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The Impact of Lean and Modularity on Pharmaceutical
Facilities in Ireland

By

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DECLARATION

I, Ayodeji Awe, declare that this thesis has been composed solely by myself and that it has not been submitted, in whole or in part, in any previous application for a degree or professional qualification. Except where stated otherwise by reference or acknowledgement, the work presented is entirely my own.

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ABSTRACT

Modularity is a systematic process where the various modules of a system or product can be combined in multiple ways to form a different product or system while Lean is a user-centric approach that focuses on continuous improvement, waste elimination and project management. This piece of research is an exploratory study aimed at investigating the adoption of Modularity and Lean in pharmaceutical facilities in Ireland. This research analyzed Pharmaceutical production managers, quality managers and construction Engineers who have implemented Lean and Modularity in the development or operation of production facilities. A mixed method questionnaire survey was sent to pharmaceutical personnel involved in the implementation of Lean and Modularity to analyze the critical areas of Lean manufacturing and modular manufacturing within the pharmaceutical industry. The various Topics associated with Modularity and Lean such as benefits, challenges and contributing factors to implementation success were examined within the questions. The results obtained show that facilities implemented Modularity extensively in the production area and its components while there has been a moderate to extensive implementation of lean across critical areas. It was concluded that pharmaceutical facilities valued scalability, flexibility, order, and waste elimination.

Table of Contents

ABSTRACT	3
1.0 Introduction	9
1.1 Background of Study	9
1.2 Pharmaceutical Industry in Ireland	13
1.4 Research Questions	14
1.3 Aims and Objectives	14
2.0 Literature Review	15
2.1 The Roots and Evolution of Lean	15
2.2 What is Lean Manufacturing	18
2.3 Major Components of Lean	20
2.3.1 Nine Lean Elements	21
2.3.2 Five Principles of Lean	27
2.3.3 Seven Organizational Waste	29
2.4 Evolution of Modularity	29
2.5 What is Modularity	30
2.6 Modular Manufacturing	31
2.6.1 Modular Manufacturing Options	35
2.7 Benefits of Modular Manufacturing	36
2.8 Going Lean with Modular Manufacturing and its Challenges	40
2.9 Modularity as a Lean manufacturing tool	41

3.0 Methodology	43
3.1 Sampling	44
3.2 The Questionnaire	45
3.3 Ethical Considerations	45
4.0 Data Analysis and Discussion	47
4.1 Modularity in Irish pharmaceutical facilities	47
4.1.1 Degree of Modularity Implementation in Key Pharma Areas	48
4.1.2 Method of Modularity Used	49
4.1.3 Benefits of Modularity	50
4.1.4 Applying Lean to Modular Manufacturing	51
4.1.5 Factors contributing to the Implementation success of the Type of Modularity Used	53
4.1.6 Challenges of going Lean in Modular manufacturing	54
4.2 Lean in Irish pharmaceutical facilities	55
4.2.1 Extent of Lean Implementation in Key Pharma Areas	55
4.2.2 Lean tools and Techniques Implemented	56
4.2.3 Benefits of Lean	58
4.2.4 Factors Contributing to the Implementation Success of Lean	58
4.2.5 Lean Implementation Challenges	59
5.0 Conclusion	61
5.1 Limitations and Future Scope	62
5.2 Recommendation	62

Bibliography	64
APENDIX	69

Table of Figures

Figure 1: Basic Drivers behind Modularity (Miller and Elgard, 1998)	12
Figure 2: History of Lean Manufacturing (Iuga and Blaga, 2013)	17
Figure 3: The Toyota Production system house (Liker and Morgan, 2006).....	18
Figure 4: The nine major lean elements in relation to the seven wastes and five lean principles (Cornelissen and Trienekens, 2013).....	21
Figure 5: An example of a working Kanban system (Black, 2007).....	22
Figure 6: An example of a U-shaped Production Cell (Cornelissen and Trienekens, 2013)	23
Figure 7: Five Lean Principles (Doanh, 2017)	27
Figure 8: Five Approaches to Modularity (Evans et al., 2019).....	30
Figure 9: Scope of Facility Modularization (Dalby et al., 2019).....	31
Figure 10: The journey towards modularity (Bannasch et al., 2017).....	33
Figure 11: Organizational changes modularity requires (Bannasch et al., 2017)	34
Figure 12: Construction Modules Definition/Options (Dalby et al., 2019).....	36
Figure 13: Questionnaire	45
Figure 14: Extent of Agreement on the application of Lean Principles to Modular Manufacturing	47
Figure 15: Degree of Utilization of Modularity in Key Areas by Number of Respondents	48
Figure 16: Method of Modularity Used	50
Figure 17: Benefits of Modularity by Number of Respondents	51
Figure 18: Extent of Lean Application to Modularity	52
Figure 19: Factors Contributing to the Implementation Success of the Type of Modularity Used	53

Figure 20: Challenges of going Lean in Modular Manufacturing	54
Figure 22: Lean tools applied.....	57
Figure 23:Benefits of Lean Manufacturing by Number of Respondents	58
Figure 24: Factors Contributing to the Implementation Success of Lean.....	59
Figure 25: Lean Implementation Challenges	60

1.0 Introduction

1.1 Background of Study

Pharmaceutical production facilities are now faced with heightened challenges such as Process technology changes, evolving drug development methods, the transformation of medical therapies, market competition, varying demand, and stringent regulatory requirements (Jornitz, 2013). It is apparent that production facilities need to embrace these constantly evolving challenges. Production facilities are therefore making improvements to critical processes or activities to face the challenges. Modularity is now being integrated into the design and development of these production facilities. Operating more efficient facilities is now critical to staying competitive in the globalized market. Lean manufacturing and Modular manufacturing are now two important components in the development and operation of pharmaceutical facilities because of the increasing need for efficiency.

There are new competitors in the global pharmaceutical industry with price and quality differentials emerging as a result of reduced trade barriers (Alves, 2015). Pharmaceutical companies are now obligated to re-evaluate their strategies in order to survive. A side effect of this is that improving operational efficiency is now a crucial requirement for pharmaceutical companies to keep and gain a competitive advantage. Improving the performance of production facilities has now become a common strategy used by pharmaceutical companies to stay competitive in the globalized market (Alves, 2015). For an organization to maintain competitive advantage, it should have a manufacturing strategy that continuously seeks to improve the management model of its production facilities and processes (Alves, 2015).

Flexibility, Reliability, and increased processing speed are factors that are core to the tenets of Lean and Modular manufacturing. Incorporating these factors into a production facility, results to an increase in market share, sales growth, and business performance for pharmaceutical companies. The adoption of Lean manufacturing and Modular manufacturing is now a strategy for incorporating these characteristics into pharmaceutical manufacturing (Singh and Mahmood, 2014).

It takes pharmaceutical facilities about 5 years to be fully operational from design to qualification (Singh and Mahmood, 2014). In most cases, these facilities are dedicated to producing a single drug product. Once the lifecycle of the product ends, the facilities require significant and capital-intensive modifications to produce additional products. The inflexibility and the difficulty in scaling up the production capacity of these facilities is a major challenge for pharmaceutical companies because of the pressure to reduce costs and get their drug products to market quickly. For pharmaceutical companies to self-produce drugs still in clinical trials on a commercial scale, significant amount of investment would have been made on a production facility before clinical results and approval from regulatory authorities. This capital investment becomes difficult to recover if the drug fails in the clinical trial stages (Singh and Mahmood, 2014).

Lean manufacturing is a user-centric approach that focuses on eliminating waste, continuous improvement, and managing a project and its supply chain with the highest quality standards (Abdelhamid, 2003). Lean construction uses lean principles to improve productivity, reduce costs and environmental impacts ultimately increasing sustainability (Abdelhamid, 2003). Lean thinking focuses on cycle time reductions, reducing wastes, defining customer value, and ensuring smooth workflow (Carleysmith *et al.*, 2009). Lean manufacturing uses half the human effort, half of the entire manufacturing space, half of the engineering hours and half of the investment in tools when compared to Mass production (Wong *et al.*, 2009). As a result of these significant advantages, Lean manufacturing has now become the preferred method of production for most production facilities (Wong *et al.*, 2009). Lean manufacturing is now a global standard of a manufacturing system with a minimum amount of waste.

In Modular Manufacturing, standardized components of a structure are produced in a factory offsite and are later assembled onsite. Interchangeability, functional independence, functional similarity, and physical similarity are some of the major characteristics of modular manufacturing (Evans *et al.*, 2019). Modularity is a systematic process that allows the different modules of a system or product to be combined in different ways to become new products or systems (Evans *et al.*, 2019). The thinking in the direction of Modularity began almost 2000 years ago in the building industry. In Ancient Rome, proportion and symmetry laws in columns and temples were made while modular bricks and tiles were used for

construction in the Chinese Qin dynasty. Modularity began to appear in new fields such as Computer Science, Biology, Ecology etc. from the 20th century.

Modular manufacturing is an effective approach that offers increased personalization, customization of facilities, and reduced production costs(Evans *et al.*, 2019). Modular manufacturing has also created the following benefits:

- Manufacturing cost is reduced because of the use of components across product families.
- Improved Efficiency and risk reduction because complex systems are broken down into more manageable modules.
- Products and equipment are easily updated and maintained.
- An increase in product variety from a smaller set of components.
- A decrease in order lead-times through the use of fast combination of modules.

Modularization is now seen as a means for increasing the competitiveness of Pharmaceutical companies. Facilities achieve this by bridging the capability of customization and flexibility that comes with Modularity with the advantages gained from standardization and rationalization. The meaning of the term module has evolved over the years from a definition based on physical presence to a definition based on structure and functionality. Modularity has evolved from a manufacturing context. It is now seen as a combination of the attributes of the system and the functionality of the module.(Miller and Elgard, 1998). There are three basic drivers behind the need for modularity at pharmaceutical facilities. They include:

- The need to reduce complexities
- The utilization of similarities
- The development of variety

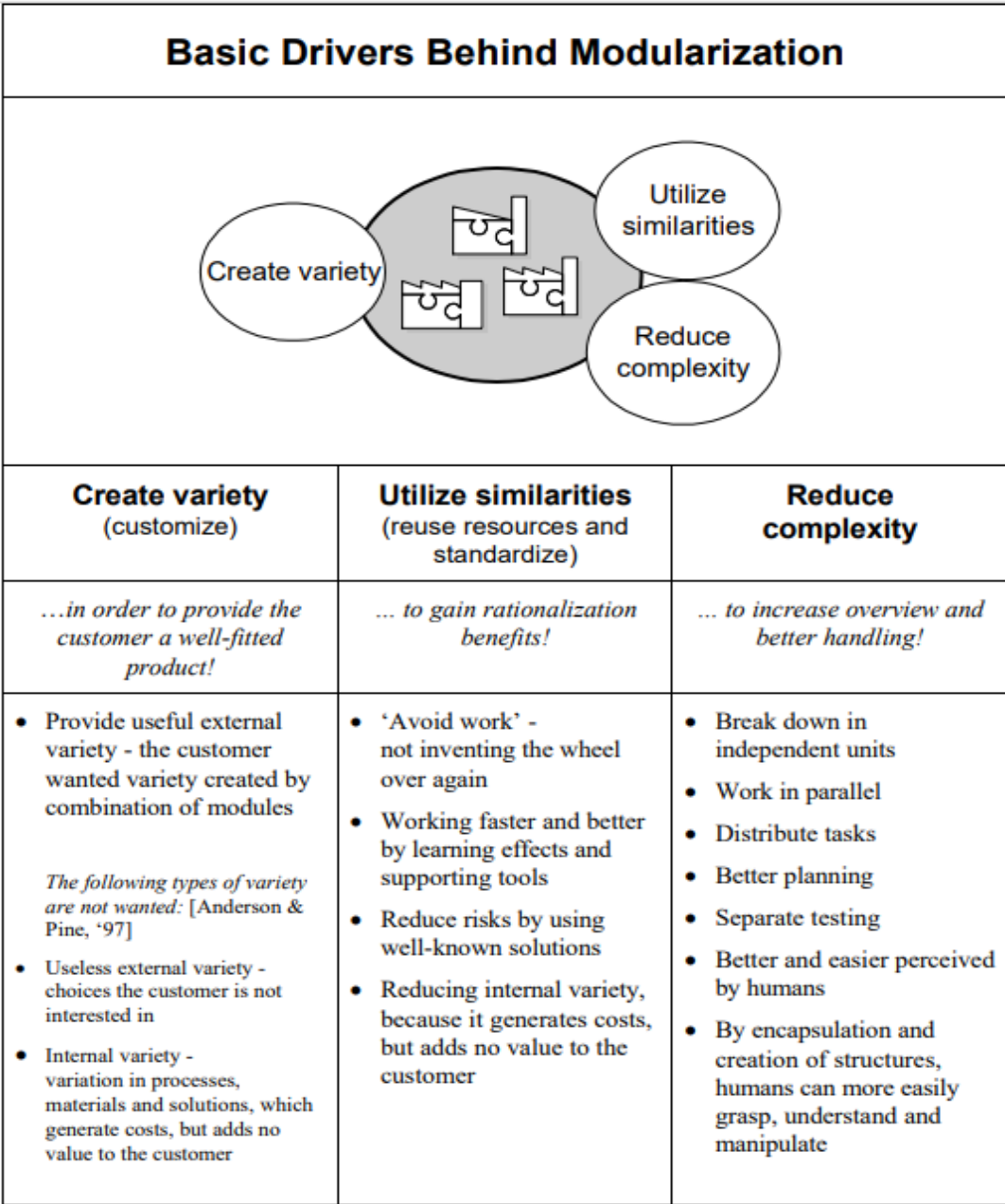


Figure 1: Basic Drivers behind Modularity (Miller and Elgard, 1998)

As a result of these advantages, Modularity is now an important research area in manufacturing systems. Having a manufacturing strategy that encompasses the practices of Modular manufacturing and Lean manufacturing is crucial to raising a Pharmaceutical company's competitive edge in today's globalized market.

Lean and Modularity helps to create powerful synergies in companies. Modularity offers effectiveness while Lean offers efficiency (Leine, 2021). Modularity aids a lean process and

provides an easy management of the major lean practices through flexibility, scheduling, and just-in-time deliveries (Bjornfot and Stehn, 2004).

1.2 Pharmaceutical Industry in Ireland

Ireland has a corporate tax rate of 12.5% which is one of the lowest in the world (Innopharma education, 2020). This factor has made Ireland a preferred investment location for Multinational companies including pharmaceutical companies. Pharmaceutical companies around the world choose Ireland as their European base because of this low statutory corporate tax. Ireland also offers geographical proximity to pharmaceutical companies that set up manufacturing facilities in the country. The pharmaceutical companies have easy access to Mainland European markets. The hassle-free international shipping across the Atlantic also gives the pharmaceutical companies easy exports to North America. Pharmaceutical companies based in Ireland also benefit from the highly skilled English speaking population Ireland has and the access to easily hire workers from other European Union (EU) member states (Innopharma education, 2020)

According to IDA Ireland, all of the world's Top 10 pharmaceutical companies have substantial operations in Ireland. Ireland's pharmaceutical industry is the 2nd largest exporter of medicinal and pharmaceutical products in the European Union and the 3rd largest exporter of pharmaceuticals globally. The value of the annual exports of the industry is estimated to be €80 billion. There are 90 biopharmaceutical plants located in Ireland and over 50 of these plants are FDA approved. The Irish Government in total has committed about €8 Billion in research funding to the pharmaceutical industry (IDA Ireland, 2020). According to the Irish Pharmaceutical Healthcare Association (IPHA), approximately 120 foreign companies have plants in Ireland. The research and development of the pharmaceutical industry in Ireland has helped improve the life expectancy in the country from fifty-seven in 1925 to Eighty-one presently. The industry also generates over 50% of Ireland's exports. The Pharmaceutical industry in Ireland also manufactures 5 of the world's top 20 medicines (IPHA, 2020).

