

**A COMPARATIVE STUDY ON LEAN AND SIX-SIGMA IMPLEMENTATION AT  
VARIOUS PHARMACEUTICAL INDUSTRIES IN INDIA AND IRELAND.**

**By**

**Bala Sneha Chavva**

**Research dissertation presented in partial fulfilment of the requirements for  
the degree of MSc in Pharmaceutical Business and Technology (QQI)**

**Griffith College Dublin**

**May 2020**

## **CANDIDATE DECLARATION**

**Candidate Name:** Bala Sneha Chavva

I certify that the dissertation entitled: A Comparative Study on Lean and Six-Sigma Implementation at Various Pharmaceutical Industries in India And Ireland.

Submitted for the degree of: MSc in Pharmaceutical Business and Technology is the result of my own work and that where reference is made to the work of others, due acknowledgment is given.

Candidate Signature: Bala Sneha Chavva

Date: 24.05.2020

Supervisor Name: Paul Blunnie

Supervisor signature:

Date:

## **DEDICATION**

I dedicate this work to God almighty for his grace and to my family for their endless support.

## **ACKNOWLEDGEMENT**

I want to thank my supervisor **Mr. Paul Blunnie** and my teacher **Mr. Finbarr Sheehy**, for his support, guidance and cooperation throughout my research. I also experience sincere gratitude to **Mrs. Barbara O' Hanrahan** for helping me to gain knowledge towards the research.

Special thanks to my family, Fathima Mary (Mom) for her endless love, concern, calls, care and support. Ignatius (aunt) for being a listening ear, support system, a great adviser, to Sindhu Thomas (sister) for being my inspiration and a shoulder to lay down. Govind (friend) for being a hand all through my research work.

I would like to thank all employees who participated in my research. To all my friends and extended family, thank you for your support.

**Bala Sneha Chavva**

## Table of Contents

<b>List of Figures</b> .....	<b>iv</b>
<b>List of Tables</b> .....	<b>v</b>
<b>Abstract</b> .....	<b>vi</b>
<b>Chapter 1: Introduction</b> .....	<b>1</b>
1.1 The Pharmaceutical Industry.....	1
1.2 Six Sigma and Lean Methodologies.....	1
1.3 Research Purpose .....	2
1.4 Significance of the study .....	5
1.5 Research Objective.....	5
1.6 Structure of the research.....	6
<b>Chapter 2: Literature Review</b> .....	<b>7</b>
2.1 Introduction:.....	7
2.2 Six Sigma in Pharmaceutical Industry:.....	8
2.3 Introduction to lean methods .....	9
What is lean? .....	9
Lean in Manufacturing:.....	10
Lean applications in pharmaceutical industry:.....	10
2.4 Tools of LSS:.....	11
2.5 Methodology of LSS:.....	13
Concept and Process of Six Sigma and Lean:.....	13
2.6 Design for Lean Six Sigma: .....	15
2.7 LSS In Pharmaceutical Manufacturing:.....	18
2.8 LSS Implementation:.....	20
2.9 Advantages of using Six Sigma and Lean in manufacturing industry: .....	20

2.10 Facilitators in LSS: .....	22
2.11 Barriers in LSS Implementation: .....	24
2.12 LSS In Ireland: .....	25
2.13 LSS In India:.....	27
2.14 Conceptual Framework: .....	28
2.15 Literature Gap .....	28
<b>Chapter 3: Research Methodology .....</b>	<b>30</b>
3.1 Introduction .....	30
3.2 Overview of Philosophy and Approach .....	30
3.3 Research approaches:.....	32
3.4 Research Design: .....	33
3.5 Research Strategy:.....	34
3.6 Recruitment: .....	35
3.7 Sampling: .....	36
3.8 Role of the Researcher:.....	36
3.9 Ethical Issues: .....	37
3.10 Conclusion:.....	37
<b>Chapter 4: Findings and Discussion .....</b>	<b>38</b>
4.2 Overview .....	38
4.1 Research Findings and Discussion .....	39
i. Country wise participants:.....	39
ii. Knowledge on LSS: .....	40
iii. The Designations of the participants:.....	41
iv. Level of experience:.....	42
v. Experience with LSS: .....	42
vi. Size of the organization:.....	43

ix.	Comparison of experience between the India and Ireland: .....	47
x.	Impact of culture in LSS implementation: .....	49
xi.	LSS certification: .....	51
xii.	Comparison of LSS implementation and its tools used in India and Ireland. ...	51
xiii.	Justification for the usage of current tools and future recommendations: .....	55
xiv.	Experience of LSS benefits: .....	56
xv.	Facilitators/ CSF's: .....	59
xvi.	Barriers: .....	61
	Possible Solutions: .....	62
xvii.	Benefits: .....	63
<b>Chapter 5: Conclusion .....</b>		<b>65</b>
5.1	Research conclusions: .....	65
5.2	Limitations of the study: .....	68
5.3	Strengths of the research: .....	68
5.4	Recommendations: .....	68
5.5	Final conclusion and reflections: .....	69
<b>References: .....</b>		<b>70</b>

