^2 to 608 m^2, freeing up 108 m^2 of controlled manufacturing space. The re-layout also improved space utilisation from 138.9 units per m^2 to 163.6 units per m^2 (Table 3). The project also increased the total amount of free space from 217 m^2 to 323 m^2. The cost savings from the validation project are €280,473, and the process will produce total savings across the entire manufacturing area of €2.2 million (Table 3).

5. Discussion

This project demonstrated that the DMADV methodology successfully developed a new space management and approval process for a medical device manufacturing site. The key drivers of change in how space was managed in the manufacturing facility were a realisation by site leadership that there was no link between the utilisation of floor space and the site's strategic goals of attracting new business to the site and a lack of data on how efficiently that space was being utilised. The results of this project have demonstrated that the DMADV framework can be used to develop new operational processes that link in with existing processes and align the various departments towards the site's strategic goals. The current results have also confirmed the importance of the company investing resources in ensuring that staff in all departments clearly understand the company's strategic goals and how they can impact the achievement of those goals (McDermott *et al.*, 2022c). This project has led to

Completed	Before	After	Result
Space saving, plastic stents, m^2	716	608	15%
Space utilisation, plastic stents, units per m^2	139	164	18%
Free space, plastic stents, m^2	0	108	–
Current total free space, m^2	217	325	50%
Planned			
Designed free space, m^2	217	1,979	–
Designed free space % of total space	4.9%	44.7%	–
Cost savings	*EUR*		*2,277,874*

Table 3.
Results summary

the establishment of a Lean DMADV model with the advantage of using simplified and accessible methods that can be structured to address other organisational challenges where there is a lack of strategic alignment and no clearly defined process for managing and approving the use of any company resources.

The initiative also shows a large selection of lean six sigma tools that can be utilised to achieve the desired goals. This project was developed using the DMADV model in space management, which is a novelty as the topic has hardly been invested in literature. Existing literature has tended to use individual lean tools such as 6S to organise work areas at a local level, or DMAIC has been used as a model to solve once-off-space issues (Trubetskaya *et al.*, 2022) or as previously experienced within this company, improved space utilisation had been captured only as a by-product of once off applications of lean tools rather than being the target of an overarching strategy. Moreover, while initially, the DMADV model was chosen over the more familiar DMAIC model as it was recommended for designing new processes, the present results underlined the key philosophy of the DMADV model that centres around the customers' requirements. In this case, the business and its strategic goals provide the basis for the voice of the customer approach that DMADV espouses rather than the short-term and incremental problem-solving offered by DMAIC or standalone usage of tools such as 6S.

Gijo *et al.* (2021) highlight various techniques that can be used to understand the VOC, and they distinguish between the qualitative and quantitative techniques. Of the quantitative techniques, the Kano Model and QFD (Quality Functional Deployment) can be utilised to gather the customers' requirements and transfer them into technical data (Gangurde and Patil, 2018). The Kano Model offered to categorise requirements into those that must be provided and those that would create 'delight' for the customer. The Kano model has proven useful in gathering information from several customers on several points and creating a data-based model for measuring how well those customer needs are met. QFD (Quality Functional Deployment) also provides a method to gather various customer data and then rate it against competitors' offerings and convert the requirements into specifications. For this project, where one customer was identified and a relatively small number of requirements, the team realised that simple face-to-face discussions facilitated using a CTQ tree were hugely beneficial. The customer was in a place to participate in the exercise and agreed with the CTQ targets at the end of the exercise. In this case, the customer either agreed with the targets 100% or did not agree at all.

While the use of the CTQ tree can appear less data-based than other models, it was a useful method to eliminate assumptions and provide a clear platform to build the new process. Despite the project's qualitative beginnings, a large amount of quantitative data was gathered during the measure phase to set the baseline for the new process. This data will provide evidence of the impact of strategically managing the manufacturing floor space. The floor space usage by MU per m^2 directly impacts the company's bottom line results. Sodhi (2020) puts it that DMADV is a data-intensive approach. This perception of DMADV as data-intensive may be why it has not been used extensively for developing organisational processes. This project has demonstrated that within the DMADV framework, conducting interviews and using the CTQ tree can transform a strategic need of a business where there is initially a lack of data and use it as a platform to transform it into a data based operation.