There is also a need for the pharmaceutical industry in Ireland to stay competitive in the globalized market. Efficiency in production is one of the key avenues of staying competitive

in the globalized market, hence the need for Lean Manufacturing and Modularity in the facilities of pharmaceutical companies in Ireland.

1.4 Research Questions

- Is Modular manufacturing currently being utilized in Pharmaceutical facilities in Ireland?
- To what extent has Modular manufacturing been utilized?
- Is Lean manufacturing currently being implemented In Pharmaceutical facilities in Ireland?
- To what extent has Lean manufacturing been implemented?

1.3 Aims and Objectives

- To further investigate the extent to which modularity has been used as a Lean tool in the development and operation of pharmaceutical facilities in Ireland and challenges faced
- To research the extent to which Lean thinking has been integrated in pharmaceutical facilities in Ireland and the challenges faced

2.0 Literature Review

2.1 The Roots and Evolution of Lean

The Toyota Motor Corporation created the Toyota Production System which gave birth to a new concept in Management called 'Lean Thinking'. The Toyota production system could be traced back to the early twentieth century. The founding members of the system include Sakichi Toyoda, his sons: Kiichiro Toyoda and Eiji Toyoda, and a manufacturing Engineer named Taiichi Ohno. Sakichi Toyoda previously worked in the textile industry where he invented a loom that was motor driven. In the event of breaking off the thread, the loom had a mechanism that was designed to stop. This mechanism was later used as a foundation for automatization with human manufacturing. This is also called Jidoka and it is one of the two pillars of the Toyota Production System (Dekier, 2012). A fault detection sensor was used to reduce human-related errors, and this increased production capacity.

In Kiichiro Toyoda's travel to the United States of America in 1929, he became fascinated with the serial production that was introduced by the Ford Production system in 1913. Kiichiro Toyoda implemented some of the witnessed changes into Toyota's production. He later understood the need for a production system that was fast and flexible which would in turn improve the quality and reduce the price of automobiles produced. Kiichiro Toyoda began working on making Toyota produce in a Just-in-time system in order to reduce waste drastically and increase production capacity.

In the 1950's, Eiji Toyoda also visited Ford's company in the USA. After this visit, Taiichi Ohno and Eiji Toyoda linked Jidoka and Just-in-time which are the two pillars of the Toyota production system with the methods of the Ford production line (Dekier, 2012). After the Second World War, Toyota decided to cancel modernizing production equipment and focused on improving production internally. To achieve this, Toyota combined Taylorism elements like multitasking and production flow and integrated it into their production system. This led to over production which was a type of waste that the Toyota Production System originally tried to eliminate in the facilities (Iuga and Blaga, 2013).

In order to reduce over production, Toyota began supplying their automobiles to the American Military. In addition to this, Taiichi Ohno, a Manufacturing Engineer at Toyota later made advancement to an already existing system called “Pull-Flow-Production”. This concept was already in use in Supermarkets in the USA at the time. The Pull-flow-production system also helped reduce over production. The Japanese and American production market started to notice the significant progress Toyota had made in their production facilities when Toyota began to reduce production. The production cut coupled with the noticeable outcomes of the Toyota Production system brought a lot of attention to the system (Dekier, 2012).

In the 1950’s, Edward W. Deming introduced the Statistic Quality Control (SQC) in Japan. He also formed the Deming Circle of Plan, Do, Check and Act. In the Japanese Quality sector, Joseph M. Juran in 1954 made the following significant contributions:

- He defined the Quality Management System
- He Implemented the Pareto Principle in Quality Control. The Pareto Principle was created in 1906 by the Italian Economist Vilfredo Pareto. It is also known as the 80/20 rule and it is an observation that 80% of consequences arise from 20% of the causes (Iuga and Blaga, 2013).
- He developed the Non-quality cost study also known as the “Juran Trilogy”.

Kanban, a stock gestation system was introduced by Toyota towards the end of the 1950’s to reduce waste generated from stock. Dr. Shigeo Shingo, a Japanese Engineer also contributed to the development of the Toyota Motor Corporation and Lean management. He developed the Single Minute Exchange of Die (SMED) method which reduced the setting time of equipment. It ensured that machines were set up rapidly (Shingo Institute, 2020). He also created the Non-Stock Production system in 1975 which was aimed at reducing the stock products. His idea was to work with zero inventories.

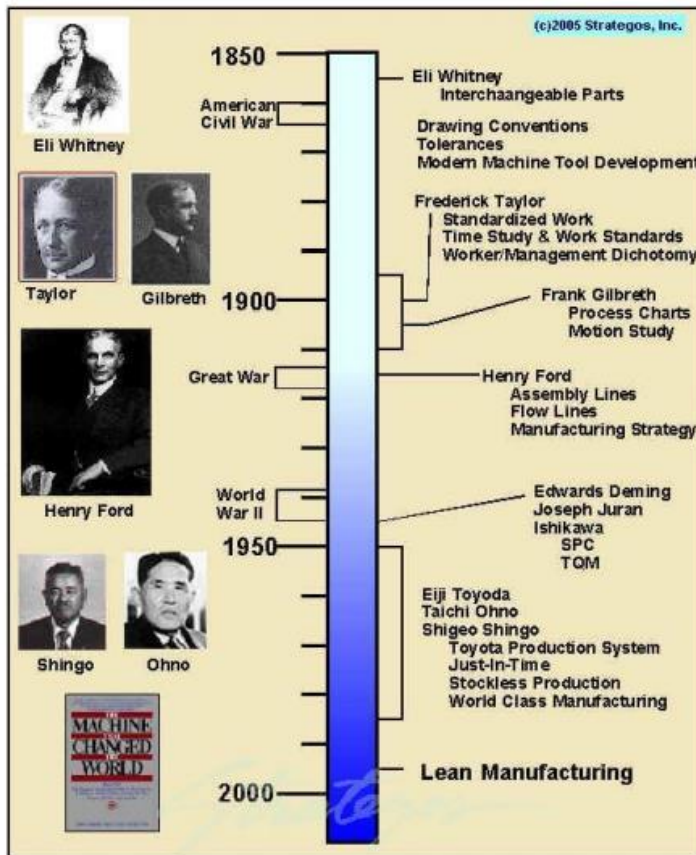


Figure 2: History of Lean Manufacturing (Iuga and Blaga, 2013)

When Lean thinking is applied to Manufacturing, it is called Lean Manufacturing. Lean manufacturing reduces production cost, manufacturing cycle times and development cycle times. Lean manufacturing also enhances the competitiveness of the entire organization (Rameez and Inamdar, 2010). Besides the Automotive industry, Lean production was also applied to the electronics industry, shipbuilding, consumer goods, machinery production and aerospace industry. Lean production became the next milestone in modern production methods after mass production.

The implementation of Lean thinking has evolved over the years into a management revolution in the 21st century. In Lean manufacturing, waste is eliminated by identifying activities that are non-value adding in the entire supply chain.

Lean manufacturing began in the automotive industry, but it is now a universal production method that has been successfully implemented in different disciplines and by different companies around the world. Several companies are turning to this production method because of the increasing competitive landscape of their respective industries. The Toyota

Production system also known as lean manufacturing is now an integrated system that is made of elements that are inter-related and management practices like cellular manufacturing and Just-In-Time etc.

The fundamental reason Lean manufacturing is implemented is to reduce cost and Lead time, increase productivity and improve quality thus providing the most value to customers (Rameez and Inamdar, 2010).



Figure 3: The Toyota Production system house (Liker and Morgan, 2006)

The Toyota production system shows lean processes in action. It is a beacon for competitive manufacturing around the world. It is presented in the form of a house because a house is a system. Even if other parts of a house are strong, a house with a weak foundation or pillars is not stable hence the Lean concept. All the different parts of the house work together to make the house.

2.2 What is Lean Manufacturing

The concept of Lean manufacturing was formed by authors James P. Womack, Daniel Roos, and Daniel T. Jones in the book titled “The Machine That Changed the World” in 1991 (Dekier, 2012). The authors made a comparison between Japanese and American companies. They concluded that the Toyota Production System (TPS) of the Toyota Motor Corporation was the most efficient system. Lean Manufacturing is seen as the concept that has succeeded the Toyota Production System (TPS) because of its application of Toyota’s instruments.

Lean manufacturing can simply be defined as an optimal production of goods through the removal of waste. It is the systematic or continuous removal of waste from a system (Rameez and Inamdar, 2010). Lean Manufacturing can also be defined as an operational excellence strategy geared towards achieving the best possible cycle times through the elimination of wastes (Badurdeen, 2007). When initiating a Lean transformation process, production improvements should not be seen by Senior management as an avenue for cost reduction only. This method of thinking is attributed to mass production and it will ultimately limit the progress that could be made from the Lean initiative. In a Lean transformation process, physical changes such as implementing Lean tools, reducing inventory, making layout changes to improve flow and standardization etc. only represent about 20% of Lean implementation measures. Transforming the entire culture of the organization into a Lean way takes up the remaining 80% of Lean implementation measures. This transformation is less obvious and much more difficult to implement (Alves, 2015). Lean manufacturing techniques are revolutionary and different from the traditional mass production systems. It uses logical principles that are focused on the identification and elimination of waste. Lean manufacturing requires a new and radical way of viewing the manufacturing process. The discipline needed to implement the new principles of Lean manufacturing requires a culture change in an organization (Alves, 2015)

Lean manufacturing is associated with reducing seven different types of important waste. The seven wastes are: Over processing or wrong processing, over production, Excess inventory, Unnecessary movement, Unnecessary transport, Waiting and Defects. In Lean manufacturing, less than half of the required inventory is stored in the production facility. The number of defects that occur from production reduces significantly as a result of implementing a Lean thinking to the production facility.

Lean manufacturing is of the view that reliable workflow can be achieved if the sources of variability are controlled. Under a lean model, the effects of variability can be buffered through flexible capacity, work-ready backlogs, and excess inventory. These approaches only combat the effects of variability, but they cannot reduce or eliminate variability.

Lean manufacturing is a user-centric approach that focuses on eliminating waste, continuous improvements, and managing a project and its supply chain with the highest quality standards. Lean construction uses lean principles to improve productivity, reduce costs and

environmental impacts ultimately increasing sustainability. Six Sigma reduces process variability through a statistical based structured framework. Lean manufacturing transforms the traditional approach to construction. Lean manufacturing changes construction management from the concept of allocating resources to ensure that projects are completed on time, at desired quality and under budget to a concept where resources are allocated to transform inputs to outputs while flow and customer value is maximized. Some sources of variability include equipment breakdowns, late delivery of materials, tool malfunctions, design errors, environmental factors, and accidents. Variability mainly manifests through production processes with bad workflow reliability. The root causes of variability need to be identified and removed for variability reduction to occur. The structured Six Sigma approach to reducing variability involves the DMAIC approach which symbolizes Define, Measure, Analyse, Improve, Control or the DFSS approach which symbolizes Design for Six Sigma. Design for Six Sigma uses techniques like the theory of inventive problem solving (TRIZ) and Quality Function Deployment (QFD) to develop designs for issues like ergonomics, assembly, performance, reliability, and manufacturability. Lean sets the standard while six sigma investigates the variations associated with the standard and resolves it. The problems that are difficult to find but have easy fixes can be resolved using Six Sigma tools while problems that can be easily spotted but are difficult to fix can be resolved with Lean tools (Abdelhamid, 2003).

Lean manufacturing practices make use of value stream mapping in its implementation process to map out all the activities involved in taking a product or service from its initial stage of development through to the customer. The maps are used to analyze current difficulties and also design future states where waste has been reduced. Value stream mapping maps out the products water usage, raw materials usage and energy usage thereby catering to environmental issues. Lean manufacturing practices can be grouped into four factors which include Control factors, Supplier factors, process factors and human factors. It also improves challenges related to health and safety ultimately increasing return on investments (Kamble *et al.*, 2020).

2.3 Major Components of Lean

The major lean components consist of Nine elements, seven wastes and five principles. These components are central to the implementation of Lean. The implementation of lean revolves

around minimizing the seven wastes. The five lean principles help in maximizing the benefits of implementing lean. The five lean principles and the seven lean wastes are interconnected and helps in the proper understanding of the nine elements of lean.

The lean elements	reduce the lean wastes							and fits the following lean steps (as mentioned by Womack & Jones (2003))
	over-production	excess motion	waiting	transport	excess processing	inventory	defects	
Just in time	x		x					creating flow / establishing pull
Resource reduction	x					x		identifying value / creating flow
Human Resource management			x				x	creating flow / striving for perfection
Improvement strategies	x	x	x	x	x	x	x	striving for perfection
Defects control					x		x	striving for perfection
Supply Chain Management	x		x			x		identifying the value stream / establishing pull
Standardization		x					x	creating flow / striving for perfection
Scientific Management		x		x				creating flow
Bundled techniques			x				x	creating flow / striving for perfection

Figure 4: The nine major lean elements in relation to the seven wastes and five lean principles (Cornelissen and Trienekens, 2013)

In the figure above, each of the nine lean elements minimizes at least one of the seven wastes and conforms to at least one of the five lean principles. The table above links all of these components. The proper sequence of implementing lean is achieved when one knows which lean principle fits each of the nine elements. From the table above, an understanding of the tools and strategies that reduces a certain waste assists in knowing which of the elements is best suited for achieving specific goals in an organization.

2.3.1 Nine Lean Elements

Just-in-time practices

Just-in-time consists of pull, takt production also known as standard time, production leveling and process synchronization. This component is one of the most important lean practices.

Heijunka is the Japanese word used to describe leveling or smoothing of production(Cornelissen and Trienekens, 2013). It is the use of daily demand. This daily demand can be calculated with the formula below(Black, 2007)

$$\text{Daily Demand} = \frac{\text{Number of outputs per month}}{\text{Number of days in month}}$$

Making use of production leveling eliminates the occurrence of sudden big fluctuations in the required production capacity. **Pull production** simply means producing only when there is a customer request. This eliminates overproduction which is a waste. **Kanban** is a tool that makes pull possible. It is also known as signal cards. It gives signals to preceding production steps to commence production. Kanban can also be used in combination with other visual controls.

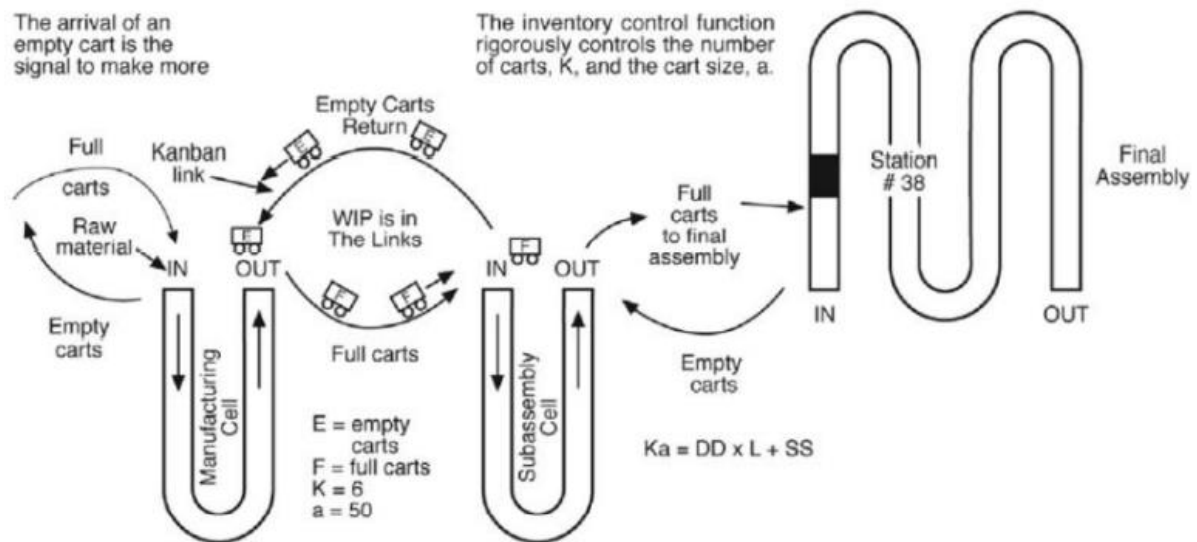


Figure 5: An example of a working Kanban system (Black, 2007)

The figure above visualizes how a pull system works. The manufacturing cell uses raw materials from the cart and the empty carts are returned and this is a signal to order new raw materials from the suppliers. The full cart containing parts move to the subassembly where they are sub assembled. The empty carts returning from subassembly to the manufacturing cell is a signal for the production of more parts and this cycle continues through the production stages. In this system, unnecessary waiting for a previous production step to be completed is eliminated. This requires adjusting every step in the production cycle to standard time frame. This concept is known as **Takt time**. Takt time can be calculated using the formula below (Black, 2007).

$$Takt\ Time = \frac{Minutes\ available\ per\ day}{Daily\ Demand}$$

It is important for cycle time to be slightly less than takt time (Black, 2007). This provides a buffer for change over times. Flow is **process synchronization**. One-piece flow can occur if

Kanban is combined with takt time. This means work can be carried out on a product from start to finish without interruptions. This eliminates waiting which is also a lean waste. Products can be finished in the quickest time possible. This also reduces the amount of work-in-progress carried out on a product. Implementing Just-in-time eliminates wastes like overproduction and waiting (Cornelissen and Trienekens, 2013).

Resource Reduction

This encompasses inventory reduction, small lot production, setup time reduction, lead-time reduction, and waste elimination. Batch size is as small as possible in small lot production and this minimizes overproduction and inventory wastes. Inventories can be understood using water as an analogy. Taiichi Ohno, one of the founders of the Toyota Production system gave this analogy. The inventories can be equated to water in the production system. In a high-water level, the rocks at the river bottom are invisible and this symbolizes unexposed waste. When the water level (Inventory) lowers, the rocks (problems) can be removed because they become visible, and this cause the river to flow faster and with ease. Setup time reduction is also referred to as **Single Minute Exchange of Dies (SMED)**. The purpose of SMED is to reduce the time used to adjust a machine to produce a specific product. **Lead time reduction** occurs with the use of the flow element which reduces the waiting between processes. Breaking down the production steps into smaller steps lower than the takt time also reduce lead time.

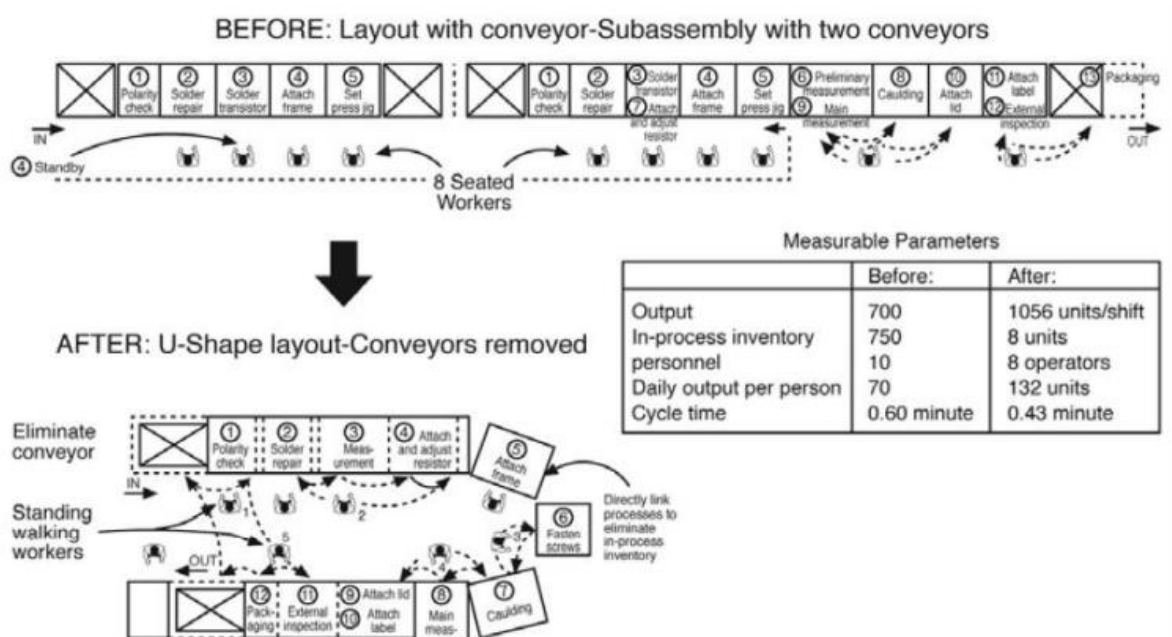


Figure 6: An example of a U-shaped Production Cell (Cornelissen and Trienekens, 2013)

The U-shaped production cell is one of the most efficient production methods. The U-shaped production cell has the following advantages:

- Elements flow with ease
- Unnecessary movement is minimized
- Distance between machines is reduced because of the u-shape and the production line principle that allows products to flow from one machine to the other is still maintained.
- In one cycle time, a single operator can work on several machines.

Value remains when waste is eliminated, and this links resource reduction to the first lean principle which is Value. The third principle of lean which is creating flow is applicable here because resource reduction enables flow of production processes. Over production and inventory is minimized with resource reduction (Cornelissen and Trienekens, 2013).

Human relationship management

Human relationship management encompasses cross training, team organization and employee involvement. **Team organization** entails organizing the workforce into smaller teams with diverse characters responsible for parts of the production process. Each team is responsible for a product family. The diversity in expertise and backgrounds makes each team to approach waste from different perspectives. **Cross training** means training staffs on how to handle different tasks. Cross training allows absent staffs to be easily replaced. It also gives staffs the ability to contribute easily to areas where extra capacity is needed. This reduces another waste called waiting time. Cross training gives flexibility and responsiveness to companies while also making work more interesting for employees. **Employee involvement** is a critical component of lean implementation. A more involved workforce makes a change in culture easier. The workforce becomes part of the decision making on lean in the organization. It is also important to communicate the lean results with the workforce as this keeps them motivated. Waiting is reduced if employees are able to be used in areas they are mostly needed. Defects can be prevented with the proper training of employees on quality checks. The third principle of flow is cultivated because the workforce is cross trained. The fifth lean principle of pursuing perfection is at play when the workforce is trained on identifying and eliminating waste (Womack and Jones, 2003).

Improvement Strategies

Improvement strategies encompasses root cause analysis, improvement circles and continuous improvement. **Improvement circles** is made up of a multidisciplinary team with a broad view of all processes and the ability to identify waste in a broader scope. **Continuous improvement** began with the plan-do-check-act of Edward Demming. It has now evolved into the name Total Quality Management (TQM) (Womack and Jones, 2003). Total Quality Management involves preventing failure and different quality checking tools. Kaizen is also continuous improvement. Specific improvement goals are achieved in Kaizen with teams focusing on specific elements of waste. The 5 Why's is also called **root cause analysis**. In this method, one can arrive at the root of a cause by asking why five times. The fifth lean principle of pursuing perfection is applicable here. All seven wastes are eliminated with improvement strategies (Cornelissen and Trienekens, 2013).

Defects Control

Defects control has four elements which are Line stop (Andon), failure prevention (poka yoke), automation (Jidoka) and 100% inspection. The **automation concept or Jidoka** involves embedding visual and electronic controls in each process step. This allows defects to be detected instantly rather than at the end of the process. When there is an issue on the line or when a defect is detected either manually or by a machine, the Andon (line stop) button is used to bring the machine to a halt. The light or sound signal generated attracts the attention of the quality manager. Poka yoke is the Japanese word for failure prevention. Jidoka focuses on detecting problems while poka yoke focuses on preventing problems. **100% inspection** entails checking products in subsequent production steps. These controls minimize defects as a waste. Excess processing as a waste is also reduced because the defective products do not undergo further processing. Lean manufacturing is aimed at zero defects. The fifth lean principle of pursuing perfection is applicable in this scenario (Cornelissen and Trienekens, 2013).

Supply Chain management

Supply chain management encompasses value stream mapping (VSM) and involvement of the suppliers. It is important to utilize value stream mapping before implementing other lean elements. Waste can be easily identified when the value stream of a product or service is

mapped out. Involving suppliers in the lean implementation process is important for just-in-time to work properly. A company that has a lean philosophy with suppliers that are not lean will have waste in the supply chain. The waste could be present in the entire value stream from raw materials to products (Cornelissen and Trienekens, 2013). The second lean principle of identifying the value stream is applicable to supply chain management while the fourth principle of establishing pull is achieved by involving suppliers in the company's lean implementation process.

Standardization

Standardization also involves visual controls and housekeeping. Housekeeping is also known as the **5S**. This stands for sort, set in order, shine, standardize, sustain. Implementing these in order would allow employees to easily clean and locate tools and equipment. It also makes tools and equipment ready to use. To standardize work means to maintain a standard in all production steps. Standardized work allows employees to easily work in different production cells. It also allows improvements found in one production area to be easily applied to other production areas. Standardization minimizes excess motion which is a lean waste because tools and equipment have a defined position. Standardization can be applied to the lean principles of creating flow and pursuing perfection because flow is disrupted with excess motion and applying improvement ideas to the entire chain supports the aim of perfection (Cornelissen and Trienekens, 2013).

Scientific management

The elements of scientific management include multi manning, adjusting layouts, workforce reduction, cellular manufacturing, and policy deployment. **Hoshin Kanri** is also called Policy deployment. This concept involves assigning responsibility to the employees. It involves ensuring that all employees are actively involved. The output of activities can be optimized by changing machinery layout and conducting time and motion studies. **Cellular manufacturing** involves installing machines and equipment together. This reduced distance helps in reducing walking times. Decouplers can be used to connect different machines. The decouplers are also used to carry out quality checks. Decouplers have a maximum capacity of two and this can only be exceeded when they are carrying out process delays (Black, 2007). **Multi manning** is mostly in place by virtue of the design feature of manufacturing cells that allows it to be operated by one person. Excess motion and transportation waste is minimized

through scientific management. The third lean principle of creating flow is applicable here because by adjusting the layout, products are moved easily and faster (Cornelissen and Trienekens, 2013).

Bundled Techniques

This involves the use of Six sigma. This is a process that calculates the impact of system changes on the number of defects using statistical quality control. Statistical quality control can be used to measure and reduce defects. The fifth lean principle of striving for perfection is applicable to Six Sigma.

2.3.2 Five Principles of Lean

The five lean principles are also known as the five steps to lean. They are critical to the implementation of lean. The five fundamental principles of Lean revolve around ensuring that value is specified from the customer's point of view, identifying the value stream, ensuring that the value identified flows, setting a pull system which simply means producing only as needed and producing in accordance with the wants of the customer, at the time required by the customer, in the right quantity as required by the customer while operating with minimum waste (Rameez and Inamdar, 2010).



Figure 7: Five Lean Principles (Doanh, 2017)

The five principles are as follows:

- **Value**

A product's value can only be properly defined by the customer. In Lean Manufacturing, value can be identified by having a clear understanding of all the

activities required to get a specific product to market and then going ahead to optimize the entire process from the perspective of the end user. Irrespective of the financial expenses incurred or the technology utilized in getting a product or service to the customer, customers will evaluate the value of the product or service according to how it will fulfill their individual requirements.

- **Identifying the Value stream**

This entails mapping the route of a product. Achieving a Lean state is not a destination that is reached, and improvement stops. A culture of continuous improvement of products, services and processes over time while reducing waste with the goal of enhancing the performance of products or services and improving workplace functionality.

- **Creating Flow**

This involves using a continuous flow process to connect all the value creating activities (Engelund *et al.*, 2008). Production should have an uninterrupted flow, and this can be achieved by avoiding bottleneck processes. Production facilities should have maps that display the production flow. The maps should indicate changes to existing procedures and relocated equipment.

- **Establishing Pull**

Only things needed 'downstream' should be produced 'upstream'. This is quite different from the 'batch and queue' process utilized in mass production. The pull system reduces the resources kept in inventories (Engelund *et al.*, 2008). Production is carried out internally in a just-in-time manner in between processes and also externally during product delivery to customers.

- **Pursuing Perfection**

In lean Manufacturing, there are endless ways to improve the use of all asset types. Waste elimination maximizes value for customers because it reduces the organization's operating cost which leads to lower prices for the customers (Rameez and Inamdar, 2010). This also includes perfecting all actions related to the production process. This is a holistic approach that should include all employees because of their close involvement with procedures (Engelund *et al.*, 2008)

2.3.3 Seven Organizational Waste

Taiichi Ohno, one of the founders of the Toyota Production system mentioned the significance of eliminating 'Muda' which is the Japanese word for waste. He also defined seven wastes. A critical aspect of Lean manufacturing is Waste Elimination. This can be done by compressing time. In production, wastes are all elements that increase cost but do not add value (Rameez and Inamdar, 2010).

The seven wastes defined by Taiichi Ohno include the following:

1. Overproduction
2. Excess Motion, which could be from the operator, material, or machine
3. Waiting, which could be from the operator, material, or machine
4. Transportation
5. Extra Processing
6. Inventory
7. Defects, which could be from scraps or rework

Waste could be activities that consume resources but do not create value (Cornelissen and Trienekens, 2013). Wastes are also divided into Type 1 and Type 2 wastes. Type 1 wastes are wastes that cannot be removed with the current technology used in the organization. Type 2 wastes are wastes that can be removed instantly with the current technology used in the organization.

2.4 Evolution of Modularity

The introduction of industrial building blocks in Architecture at the beginning of the 20th century contributed to the understanding of Modularity. The word Module originated from the Latin word 'modulus' which was used as a measure of Length. The word module was used as a standard measure to ensure right proportions. Marcus Vitruvius Polio gave a description to the word in his book titled 'Ten books on Architecture' (Miller and Elgard, 1998). He wrote about symmetry and proportion laws in columns and temples.

The German Architect Walter Gropius during the Bauhaus era combined the standardization idea with functional thinking and the industrial production concept in the construction industry. The term module was originally associated to a building block concept. The functional units in a building are the building blocks. In this era, the module was a standard

measurement that allowed several building blocks to be combined. Also, the functional ability of the building blocks was not directly linked to the module during this era because the module was linked to the geometry of the interface. The building block system had the ability to create variety through the combination and exchange of different building blocks. The concept of building blocks has evolved over the years. Companies now utilize the advantages of standardization and customization in production. The concept of the module and the building block has been merged.

The module is now used to describe a building block with functionality and interface specifications that can be used in combination with other modules. A module has a functionality that is similar to the final product. The functionality of a module must be sufficient for independent testing. The traditional bricks are not modules but building blocks.

The traditional bricks do not have any significant functionality that can be compared to the complete building.