The study has also demonstrated that repeated changes at the departmental level without a process for strategic oversight can be hugely expensive. Previous changes to the layout of production lines have had costs ranging between EUR155,000 and EUR490,000. The validation of the new process resulted in an immediate cost saving of just over €280,000 and will reduce costs by €2.2 million by the end of 2023 (Table 3). Without using a process designed with DMADV, the company will potentially experience those costs as repeat expenditures and longer implementation times. When the need for space management is identified, the application of the DMADV methodology will ensure the design process will proceed smoothly and in a short timeline. The results in Table 3 show that 50% of floor space can be freed to be ready for building new product lines. Without using the DMADV model, the company is faced with the potential of expensive space re-layouts every time there is a fluctuation in demand and by using short-term activities based on DMAIC or other models.

5.1 Theoretical implications

This is the first attempt in the literature to present a model for strategic space management using the DMADV framework. While the model's validation is limited to a single manufacturing site and has not been demonstrated to other sites or industries, it does provide a platform for further research into how strategic space management can be developed using the DMADV model.

This study has several significant implications for state of the art in terms of demonstrating how DMADV implementation can be successfully deployed in manufacturing companies. First, this study was deployed in a manufacturing company and a highly regulated manufacturing environment where changes are expensive and difficult to implement because of regulatory requirements. LSS methodology in the MedTech industry (McDermott *et al.*, 2022b; Trubetskaya *et al.*, 2022).

5.2 Managerial implications

There are several managerial implications in this study. First, utilising a process based on the company's longer-term strategic goals can ensure floor space capacity can be increased, and baselines for efficiencies are set (Nelson *et al.*, 2022). By using DMADV to design for future increases in space requirement, the company can plan for demand and build it into their capacity.

Furthermore, lessons learnt from the present study for organisations show that DMADV implementation, particularly in the early stages, can take much commitment and focus from the project's sponsors. The company may need to utilise many resources, such as engineering and external contractors, to develop its goals and measure its current baseline. Without understanding the required level of commitment, companies may abandon the implementation prematurely, before realising the benefits of such an initiative. A layout design based on big data can be more efficient and effective (Kumar *et al.*, 2018). With the advent of Industry 4.0, this use of data could be integrated with the existing DMADV design to develop a maturity model that provides the company with a more precise understanding of its resources (McGovern *et al.*, 2023).

6. Conclusion

The novelty of this relies on the integration of Lean DMADV methodology into the improvement of floor space management. The DMADV model ensured simplicity for all participants to engage with the medium-sized enterprise improvement steps (RQ1). The project's activity in bringing various departments and managers together has also had the impact of reducing the barriers between those departments and a greater understanding of the impacts each department and each employee can have on the future of the company to achieve a structured space environment (RQ2). A key factor for the success of this project is that it was conceived and supported by the senior management emphasising the importance of leadership in Lean improvement. While this model has yet to be validated in other scenarios, this simple approach should make it adaptable to any organisation that needs to develop processes to transform how they utilise their operational resources. Although this project took place in a medical device manufacturing site to strategically manage and free up space, the method can be used in any setting where there is no defined process. Other industries where space is limited or needs to be repurposed for use could transform the qualitative inputs into quantitative outputs that will meet customer expectations.

A limitation of this study could be that the project did not measure the impact of the new process on the life cycle of business improvement projects. Some expressed concerns that the new process may be seen as another administrative hurdle for project teams to jump over. A counterargument to this is that the process would help screen the projects and ensure that they were strategically aligned and improve their chances of success. A further limitation is that the case study was confined to one site, so the findings may not be generalisable.

Opportunities for future research are to deploy the learnings to the parent company of the manufacturing site. Based on the success of the new process at a local level, digital platforms could be utilised in other sites to replicate the face-to-face voice of the customer activities, such as surveys and interviews, at various geographical locations in the earlier stages of the project. Future research around layout design based on Industry 4.0 technology integrated with the existing DMADV design to develop a maturity model is an opportunity for more investigation. Thus, this will give its leadership the ability to make the most effective decisions about the strategic utilisation of manufacturing space.

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