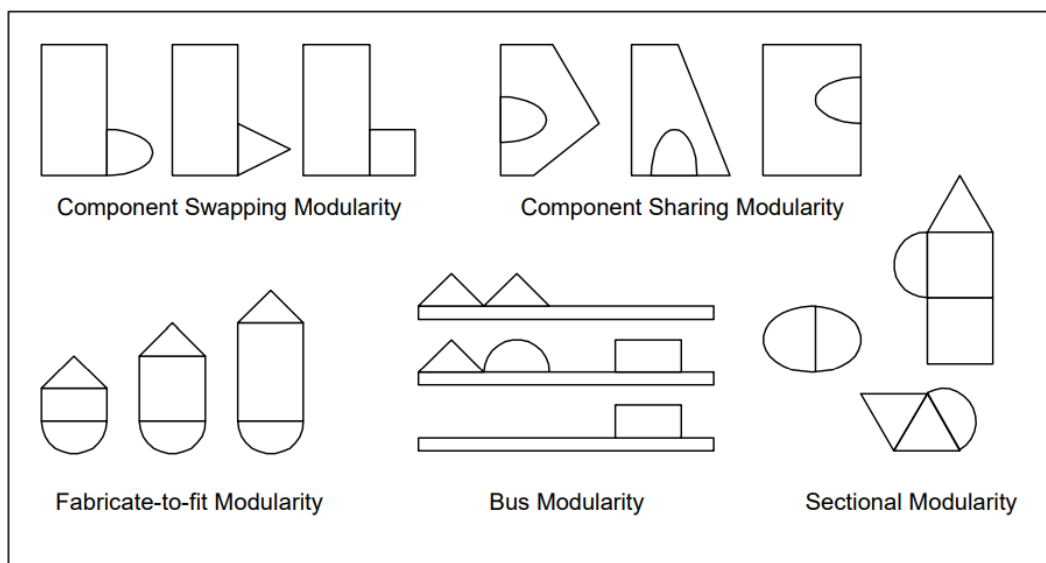


Figure 8: Five Approaches to Modularity (Evans et al., 2019)

2.5 What is Modularity

Modularity is a systematic process where the various modules of a system or product can be combined in multiple ways to form a different product or system (Evans *et al.*, 2019). Modular construction is a type of off-site construction whereby a building's components or modules

are constructed in a facility before they are transported to site for assembly (Road, 2020). It is a process whereby a building is constructed off-site in controlled plant conditions using the same materials as conventionally built facilities. The design of these buildings is done to the same standard and codes of traditionally built facilities. Modular constructions are completed in about half the time it takes to complete conventional on-site constructions. Modules can be constructed from wood, cold-steel framings, or concrete. An inside-out approach is used in modular manufacturing compared to the outside-in approach of on-site constructions (Modular Building Institute, 2020).

2.6 Modular Manufacturing

In a modular design approach for production facilities, each process unit operation is seen as an independent module and this also includes process utilities, equipment, and personnel (Dalby *et al.*, 2019). The term modular also covers the facility design approach and construction method. A modular design approach for a facility also gives a description of the process envelope from an environmental and dimensional perspective. In Modular Manufacturing, the complete manufacturing process is formed from the combination of Modules to ensure material, product, waste, and personnel flow.

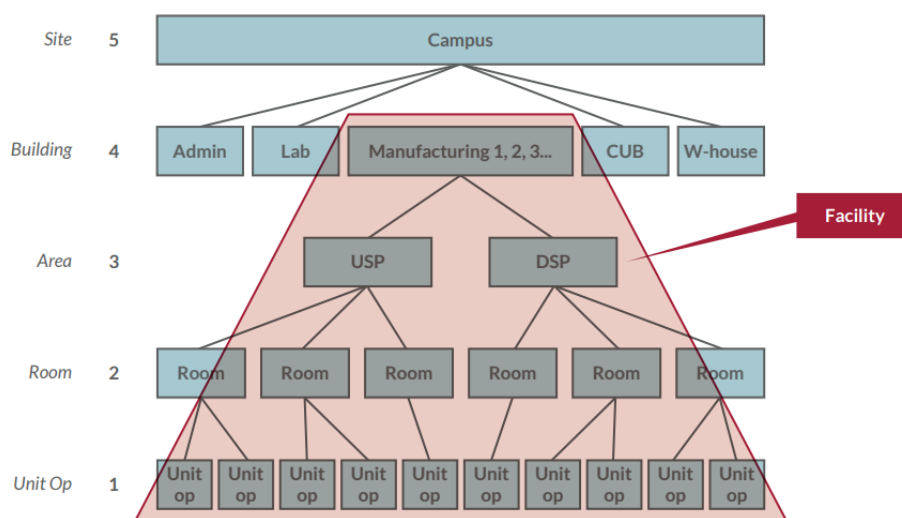


Figure 9: Scope of Facility Modularization (Dalby *et al.*, 2019)

As illustrated in the figure above, the design of production facilities now involves putting together predefined modules of different unit operations. This supports spaces for the creation of larger modular elements across different levels of standardization. This concept

of modularity in facilities also includes the creation of design modules that covers predefined solutions for operating equipment and accessory support areas. It also includes creating space modules to be used for circulation, component, and access staging. Extra facility information can be integrated to each module based on the sophistication of the digital platform the modules are composed of with the use of a database to account for elements like power loads, level of lighting, utility requirements and data connections. As part of the development process, it is important for module-to-module connections to be conceptually solved. This would allow the building blocks to be quickly arranged in different combinations that would create 'plug and play' design solutions.

In the last four decades, traditional approaches to design and construction methods have been majorly used for biopharmaceutical facilities. There is now a need for innovative and accelerated approaches for the development of pharmaceutical facilities. This is as a result of advances in manufacturing processing, numerous product types and increasing economic pressures the pharmaceutical industry faces. The development of pharmaceutical facilities is now moving towards the use of high levels of standardization and Modularization. This changing landscape requires a fundamental mindset shift in the design and construction methods utilized in the development of these facilities. This mindset shift cuts across the entire project lifecycle and this includes constructors, Engineering consultants, manufacturers, and suppliers. The future state of modularity is targeted to achieve at least 80% reuse of design and elements of construction from one project to the other. This includes repeatable and consistent supply chains, qualification practices for facilities in conjunction with regulators, automated process, or utility interconnections, and equipment modules (Dalby *et al.*, 2019).

Changes are necessary in the journey toward modularity.

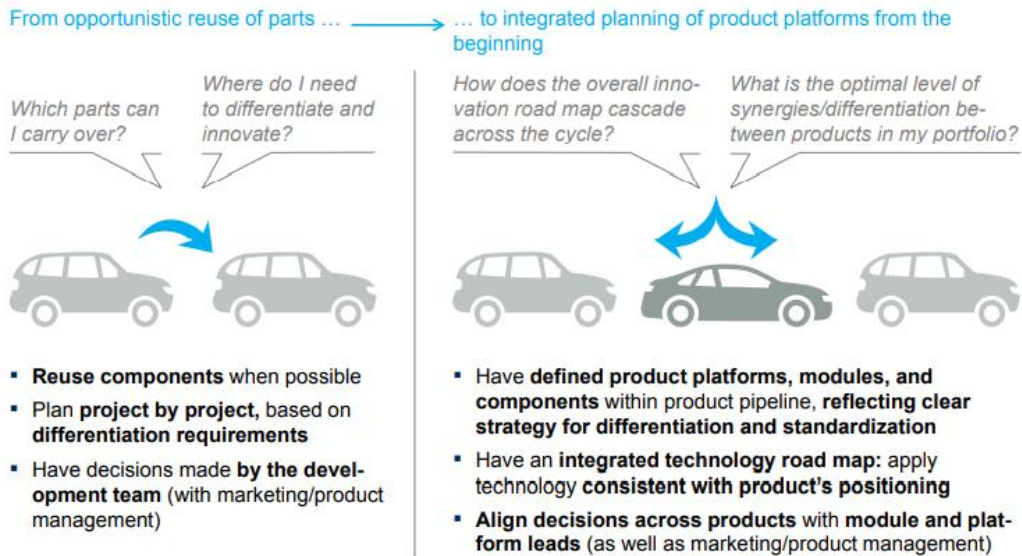


Figure 10: The journey towards modularity (Bannasch et al., 2017)

In the journey towards modularity, the freedom project teams have had in the past to make design and development choices is reduced. Modularity requires project engineers to follow a given set of rules in order to gain the scalability offered by the module concept. The modules are clearly defined for standards and interface robustness. The modules must be implemented without causing changes to the product. Adopting a modular strategy often requires a new approach and culture of working that involves reappointing responsibilities in an organization. New roles need to be defined while existing roles need to be modified.

Modularity requires certain organizational changes that reflect a different way of working.

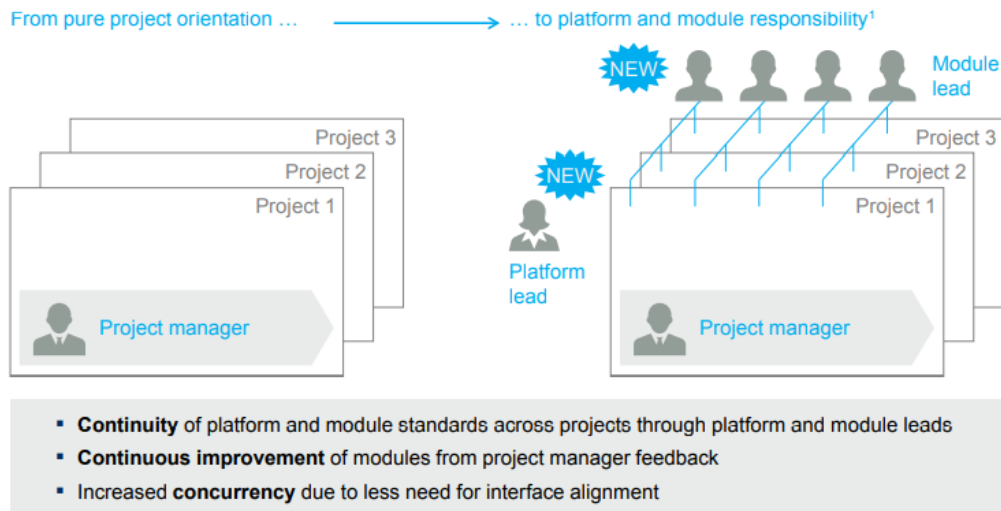


Figure 11: Organizational changes modularity requires (Bannasch et al., 2017)

Examples of new roles include the following:

- Modular strategy lead- This person defines the overall strategy of the company for indicating where the modules are to be applied in product architecture and also indicating where product specific solutions are to be applied.
- Module Lead- This role entails ensuring that the modules are applied without causing changes to products. This person is responsible for charting a roadmap for the module development. The person also prevents module overcomplexities, ensures reuse and drives module innovation.
- Platform Lead- This person works together with the sales and portfolio strategy teams to define the product differentiation across the platform and define module interfaces.

Examples of modified roles include the following:

- A modification from project manager to system integrator- The existing responsibility for developing products in a timely manner according to specifications and within

budget remains. The difference is that existing systems and modules are integrated rather than developing from scratch.

- Portfolio strategy lead- This role entails working with the modular strategy lead on differentiation and commonalities across products.

The role shift changes the orientation of the product development organization from project orientation to platform and module orientation. The new roles are important for development success. The module lead is in charge of innovation and scalability while the platform lead ensures proper integration of modules, optimal architecture, and information feedback to the module lead. There must be a balance between commonality and differentiation across products for success (Bannasch *et al.*, 2017).

2.6.1 Modular Manufacturing Options

There are two major categories for modular manufacturing:

- 1) Hybrid Modules: These modules require an existing or traditional building shell where they are placed or constructed. Examples include equipment skids, prefabricated units of cleanrooms that can be easily plugged into the utility service of the shell building
- 2) Full Facility Modules: This includes the entire building superstructure and infrastructure. It could also include exterior cladding and roofing.

An example of a modular construction solution is a Cleanroom wall and Ceiling panel systems which utilizes a box-to-box approach where the cleanroom is installed in a pre-engineered shell building box. Another example is the facility solution approach where a facility is completely constructed using different modular sections. What the different modular construction solutions share in common is that fabrication of some part of the facility is done in a controlled location offsite and it is later moved to the construction site for assembly. The construction time varies with the design. These different methods reduce cost, accelerate schedule, and ultimately improves the performance of pharmaceutical production facilities (Dalby *et al.*, 2019).

These different options have performance trade-offs. Increased modularization during construction reduces time taken from project definition to operational qualification (OQ). The level of modular construction to be utilized must be considered by project teams in relation

to the site location and specific project goals and requirements. The total lifecycle cost targets and schedule priorities contributes to the evaluations made by the project team. In addition, future mobility, flexibility, and adaptability of the facility should guide the decision-making in relation to project requirements. The availability of materials, import duties, labor skills and transportation access should also be included in the Site condition criteria.





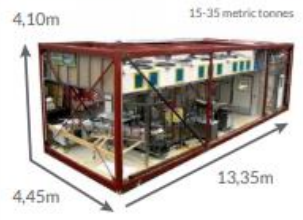
Option		Typical elements
Hybrid modules <i>Stick-built building shell with</i> Process units Technical units Room units (Box-in-Box)		Process/utilities Package units Skids and superskids
		Interstitial zones Piperacks HVAC
		Prefabricated wall/ceiling components
		Prefabricated cleanroom units
Facility modules Complete structural building units		Standard bay Large bay

Figure 12: Construction Modules Definition/Options (Dalby et al., 2019)

2.7 Benefits of Modular Manufacturing

- 1) Shorter and More Predictable Timelines: This approach allows the whole project schedule to be properly controlled and makes it more predictable. This in turn improves the confidence level of the manufacturer on when the facility becomes operational. It also improves the manufacturer’s ability to effectively utilize capital. This short and predictable project timeline minimizes the manufacturers risk because

investment in a new facility can be delayed until the later stages of a drugs clinical trials. Also, a manufacturing and facility capability that is available anytime production is needed gives the manufacturer the ability to maximize profit. A modular approach reduces the timeline across all stages of the project. The design phase can be reduced to less than 12 weeks if a pre-engineered design is used. This allows quick evaluation and feedback from all stakeholders at the design phase. The standard design would at least meet 80% of the manufacturer's requirement and modifications in design can be used to reach a 100% acceptance level (Dalby *et al.*, 2019). This 20% modifications could save about six months in time in comparison to the traditional design method. In a modular approach, the time required to oversee activities on-site reduces significantly and the end-user team can fully focus on their primary responsibilities because 80% of the facility can be fabricated off-site. The on-site assembly time differs based on the modular approach used. Prefabricated Cleanroom units can be installed and assembled in a facility within days because of the prefabrication work that would have been done in the factory while integrating a Cleanroom wall or ceiling panel system with the utility system of a facility could take weeks or months based on the size and complex nature of the facility.

- **Factory Acceptance Testing-** In a modular approach, Factory acceptance testing of the cleanrooms can be done at the off-site factory before they are moved to the project site. Any installation or operational concerns could be identified and corrected with this approach. This reduces the probability of schedule delays that could occur during commissioning at the project site. The time required to validate the facility also reduces if the developer of the modular solution provides standard operating procedures (SOP's) for installation and operational qualification of the cleanrooms. This reduces repeat testing and eliminates the need for an external consultant to generate and execute validation protocols which ultimately reduces cost and time(Dalby *et al.*, 2019).

2) Efficiency in Project Execution: When compared to the traditional construction approach, a modular approach to the design and development of pharmaceutical facilities increases the speed and efficiency at which the project can be executed. The modular approach also reduces the risk associated with executing the project. A

modular facility fabricated offsite in a controlled environment gives schedule control. In a modular approach, the cleanroom and shell building structure can be constructed concurrently, and this reduces schedule. This can only be done in a sequential manner in a traditional stick-built approach because the shell building has to be constructed first before the cleanroom can be installed. Fabrication carried out in a controlled environment gives efficiency because a manufacturing team within the quality system of the manufacturer with experience in modularity controls the process (Dalby *et al.*, 2019). Fabrication activities and procurement activities can begin before the complete design package is approved with the use of a phased risk-based approach. The use of a fabrication shop allows schedule recovery to be effective in the event that the delivery of equipment and materials is delayed.

- 3) Improved Working Conditions: Modular constructions offer improved working conditions to the industry and workforce with reasons that go beyond health and safety.
 - **Job Security**- Modular constructions gives vacancies for more permanent staffs on the workforce of factory and this position comes with several financial benefits.
 - **Ability to work in all Weather Conditions**- Construction can continue in varying weather conditions as opposed to conventional on-site construction. Light machinery is present in factories to assist in lifting, placing, and fixing which improves the general working conditions as opposed to conventional build. Majority of modular construction is carried out in a factory and this mitigates the possibilities of weather delays (Krug, 2013). The complexities of the traditional approach caused by factors such as scope disagreements, weather, and labor contracts reduce significantly in modular construction.
 - **Organizational Learning**- The stable workforce that comes with modular construction allows continuous product improvements from organizations.
- 4) Health and Safety: Conventional build is a dangerous activity. Conventional build has several tasks that require risk to be taken. Despite the improvements that have been made in site safety over the years, workers in on-site construction still need to carry out tasks with huge risks like working with heavy machinery, working at heights and in outdoor conditions. Modular constructions have these risks reduced to the barest

minimum. Modular construction reduces the time on site which automatically reduces accident and injury rates. This reduction is of clear benefit to the society. Modular construction reduces the risk of issues on-site because of the reduced activity and manpower it utilizes, and this ultimately reduces cost and the risk of schedule overruns. The prefabrication of major parts of a facility in a controlled environment mitigates external risk factors through the use of optimized processes (Dalby *et al.*, 2019).

5) Economic and Financial Considerations: The value that a modular approach adds to a pharmaceutical company depends on the company's strategic approach, current position, and future needs which includes Speed to market, flexibility to adapt and capital investment deferment.

- **Speed to Market**- The value of the financial benefits speed to market brings depends on price and market demand, level of competition and whether the drug product or therapy is new. The up-front financial investment needed in a modular approach is often higher than that of the traditional approach, but the modular approach often results in faster revenue generation because the facility becomes operational faster, and timelines are reduced. The additional financial investment needed in a modular approach is easily recouped from the financial benefits that comes with the facility becoming operational quickly. Millions could be generated in revenue and profits if the production facility becomes operational quickly. This speed to market is crucial because being late to market could affect the company's market share when a competitor gets to market first (Dalby *et al.*, 2019).
- **Capital Deferment**- Pharmaceutical companies often make huge capital investments on new production facilities before they require the facility's capacity for their drug therapies or products. These companies are faced with the risk of huge financial losses if the following occur: (1) the drug product the facility was built for fails in clinical trials or does not get approval from the regulatory authority. (2) the production facility was oversized and the drug product it was built for did not receive the expected acceptance from market. (3) the production facility was undersized during construction and could not

handle the market demand for the drug product. A modular approach to facilities ensures that pharmaceutical companies have the required capacity to produce whenever needed. This Modular approach also mitigates financial risks because pharma companies can delay capital investment on facilities up until an advanced stage in clinical trials where the drug product has a high probability of approval from regulatory authorities. This prevents the construction of facilities that would eventually not be used as intended thereby saving millions of dollars.

- **Flexibility to adapt-** During the design stage of a facility, it is important to determine the proposed facility's manufacturing capability and the capacity requirements. This is often done using sales forecasts, but it is challenging because of the difficulty in estimating demand over a long period of time. For facilities that will be producing drugs for different countries, this is more difficult because of the timing of the different regulatory approvals needed. Modular facilities give pharmaceutical companies the capability to respond rapidly to changing manufacturing demands and market needs. With Modular facilities, existing operations could be scaled out, new products or processes could be introduced, and manufacturing ability could be set-up in a new location.

2.8 Going Lean with Modular Manufacturing and its Challenges

In the Literature "Lean Transformation in a modular building company", Yu et al described a lean implementation initiative in a modular production line of Kullman Building Corporate (KBC), one of the biggest modular manufacturers in the United States. The initiative began with 5s and standardized work followed by Value stream mapping which was used to develop a kaizen plan and a lean production model. The results of the implementation initiative were used to verify the effects of the lean production model. From the results of this research, it was concluded that the principles and techniques of lean production could be effectively applied to Modular manufacturing. The initial practice in the organization before the lean implementation initiative revealed that processes were jumbled up and that the production line was unbalanced, and this led to a significant amount of waste. The implementation of the

lean initiative allowed processes to be stabilized and work to be restructured which led to an overall improvement of the production system. There was an initial challenge of getting the frontline workers and middle management to buy into the lean initiative being introduced into the modular production line. The 5S tool was effective in convincing these workers because it brought immediate and visible results. The 5S focused on cleaning and organizing the workplace. The 5S tool gave workers with no prior experience on lean production the ability to build discipline and a continuous improvement culture and teamwork which are considered to be the building blocks of implementing lean. In an effort to sustain results, an on-station inventory coupled with Kanban was developed. The Kanban was a scheduling system that was used to achieve Just-in-time. Standardized work also became a culture where tasks were completed at designated location that had all required equipment and materials. The lean implementation was a success because the focus was to balance the production line with process stability and seeing the entire production line as whole unit which was a deviation from the norm of improving the productivity of individual operations. Six months after the implementation of Lean, improvements in productivity, throughput and labor cost were observed (Yu *et al.*, 2013).

2.9 Modularity as a Lean manufacturing tool

The speed of construction is integrated into the Lean manufacturing concept. Modularity is also key to achieving the process goals of lean which are waste elimination and value addition. Modularity is gradually emerging as a trend in the Lean manufacturing process. Modular construction can be traced back to the early 19th century. Sears, Roebuck & Co. an organization into home building began the development of home kit assemblies and this signaled the beginning to mass production of modular homes. The prefabricated modular concept has evolved over the years from houses that are prefabricated to container shaped homes. Modular manufacturing has the distinct ability of transforming a project to its true definition which is a delivery project. Modularity contributes to the concept of Lean manufacturing. Modularity also builds on the founding principles of lean manufacturing. This can be seen from its advantages which includes:

- Increased speed
- Reduced Waste
- Increased labor productivity

- Improved safety to workers and reduced exposure to risk

The Building Information Modelling (BIM) which is also an aspect of modular construction helps improve the communication aspect of lean within modular construction (Hindhede, 2015).

3.0 Methodology

This research aims to identify the extent of implementation of Lean Manufacturing and Modular manufacturing in Pharmaceutical facilities in Ireland. To achieve this, quantitative and qualitative data was collected using a mixed method questionnaire. This questionnaire survey is a good fit for collecting data in exploratory studies because it increases the amount of data that can be gathered within the timeframe given for this dissertation.

This piece of research analyzed the implementation of Lean and Modularity in pharmaceutical facilities in Ireland. Existing phenomenon's of Lean and Modularity are being tested in this research. Thus, this research has used a deductive approach. A deductive approach sets out to explain casual relationships between concepts and variables and data is collected to evaluate propositions or hypothesis (Saunders, 2009).

I adopted a non-probability sampling technique where known pharmaceutical employees with experience on the implementation of Lean and Modularity were asked for referrals in getting similar employees in filling the questionnaire survey.

I conducted qualitative and quantitative questions survey using pharmaceutical employees who fitted the snowball non-probability sampling criteria. I used a mixed methods questionnaire with both open-ended and closed-ended questions to gather qualitative and quantitative data from my respondents on the impacts of Lean and Modularity on Pharmaceutical facilities in Ireland. The mixed methods questionnaire began with a qualifying question requesting that respondents fill their responses only if they have been involved in the implementation of Lean and Modularity in an Irish pharmaceutical setting.

The questionnaires were sent via a google forms link. They were sent through a network of friends in the pharmaceutical industry who have implemented Lean Manufacturing and Modular manufacturing. Various techniques such as sending WhatsApp messages and making follow-up calls was used to increase the response rate.

I targeted production managers, quality managers, process support operators, construction Engineers, CQV Engineers and other senior management personnel who have been involved in the implementation of Lean or Modularity in the development or operation of Pharmaceutical facilities in Ireland.

3.1 Sampling

The sample size was determined from a population size of 13,000 employees which is about half the total number of employees in the pharmaceutical industry in Ireland which the European Federation of Pharmaceutical Industries and Association (EFPIA) estimates to be about 26,000 (EFPIA, 2016). The population size is estimated to be the total number of employees that would have been involved in Lean manufacturing and Modular manufacturing in Ireland. There is a confidence level of 90% probability that this sample reflects the attitude of this population.

A margin of error of 10% was calculated which gives a view of how much this questionnaire survey result would reflect the views of the overall population.

$$\text{Margin of error} = z \times \frac{\sigma}{\sqrt{n}}$$

n = sample size • σ = population standard deviation • z = z-score

$$\text{Sample size} = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p(1-p)}{e^2 N} \right)}$$

Population Size=13,000

Confidence Level= 90

Margin of Error=10%

The sample size was calculated to be 68. The questionnaires were sent to 105 industry professionals. A total of 73 responses were returned. 68 of those responses indicated that they had implemented Lean and Modular manufacturing and so were valid for analysis. From the 68 valid responses, the response rate was 65%.

3.2 The Questionnaire

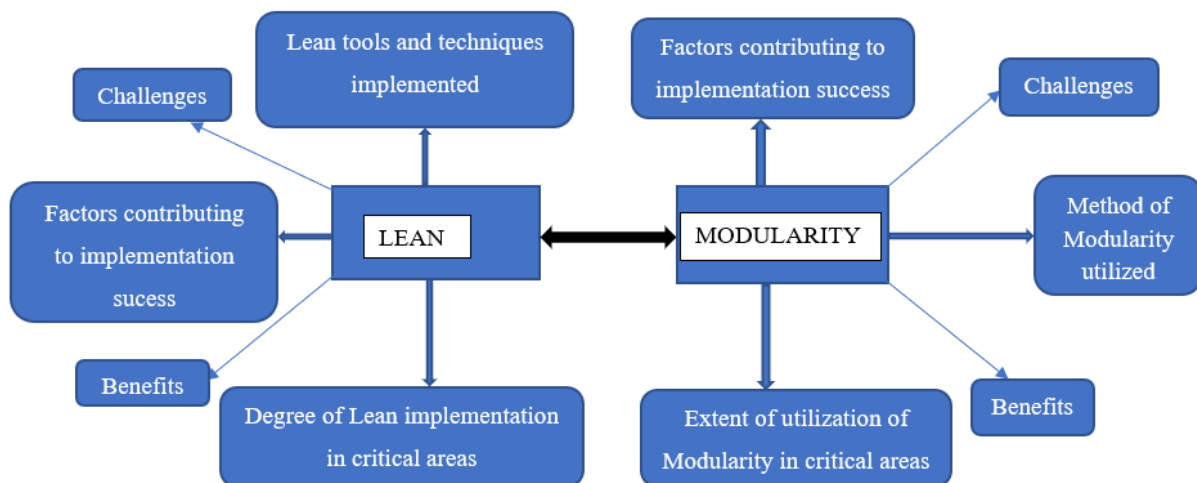


Figure 13: Questionnaire

The questionnaire contained mostly closed-ended Likert scale questions, and this enabled respondents to answer the questions in less than 8 minutes. A four-point Likert scale was used for the questions assessing the degree of implementation in critical areas of Lean and Modularity. In the four-point scale, 1= Not at all, 2=Very little, 3=Somewhat, 4=Great extent. The questionnaire also contained open-ended questions.

Data collated for the degree of utilization of Modularity in Key pharma areas was statistically tested for significance using a Chi-square Test. A p-value was generated using an online Chi-Square Calculator. The significance threshold was set at 0.05.

$$X^2 = \sum \frac{(O - E)^2}{E}$$

Where O=Observed value, E=Expected value

3.3 Ethical Considerations

It was ensured that this research was conducted in an ethical manner. No unlawful or unethical activities were conducted while conducting this research. Participation was voluntary and a decision to consent or reject consent did not have any adverse consequences. Respondents remained anonymous and no personal identifiable information was requested from participants. Respondents were allowed to withdraw at any time. This research was

composed solely by me and it has not been submitted, in whole or in part, in any previous application for a degree or professional qualification. The data collected data was not shared with any third party and was solely used for the purpose of conducting the present research. The data will be stored electronically for 3 years and destroyed afterwards according to the General Data Protection Regulation (EU) 2016/679.

4.0 Data Analysis and Discussion

4.1 Modularity in Irish pharmaceutical facilities

The respondents were asked the extent to which they agreed if the principles of Lean could be applied to Modular manufacturing.

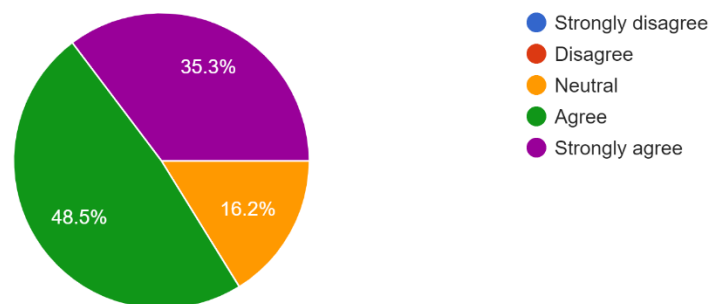


Figure 14: Extent of Agreement on the application of Lean Principles to Modular Manufacturing

From the figure above, 33 respondents who represent 48.5% of the sample size agreed that the principles of Lean could be applied to Modular manufacturing. 24 respondents who represent 35.3% of the sample size strongly agreed to this while 11 respondents who represents 16.2% of the sample size were neutral about the possibility of applying Lean principles to Modular manufacturing. This agreement by a major percentage of these industry professionals who have implemented Lean, and Modularity further supports the conclusion made in the literature “Lean Transformation in a modular building company”(Yu *et al.*, 2013). In this literature, a description of a lean implementation initiative in the modular production line of Kullman Building Corporate (KBC) was given and it was concluded that the principles of Lean could be effectively applied to Modular manufacturing.

4.1.1 Degree of Modularity Implementation in Key Pharma Areas

The respondents were asked to indicate the extent to which they had utilized Modularity in the following key areas.

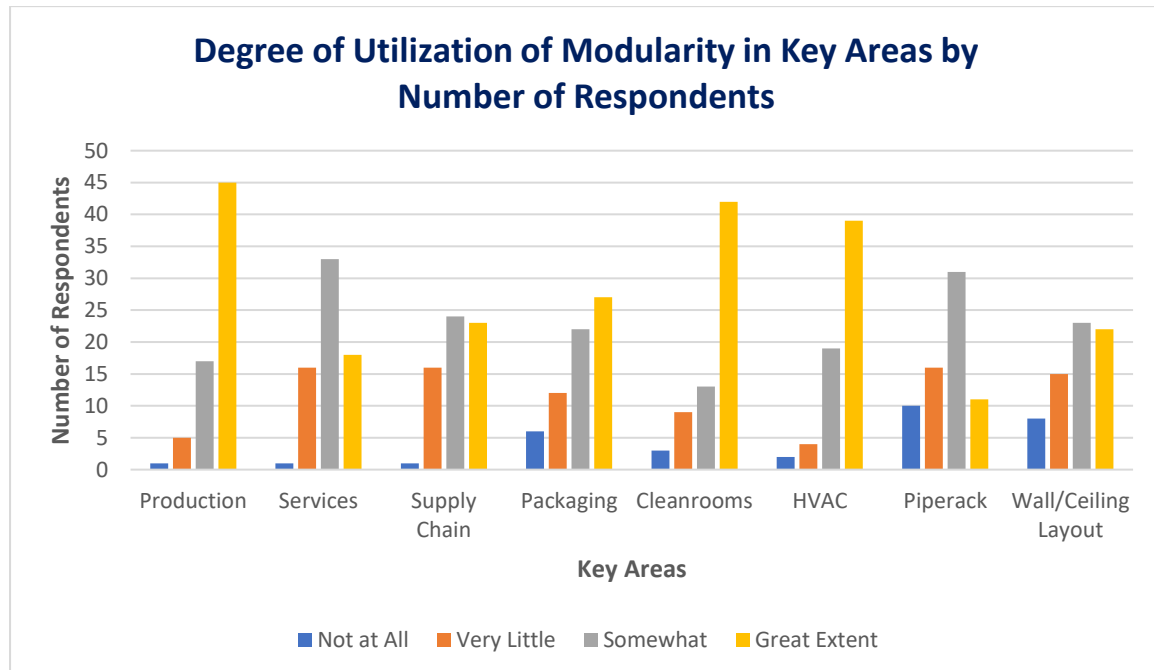


Figure 15: Degree of Utilization of Modularity in Key Areas by Number of Respondents

The figure above shows the extent to which the respondents have utilized modularity in different key areas. Modularity has been implemented to the greatest degree in the Production area in pharma. Cleanrooms had the second highest extent of modular implementation with 62% of respondents indicating utilization of modularity. HVAC systems had the third-highest level of Modular implementation with 57.4% of respondents indicating the utilization of Modularity in a great extent. Only 11 respondents indicated that they have utilized Modularity in Piperack systems in a great extent which represents 16.2% of respondents. This ranked the Piperack system as the lowest area where respondents had indicated a great utilization of Modularity. Interestingly, 10 respondents which accounts for 14.7% of respondents indicated that they have never utilized Modularity in Piperack systems. This also ranked the Piperack systems as the highest area where respondents indicated a zero utilization of modularity. The Wall/Ceiling Layout area is the second-highest area where respondents indicated a zero utilization of Modularity with 11.8% of respondents indicating this. Production, Services, and supply chain were the lowest areas where respondents

indicated a non-utilization of modularity with only 1.5% of respondents indicating this, respectively.

The high degree of utilization of Modularity in the Production area of facilities infers that most pharmaceutical companies were committed to having a flexible and scalable production facility which improves speed to market.

From the Chi-Square Test, $p < .001$. This means the data from this question is significant and the probability of it occurring by chance is 1 in a thousand.

The Low degree of Utilization of modularity in Piperack systems might be due to the complexity of assembly. Looking at the utilization of modularity in the area of Supply chain, 33.8% of respondents indicated that they had utilized Modularity in a great extent in the supply chain while 35.2% indicated that modularity has been utilized to a moderate extent in Supply chain. In the Literature “Classifying different types of Modularity for technical systems”, A case study on the supply chain of Micro Compact Car (MCC), a smart car manufacturing company created from a joint venture between Swatch of Switzerland and Mercedes-Benz was in focus. Five modules were implemented based on the model of the product in design and assembly, and it was discovered that the production cost of the company reduced because of the supply chain integration and control. Modularity is important for both product design and supply chain design because it affects how components and module suppliers are selected in the assembly sequence. System performance greatly improves when an existing supply chain network is rearranged based on product characteristics (Evans *et al.*, 2019). Thus, the moderate implementation of Modularity in the supply chain from respondents show that companies are at an early phase of utilizing modularity in supply chain.

4.1.2 Method of Modularity Used

The respondents were asked to indicate the method of Modularity they had utilized to get a further understanding of how they had implemented Modular manufacturing.

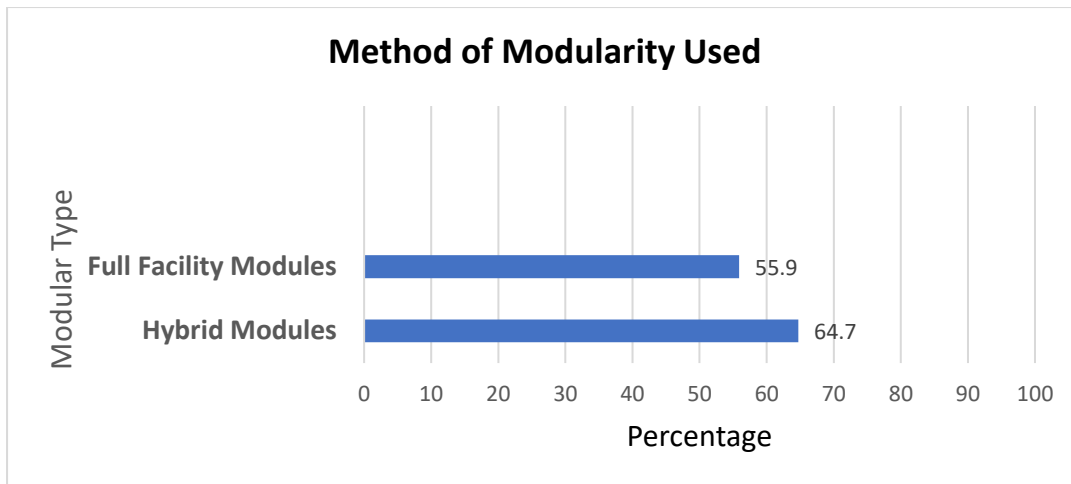


Figure 16: Method of Modularity Used

From the figure above, hybrid modules (64.7%) have been utilized the most. This shows that typical elements of hybrid modules that are easily plugged into utility services of the stick built building shell has been mostly utilized by organizations of the respondents. These typical elements include Process utilities like package units, skids and super skids; Interstitial zones like Piperack and HVAC systems; prefabricated wall and ceiling components, and prefabricated cleanroom units (Dalby *et al.*, 2019). This also shows that having a flexible and reusable facility that can accommodate late design changes and future modifications for operations seems to be a priority for production facilities in Ireland.

4.1.3 Benefits of Modularity

The respondents were asked to identify the benefits derived from their utilization of Modularity.

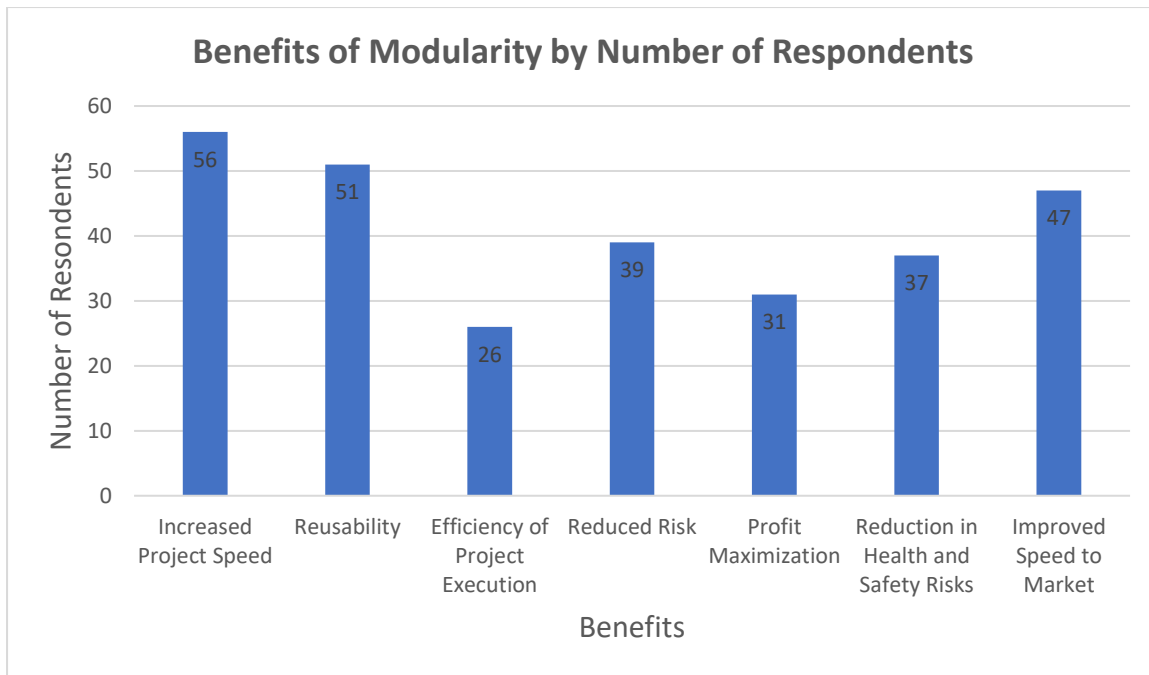


Figure 17: Benefits of Modularity by Number of Respondents

From the Figure above, it was clear that respondents had gained various benefits from their utilization of Modularity in pharmaceutical facilities. The highest benefit recorded was for increased project speed which was selected by 56 respondents. This was followed by reusability which was selected by 51 respondents and improved speed to market which was selected by 47 respondents. The least occurring benefit is efficiency of project execution.

The opinion from respondents that Modularity increases project speed supports the McKinsey & Company findings, “Modular Construction: From projects to products” that Modular construction can speed up construction by as much as 50% and deliver \$20 billion in annual savings in the European and American market. The McKinsey and Company findings also indicated that construction schedule is reduced by 20-50% although cost could potentially increase by 10% if logistics or material costs outweigh labor savings (Bertram *et al.*, 2019).

4.1.4 Applying Lean to Modular Manufacturing

Modularity contributes to the concept of Lean manufacturing and it is also key to achieving the process goals of Lean. As a result of this, the respondents were asked to indicate the extent to which they had applied Lean manufacturing techniques to Modular projects.

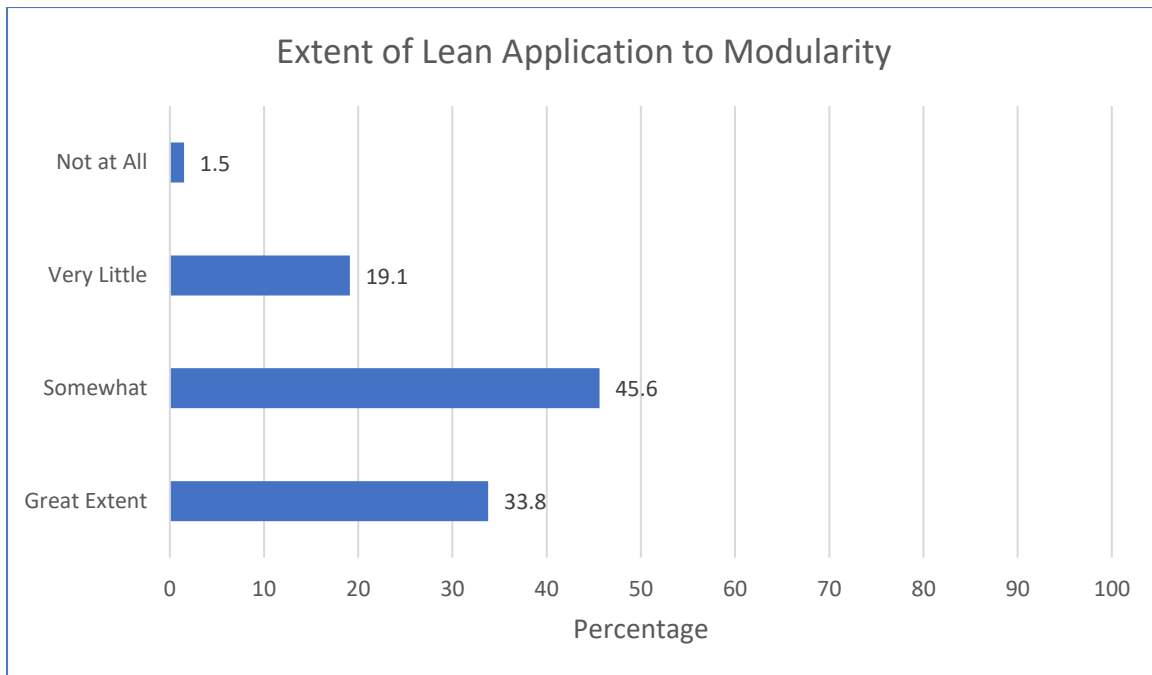


Figure 18: Extent of Lean Application to Modularity

The figure above shows that 33.8% of respondents indicated that they have applied Lean techniques to Modular manufacturing to a great extent. 45.6% of respondents indicated that they have applied lean techniques moderately to Modular projects. 19.1 % indicated a very little application of Lean techniques to Modular manufacturing while 1.5% of respondents indicated that they have not applied lean techniques to Modular manufacturing.

In the literature, “Integrating Lean into Modular Construction”, the process of Modular lean production was researched in a company that produced precast pre-slabs and a future state map was drawn to enhance performance (Sakka *et al.*, 2016). Cycle time improvements, revenue and productivity improvements were recorded as a result of integrating Lean into Modular construction (Sakka *et al.*, 2016). Another study that this result compliments is where Yu et al (2013) described a lean implementation initiative in the modular production line of Kullman Building Corporate (KBC), one of the biggest modular manufacturers in the United States (Yu *et al.*, 2013). From the results of this research, it was concluded that the principles and techniques of lean production could be effectively applied to Modular manufacturing (Yu *et al.*, 2013).

4.1.5 Factors contributing to the Implementation success of the Type of Modularity Used

The respondents were also asked in an open-ended question format to indicate the factors that have contributed to the implementation success of the type of modularity they have used.

Factors Contributing to the Implementation Success of the type of Modularity Used

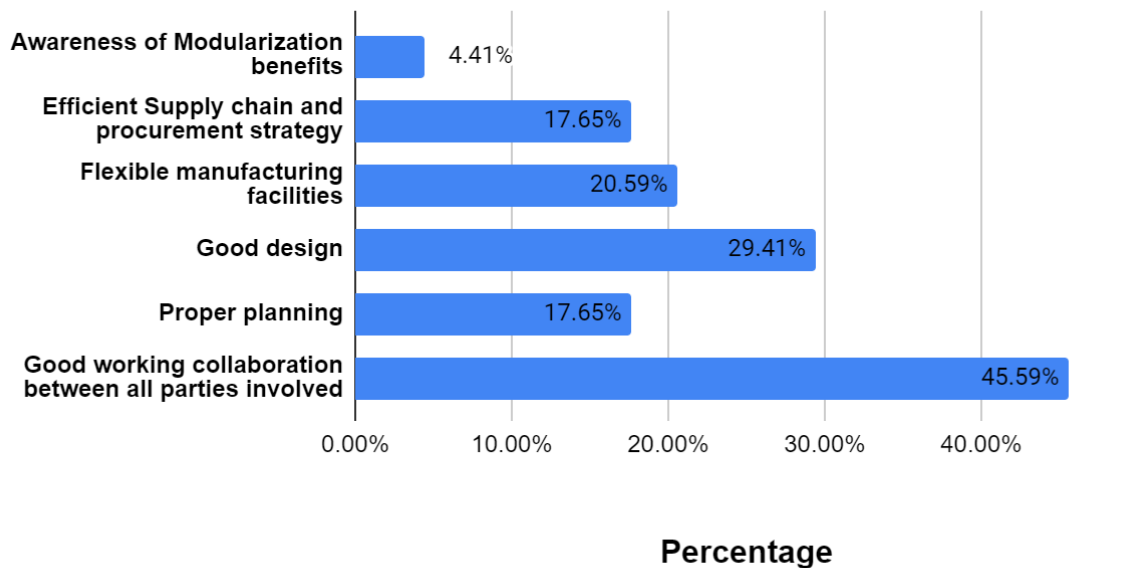


Figure 19: Factors Contributing to the Implementation Success of the Type of Modularity Used

From the findings, the recurring factor that has contributed to the implementation success of the type of modularity used is a good working collaboration between all parties involved in the project and this includes both the offsite team and onsite team. 45.59% of responses was grouped into this category. The second most occurring factor is good design, 29.41% of responses was grouped into this category. The third most occurring factor is a flexible manufacturing facility and 20.59% of responses were grouped into this category. Interestingly, having an awareness of the benefits of utilizing modularity was the least occurring factor listed by respondents. This did not seem to have a great deal of effect on the successful implementation of the modularity type used.

Micheli et al (2019) further expanded the concept of Modularity throughout a system's lifecycle. 161 articles were reviewed by Micheli et al (2019). Communication, coordination,

and information sharing between stakeholders were listed as one of the major drivers of modularization. The competence of the designers was also included as a modularization driver (Micheli *et al.*, 2019). From figure 11 above, it can be seen that the responses given by the respondents in the questionnaire sent for this research are similar to the findings in the literature by Micheli *et al.* (2019).

4.1.6 Challenges of going Lean in Modular manufacturing

The challenges of going lean in Modular manufacturing was also investigated.

Challenges of going Lean in Modular manufacturing

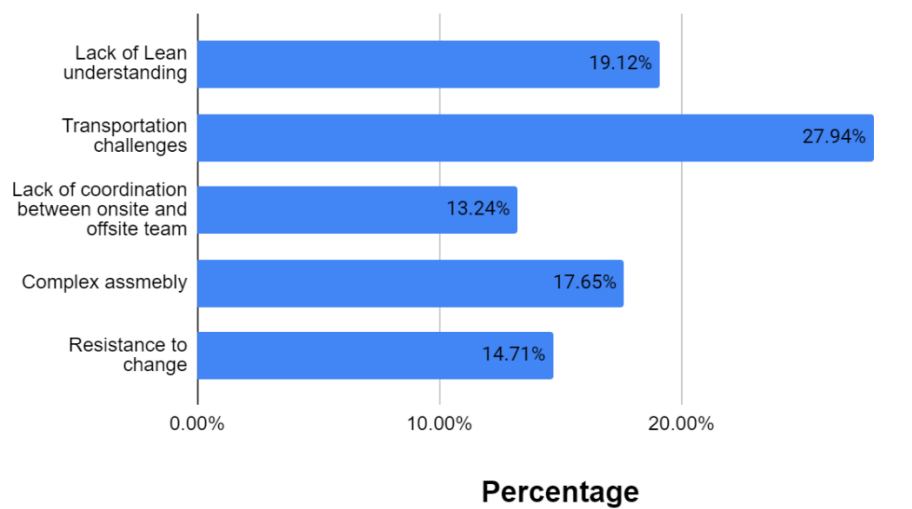


Figure 20: Challenges of going Lean in Modular Manufacturing

From the findings, the biggest obstacle of going lean in modular manufacturing revolved around transportation. The second most occurring challenge faced by respondents is a lack of lean understanding while the third most occurring challenge is complex assembly. In “Difficulties posed and Overcoming Challenges in Modular construction”, Meehleis (2019) conducted an extensive research to provide better insights into the difficulties surrounding modular construction (Meehleis, 2019). One of the most critical challenges recorded in this literature is the movement of modules from the factory to site. The height and width requirements of the modules poses a significant constraint to transportation. Modules that are considered a wide load because of their width can only be transported at night. Modules being transported by road often require road pre-assessments to ensure that the modules fit into the route’s parameters. Modules are sometimes transported through alternate routes

which eventually increases cost. This transportation challenge faced in modular construction would have impacted the implementation of lean. Another challenge recorded in this literature is complex assembly and processes. This is the challenge of ensuring that the modules align precisely with individual units. The designing of modules is complex, and detail oriented because of several factors that needs to be considered. The fitting of the different components during assembly must be considered during design. The complexity of the processes and assembly of modular units would have posed a challenge to the implementation of Lean(Meehleis, 2019).

4.2 Lean in Irish pharmaceutical facilities

4.2.1 Extent of Lean Implementation in Key Pharma Areas

This survey also investigated the extent to which respondents have implemented lean in key areas. The key areas were based on the review of previous literatures.

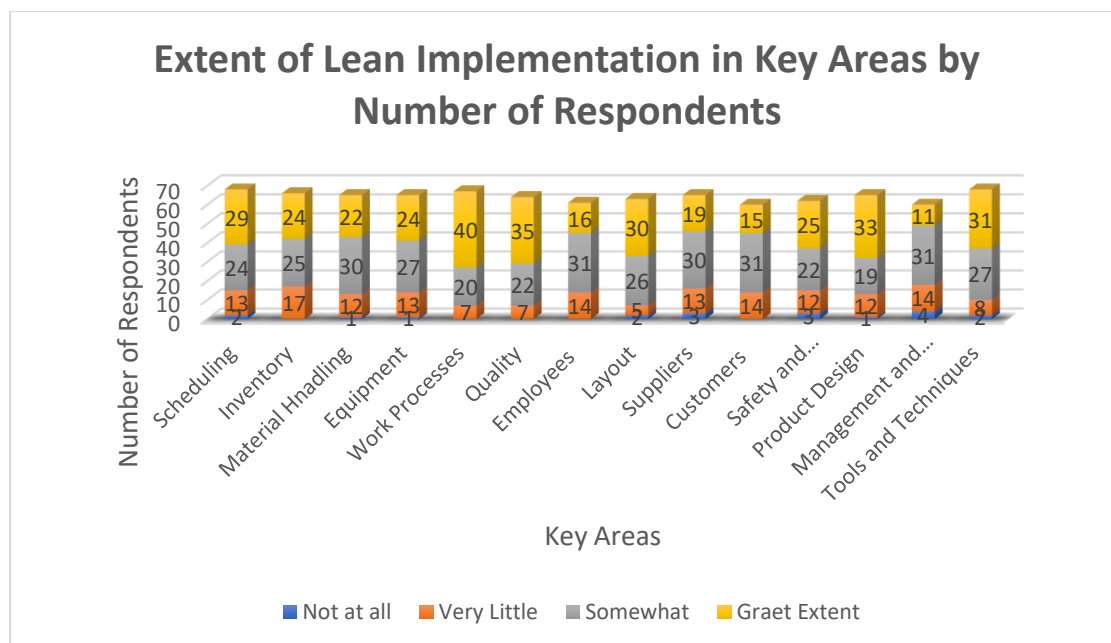


Figure 21: Extent of Lean Implementation in Key areas

One of the objectives of this research is to explore the extent of Lean manufacturing implementation in pharmaceutical facilities in Ireland. From the figure above, the

respondents have implemented lean to the greatest extent in work processes. 58.8% of respondents indicated that they have implemented lean at the greatest extent in work processes. 51.5% of respondents indicated a great implementation of lean in Quality while 48.5% of respondents indicated a great implementation of lean in the design of products. Work processes, quality and product design being the top three areas with a great implementation of lean indicates that production was given the highest priority. The major reason why lean is implemented is to reduce cost and lead time, increase productivity and improve quality thus providing the most value to customers (Rameez and Inamdar, 2010). Implementing lean in the work processes would reduce lead time and increase productivity while implementing lean in quality checks and the design of products would definitely improve the overall quality of the final products. A great implementation of lean in work processes would help create Flow. Creating flow is the third lean principle. Creating flow involves using a continuous flow process to connect all the value creating activities (Engelund *et al.*, 2008). Two of the three lowest areas that received a great lean implementation were Employees and, management and culture. This indicates that people were resistant to change. People management is one of the greatest challenges faced in implementing lean. This encompasses getting rid of the short-term philosophy, management showing commitment and avoiding sliding to the old methods of operation (Cornelissen and Trienekens, 2013).

4.2.2 Lean tools and Techniques Implemented

The respondents were also asked to indicate the lean tools they had implemented from a list of 15 tools.

Tools and Techniques	Overall %	Rank
5s	72.06%	1
Just-in-time	70.59%	2
Total Quality Management	63.24%	3
Kaizen	57.35%	4

Total Productive Maintenance	57.35%	4
Value Stream Mapping	44.12%	6
Single Minute Exchange of Dies	41.18%	7
Standardization	35.29%	8
Cellular Layouts	32.35%	9
Plan-Do-Check-Act	30.88%	10
Kanban	27.94%	11
Jidoka	27.94%	11
Heijunka	19.12%	13
Andon	13.24%	14
Poka Yoke	10.29%	15

Figure 22: Lean tools applied

From the figure above, it can be seen that the most implemented tool is 5S (72.06%). The second most implemented tool is Just-in-time (70.59%). The least adopted tool was poka yoke (10.29%). In a study conducted by Wong et al on the implementation extent of lean in the electrical and electronics industry in Malaysia, 5S was also found to be the most adopted lean tool (Wong *et al.*, 2009).

5s being the most adopted tool used by respondents from my survey shows that maintaining order in the manufacturing plant is a priority in facilities in Ireland. The high use of just-in-time by respondents in this survey also indicates that eliminating wastes like overproduction and waiting is also a priority to facilities in Ireland.

However, poka yoke was the least adopted tool by respondents. Implementing poka yoke is capital intensive and time consuming (Wong *et al.*, 2009). This is because poka yoke installs mistake proofing elements that could be instruments, fixtures or even design changes. Wong et al. also wrote that it is not advisable to implement a single lean tool in isolation (Wong *et*

al., 2009). From the figure above, it can be seen that different lean tools are being implemented concurrently.

4.2.3 Benefits of Lean

The respondents were also asked to identify the benefits gained from implementing lean tools and techniques.

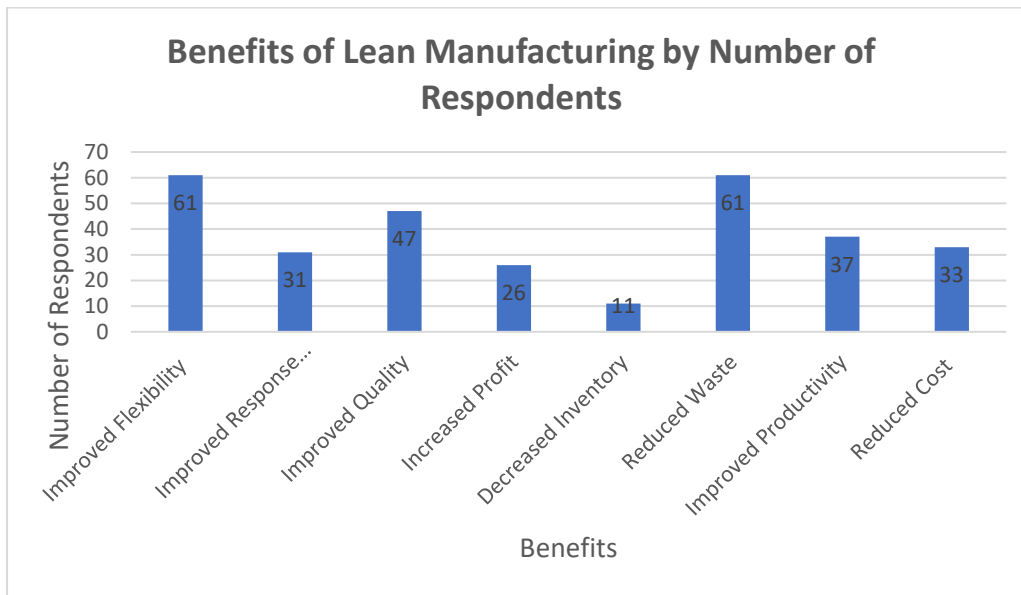


Figure 23: Benefits of Lean Manufacturing by Number of Respondents

From the findings, it is clear that the respondents have gained several benefits from implementing lean tools and techniques. The highest benefits recorded were reduced waste and improved flexibility. These benefits were both selected 61 times, respectively. This accounts for more than 80% of respondents. The third most selected benefit was improved quality while the fourth most selected benefit was improved productivity. The least occurring benefit was decreased inventory which occurred 11 times. From this result, there is a clear relationship between waste reduction, productivity, quality, and lean manufacturing.

4.2.4 Factors Contributing to the Implementation Success of Lean

The Factors that have contributed to the implementation success of lean were also investigated.

Factors Contributing to the Implementation Success of Lean

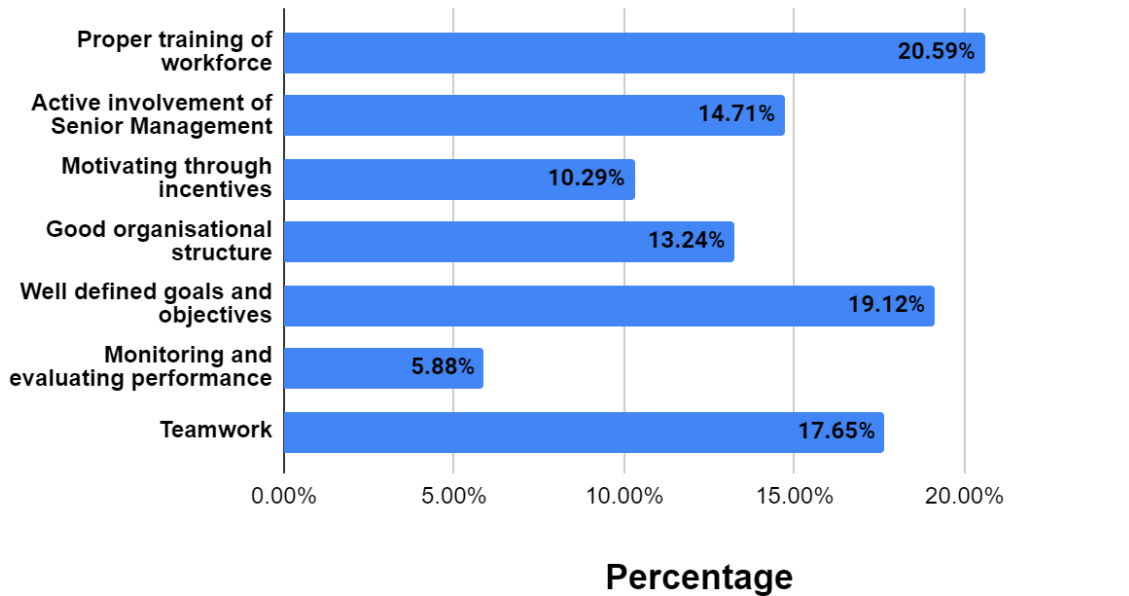


Figure 24: Factors Contributing to the Implementation Success of Lean

From the findings, a properly trained workforce was the recurring factor that contributed to the implementation success of lean among respondents. 20.59% of responses were grouped into this category. The second most occurring factor that contributed to a lean implementation success was having well defined goals and objectives. 19.12% of responses made up this factor. Teamwork was the third most occurring factor. 17.65% of responses made up this category. Monitoring and evaluating performance were the least occurring factor from respondents.

Carleysmith et al (2009) in the literature on implementing Lean Sigma in pharmaceutical research and development used a forcefield analysis framework in describing drivers for the implementation success of Lean (Carleysmith *et al.*, 2009). Some of the drivers include motivating staffs with accreditation schemes, establishment of knowledge sharing and learning through workshops and seminars, and sponsorship from senior management. All of these drivers correlate with the responses given by respondents in this research.

4.2.5 Lean Implementation Challenges

The respondents were asked in an open-ended question format to indicate the challenges faced while implementing lean.

Challenges of Implementing Lean Manufacturing

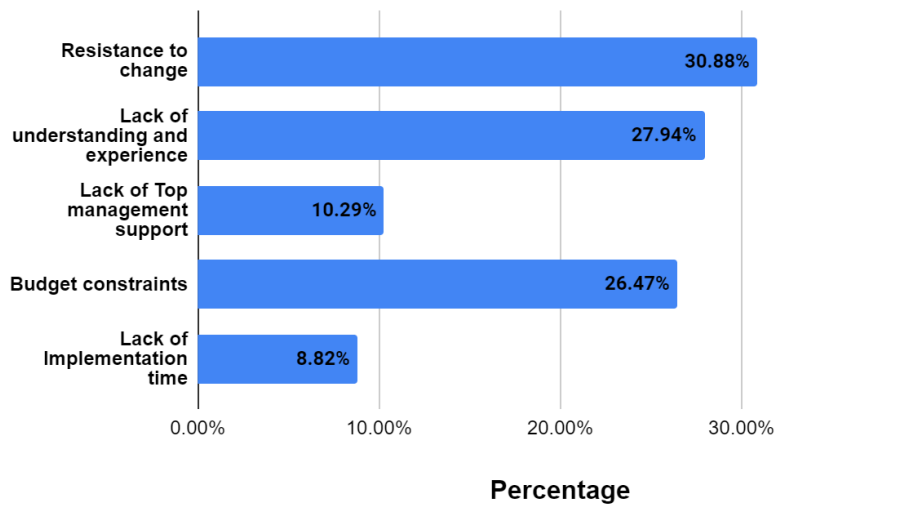


Figure 25: Lean Implementation Challenges

From the findings, the biggest challenge was a cultural resistance to change. This was followed by a lack of understanding and experience. The third most occurring challenge faced by respondents was budget constraints. A lack of implementation time was the least most occurring challenge identified by respondents. Wong et al. identified some obstacles to implementing lean in a study on the extent of lean implementation in the Malaysian Electrical and Electronics industry. Similar challenges like employees resisting change and budget constraints were identified in the literature by Wong et al (Wong *et al.*, 2009). A lack of knowledge and understanding of Lean methods and tools was also identified in the findings by Carleysmith et al (2009) on implementing lean sigma in pharmaceutical research and development (Carleysmith *et al.*, 2009)

It can be inferred that employees resisting change could be as a result of the fear of realizing that some of their jobs do not add value. This would be revealed because implementing Lean in manufacturing would definitely reveal the non-value adding activities. A resistance to change could also be mitigated if employees are well informed on the potential benefits of implementing lean in manufacturing.

5.0 Conclusion

This study has provided more insights into the current status of modular manufacturing and lean manufacturing in pharmaceutical facilities in Ireland. The issues associated with going lean in modular manufacturing and issues associated with implementing lean in pharmaceutical facilities were also highlighted in this paper. In the course of implementing modular manufacturing in facilities in Ireland, several benefits such as increased project speed, reusability, improved speed to market and risk reduction have been gained.

This study shows that modularity has been used extensively in production. Extensive utilization of Modularity in the production area and its components like Cleanrooms and HVAC systems demonstrates that Irish pharmaceutical facilities valued scalability and flexibility

A good working relationship was the most cited factor that had contributed to the implementation success of the type of Modularity utilized. Therefore, it can be concluded that that there is a good working relationship between teams (Offsite and Onsite) during the construction of modular pharmaceutical facilities in Ireland.

This study shows that 5S, Just-in-time, Total quality management and Kaizen are highly implemented Lean tools in Irish pharma. In addition, the implementation of lean gave Irish pharmaceutical facilities several benefits like reduced waste, flexibility, and improved quality. This paper shows that pharmaceutical facilities did not use lean tools in isolation. Several lean tools are being used together in pharmaceutical facilities in Ireland. As a result of 5S and just-in-time being one of the most implemented tools by respondents, it can be concluded that maintaining order and eliminating wastes like overproduction and waiting is a priority in the production process of pharmaceutical facilities in Ireland. To fully understand the extent of lean manufacturing, 14 areas that characterizes the lean manufacturing concept was evaluated. Pharmaceutical facilities implemented lean the most in work processes, quality, and product design.

In all of the 14 areas evaluated, a somewhat and great extent of implementation were the most recurring. Therefore, it can be concluded that there has been a moderate to extensive implementation of lean in pharmaceutical facilities in Ireland. Similar to the utilization of

Modularity, it can also be concluded that pharmaceutical facilities in Ireland gave the production process a priority in their lean implementation initiative. The effect of the priority given to production is obvious from the fact that improved quality was one of the most occurring lean benefits identified by respondents.

A well-trained workforce was the most occurring factor that contributed to the implementation success of lean among respondents. Therefore, it can be inferred that pharmaceutical companies in Ireland are committed to the training and personal development of their workforce. This response from participants of a well-trained workforce also corroborates a report from IDA Ireland that Ireland has the highest level of STEM (Science, Technology, Engineering and Mathematics) graduates per capita in the European Union (IDA Ireland, 2020). This also corroborates a report from Innopharma education that over 65% of employees in the pharma/med-tech sectors in Ireland are third-level graduate degree holders (Innopharma education, 2020).

5.1 Limitations and Future Scope

One of the limitations of this study is that some of the scales used in the Questionnaire survey were not incremental because they were four-point Likert scales. Another limitation is the absence of a question on the type of pharmaceutical facility respondents have implemented Lean and Modularity. Descriptive analysis has been majorly used for the interpretation of data collected in this study. For future studies, inferential analysis could be used in detail to empirically investigate the extent to which Modularity can be used as an enabler of Lean manufacturing in pharmaceutical facilities in Ireland.

5.2 Recommendation

The findings of this research indicate that Modularity and lean are at different levels of implementation in pharmaceutical facilities in Ireland. The major challenge to a lean implementation initiative according to respondents was a cultural resistance to change. Irish Pharmaceutical companies could gather and present baseline facts and data that will give employees a convincing need to change. The resistance to change can be mitigated if Irish pharmaceutical facilities split lean implementation into phases as this would allow easy feedback and progress monitoring. Mechanisms like conducting periodic reviews and having

accountability checks could be put in place to sustain the benefits gained from implementing lean.

In addition, the transportation of modules and complex assembly were one of the major challenges to modularity according to respondents. Large modules could be shipped at night to reduce transportation risk for other road users (Meehleis, 2019).

Bibliography

Abdelhamid, T.S. (2003) 'SIX-SIGMA IN LEAN CONSTRUCTION SYSTEMS: OPPORTUNITIES AND CHALLENGES'. p. 20.

Alves, J.R.X. (2015) 'Production Management Model Integrating the Principles of Lean Manufacturing and Sustainability Supported by the Cultural Transformation of a Company'. *International Journal of Production Research*, p. 15.

Badurdeen. (2007) *Lean Manufacturing Basics.Pdf*. Available at: <http://docshare04.docshare.tips/files/2452/24525675.pdf> (Accessed: 15 April 2021).

Bannasch, F., Rossi, G. and Thaidigsmann, B. (2017) 'Platform and Modularity Strategies Enable Companies to Build a Broader Portfolio of Offerings for Customers, Including Niche Products at Acceptable Cost, at Less Effort. But to Capture These Advantages, Companies Must Choose the Right Organizational Design for Their Product Development Function as Well as Manage It Strategically.' p. 7.

Bertram, N. *et al.* (2019) 'Modular Construction: From Projects to Products'. *Capital Projects*, p. 34.

Bjornfot, A. and Stehn, L. (2004) 'INDUSTRIALIZATION OF CONSTRUCTION -A LEAN MODULAR APPROACH'. p. 14.

Black, J. (2007) 'Design Rules for Implementing the Toyota Production System'. *International Journal of Production Research*, 45, pp. 3639–3664.

Carleysmith, S.W., Dufton, A.M. and Altria, K.D. (2009) 'Implementing Lean Sigma in Pharmaceutical Research and Development: A Review by Practitioners'. *R&D Management*, 39(1), pp. 95–106. DOI: 10.1111/j.1467-9310.2008.00542.x.

Cornelissen, R. and Trienekens, J. (2013) 'What Are the Main Challenges When Implementing Lean and How Do Industry and Company Characteristics Influence These Challenges?' p. 32.

Dalby, K. *et al.* (2019).

Dekier, Ł. (2012) 'The Origins and Evolution of Lean Management System'. *JOURNAL OF INTERNATIONAL STUDIES*, 5(1), pp. 46–51. DOI: 10.14254/2071-8330.2012/5-1/6.

Doanh. (2017) *The Five Principles of Lean. The Lean Way*. Available at: <https://theleanway.net/The-Five-Principles-of-Lean> (Accessed: 15 April 2021).

EFPIA. (2016) *Employment in the Pharmaceutical Industry (by Country)*. Available at: <https://www.efpia.eu/publications/data-center/the-pharma-industry-in-figures-employment/employment-in-the-pharmaceutical-industry-by-country/> (Accessed: 3 June 2021).

Engelund, E.H., Breum, G. and Friis, A. (2008) 'Optimisation of Large-Scale Food Production Using Lean Manufacturing Principles'. p. 12.

Evans, S., Li, H. and Yang, M. (2019) 'Classifying Different Types of Modularity for Technical System'. *International Journal of Technology Management*, 81(1/2), p. 1. DOI: 10.1504/IJTM.2019.10022051.

Hindhede, D. (2015) *Construction Modularization from a Lean Perspective - Apppm*. Available at:

http://apppm.man.dtu.dk/index.php/Construction_modularization_from_a_lean_perspective (Accessed: 19 February 2021).

IDA Ireland. (2020) *Bio-Pharmaceuticals & Biotechnology Ireland*. IDA Ireland. Available at: <https://www.idaireland.com/doing-business-here/industry-sectors/bio-pharmaceuticals> (Accessed: 9 April 2021).

Innopharma education. (2020) *Why Ireland Is Attracting Top Pharmaceutical Companies*. *Default*. Available at: <https://www.innopharmaeducation.com/news/why-ireland-attracting-the-worlds-top-pharmaceutical-companies-and-how-you-can-benefit> (Accessed: 20 May 2021).

IPHA. (2020) *Key Facts*. IPHA. Available at: <https://www.ipha.ie/about-the-industry/key-facts/> (Accessed: 9 April 2021).

Iuga, M.V. and Blaga, L. (2013) 'LEAN MANUFACTURING: THE WHEN, THE WHERE, THE WHO'. p. 7.

Jornitz, M.W. (2013) 'The Need for Flexible Facility Designs'. p. 5.

Kamble, S., Gunasekaran, A. and Dhone, N.C. (2020) 'Industry 4.0 and Lean Manufacturing Practices for Sustainable Organisational Performance in Indian Manufacturing Companies'. *International Journal of Production Research*, 58(5), pp. 1319–1337. DOI: 10.1080/00207543.2019.1630772.

Krug, D. (2013) 'Offsite Construction Sustainability Characteristics'. p. 20.

Leine, A. (2021) *3 Steps Implementing Lean and Modularity*. Available at: <https://www.modularmanagement.com/blog/3-steps-implementing-lean-and-modularity> (Accessed: 31 May 2021).

Liker, J.K. and Morgan, J.M. (2006) 'The Toyota Way in Services: The Case of Lean Product Development'. *Academy of Management Perspectives*, 20(2), pp. 5–20. DOI: 10.5465/amp.2006.20591002.

Meehleis, M.W. (2019) 'Difficulties Posed and Overcoming Challenges in Modular Construction: A Case Study'. p. 10.

Micheli, G.J. *et al.* (2019) 'Modularization as a System Life Cycle Management Strategy: Drivers, Barriers, Mechanisms and Impacts'. *International Journal of Engineering Business Management*, 11, p. 184797901882504. DOI: 10.1177/1847979018825041.

Miller, T. and Elgard, P. (1998) *Defining Modules, Modularity and Modularization: Evolution of the Concept in a Historical Perspective | Modularity | Modular Programming*. Scribd. Available at: <https://www.scribd.com/document/237087676/Modular-lization> (Accessed: 8 April 2021).

Modular Building Institute. (2020) *What Is Modular Construction? | Modular Building Institute*. Available at: https://www.modular.org/HtmlPage.aspx?name=why_modular (Accessed: 14 November 2020).

Rameez, H.M. and Inamdar, K.H. (2010) 'Areas of Lean Manufacturing for Productivity Improvement in a Manufacturing Unit'. 4(9), p. 4.

Road, O.D. (2020) *What Is Modular Construction?. Chapman Taylor*. Available at: <https://www.chapmantaylor.com/insights/what-is-modular-construction-and-why-has-chapman-taylor-embraced-it> (Accessed: 14 November 2020).

Sakka, F.E. *et al.* (2016) 'Integrating Lean Into Modular Construction: A Detailed Case Study of Company X'. DOI: 10.13140/RG.2.1.3487.0005.

Saunders, M. (2009).

Shingo Institute. (2020) *About the Shingo Institute - Shingo Institute | Meet the Staff!. Shingo Institute*. Available at: <https://shingo.org/about-the-shingo-institute/> (Accessed: 16 April 2021).

Singh, H. and Mahmood, R. (2014) *Manufacturing Strategy and Export Performance of Small and Medium Enterprises in Malaysia.Pdf*. Available at: <https://www.ijbcnet.com/3-5/IJBC-14-3507.pdf> (Accessed: 15 April 2021).

Womack, J. and Jones, D. (2003) 'BANISH WASTE AND CREATE WEALTH IN YOUR CORPORATION'. p. 402.

Wong, Y.C., Wong, K.Y. and Ali, A. (2009) 'A Study on Lean Manufacturing Implementation in the Malaysian Electrical and Electronics Industry'. p. 15.

Yu, H. *et al.* (2013) 'Lean Transformation in a Modular Building Company: A Case for Implementation'. *Journal of Management in Engineering*, 29(1), pp. 103–111. DOI: 10.1061/(ASCE)ME.1943-5479.0000115.

APENDIX

QUESTIONNAIRE

1. Have you been involved in a project involving the implementation of Lean and Modularity?

- Yes
- No

If Yes, proceed to the following questions

2. Do you agree that the principles and techniques of lean production could be effectively applied to Modular manufacturing?

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

3. To what degree have you used Modularity in the following key areas?

Areas	Not at All	Very Little	Somewhat	Great Extent
Production				
Services				
Supply Chain				
Packaging				
Cleanrooms				
HVAC				

Piperack				
Wall/Ceiling layout				

4. What method of Modularity have you utilized?

- Hybrid Modules
- Full Facility Modules

5. Which of the following benefits have you derived from your utilization of modularity?

Benefits	Tick Box
Increased project speed	
Reusability	
Efficiency of Project Execution	
Reduced Risk	
Profit maximization	
Reduction in health and safety risks	
Improved Speed to market	

6. To what extent have you applied lean manufacturing techniques to modular projects you have been involved with?

- To a Great Extent
- Somewhat

- Very Little
 - Not at All
7. What factors have contributed to the implementation success of the type of Modularity you have utilized?
 8. What challenges have you faced in going Lean in Modular manufacturing?

Section B

1. To What degree have you implemented Lean in the following key practice areas?

Key areas	Not at all	Very Little	Somewhat	Great Extent
Scheduling				
Inventory				
Material handling				
Equipment				
Work Processes				
Quality				
Employees				
Layout				
Suppliers				
Customers				
Safety and Ergonomics				
Product Design				

Management and Culture				
Tools and techniques				

2. Which of the following Lean tools and techniques have you implemented?

Tools and Techniques	Tick box
5S	
Kaizen	
Standardized work	
Plan-do-check-Act (PDCA)	
Poka-Yoke	
Kanban	
Just-In-Time (JIT)	
Total Productive Maintenance (TPM)	
Total Quality Management (TQM)	
Value stream mapping (VSM)	
Cellular Layouts	
Heijunka	
Six Sigma	

Andon	
Single Minute Exchange of Dyes (SMED)	
Jidoka	

3. Which of the following benefits have you derived from your implementation of Lean tools and techniques?

Benefits	Tick box
Improved flexibility	
Improved response time	
Improved quality	
Increased profit	
Decreased Inventory	
Reduced waste	
Improved productivity	
Reduced Cost	

4. What factors have contributed to the implementation success of the lean tools used?
5. What challenges have you faced while implementing Lean manufacturing?