## List of Figures

Figure 1: Lean tools (Lean Tools, n.d.).....	12
Figure 2: Lean implementation stages.....	17
Figure 3: Research philosophy (Research philosophy, n.d.) .....	32
Figure 4: Country wise distribution of the participants .....	40
Figure 5: Knowledge on LSS.....	41
Figure 6: Experience of the participants .....	42
Figure 7: Experience working with LSS.....	43
Figure 8: Size of the Organization .....	44
Figure 9: Extent of overall LSS implementation. ....	46
Figure 10: Extent of LSS implementation in the organization in each country .....	47
Figure 11: Number of participants having experience in both India and Ireland.....	48
Figure 12: Agreement of national culture's impact on successful LSS implementation. ....	50
Figure 13: Agreement on cultural differences between India and Ireland cause difference in the way of LSS implementation. ....	50
Figure 14: Participants holding LSS certification.....	51
Figure 15: Comparison of LSS implementation and its tools used in India Vs Ireland. ....	52
Figure 16: Usage of various LSS tools based on the size of the industry in India.....	53
Figure 17: Usage of various LSS tools based on the size of the industry in Ireland .....	54
Figure 18: LSS implementation and tools in Large Vs Small-medium sized pharmaceutical manufacturing sectors in India and Ireland. ....	55
Figure 19: Agreement with LSS implementation benefiting the company .....	57
Figure 20: Agreement with LSS implementation helpful in reducing the waste. ....	58
Figure 21: Agreement with LSS implementation in reducing the financial burden .....	58
Figure 22: Agreement with LSS implementation increasing customer satisfaction and product quality. ....	59
Figure 23: Top 5 facilitators in Lean Six Sigma Implementation. ....	61
Figure 24: Top 5 barriers in LSS implementation.....	63
Figure 25: Top 5 benefits in LSS implementation .....	64

## List of Tables

Table 1: Research Chapters .....	6
Table 2: Designations of the participants .....	41
Table 3: Pivot Chart between Size of the Organization, extent of LSS implemented in the organization and the Countries. ....	46

## Abstract

### A COMPARATIVE STUDY ON LEAN AND SIX-SIGMA IMPLEMENTATION AT VARIOUS PHARMACEUTICAL INDUSTRIES IN INDIA AND IRELAND.

Bala Sneha Chavva

The research was set out to compare the extent of LSS implementation and different tools used in India and Ireland in various pharmaceutical manufacturing sectors. For this, the main objectives were to compare differently sized industries like small, medium and large. To achieve this, a qualitative method was implemented and the data sourcing was done by primary and secondary methods with the questionnaire being the main source of the data. A study population of 11 participants who were presently work in the pharmaceutical manufacturing sectors of India and Ireland filled out the questionnaire. The study found out that there is not much gap in LSS implementation of these two countries. Top five facilitators, barriers and benefits were summarized, with cultural differences being the most important factor to be considered among the two countries. The study also found out that there is no gap in the LSS implementation in various industries at Ireland, as the small-scale industries too were found using the tools.

## Chapter 1: Introduction

### 1.1 The Pharmaceutical Industry

The Pharmaceutical companies now-a-days face a number of challenging tasks in getting adjusted to the unsteady and chaotic market while targeting to meet the demands of their customers for one's health maintenance. This is much worse when the population is getting hit by the pandemic, like CoVID-19. In order to satisfy all the requirements and challenges, these companies are grappling to find the best solutions to minimize the internal costs by using innovative approaches to logically respond to the sudden unexpected rise in the demand for few drugs.

Finding the balance between the urge to reduce the costs on one hand and being innovative at designs on other hand is always tough. In the same perception, the main reason behind collaboration of 2 companies is to reduce the costs. Even though there isn't any solution for these economic instabilities, process improvement and waste minimization techniques like LSS methods are thought to reduce the costs, manage time and promote the research and development. (Taylor, 2015)

### 1.2 Six Sigma and Lean Methodologies

LEAN was created by Taiichi Ohno in the 1950s and emerged from the Toyota manufacturing method with main facets including a never ever-ending search for excellence, a relentless effort to eradicate waste, and appreciation and value of employee contributions. On the other hand, Six Sigma is an updated approach to minimize errors by the use of the Define-Measure-Analyze-Improve-Control (DMAIC) model, which has evolved more in the framework of the Six Sigma system, a rigorous system focused on processes and ways to increase their performance.

Lean and Six Sigma may be used independently or together as methodologies. Six Sigma and Lean are increasingly embraced by several businesses in numerous sectors, big and small, in order to boost design, development, market and innovative property performance while minimizing costs. In the pharmaceutical and medical device industries, these principles can be implemented effectively in order to

address the dilemma of excessive costs that hinder sustainable research and innovation.

### 1.3 Research Purpose

The Pharmaceutical industry was significantly impacted by the global recession of 2008–2010, after this get down, new unique developments has emerged in the business sector of almost every industry. Hence, it may be important to force research to create better methods that are relevant for the industry. It is now widely acknowledged that Lean Six Sigma Management is of major benefit to manufacturing industries, which is why companies in the pharmaceutical industry are increasingly participating in it. (Nenni et al., 2014)

There is a vast literature on LSS implementation in various industries like automobile, aviation, service, healthcare etc., but the studies confined to pharmaceutical manufacturing are very limited. An Italian pharmaceutical company “Rottapharm” based in Dublin has invested for its new process and a new facility with expansion of four packaging lines, 2 new coating systems and capsulation machines, this led to the increased volumes of finished products and their packaging in 2010. For this reason, they have recruited 35 new positions and started Lean and six sigma methods targeting financially on the cost reduction and profit increase, during these times they have encountered difficult problems in the process and resolved them using the LSS methods which are effective ways in implementing the problem solving and process improvement methods, says (Hayes, 2013). Due to this, over past 5 years, Rottapharm have completed 20 six sigma projects successfully.

Similarly, a large number of pharmaceutical companies have implemented LSS namely, GSK, AstraZeneca, Johnson and Johnson, Teva and Pfizer and are hugely benefited. They have observed and stated that by following Lean sigma methods the financial burden can be decreased and products can be marketed more quickly. Pfizer have implemented LSS in manufacturing department and have seen reduced lead time by 50% and Teva has increased its productivity by 31%, 55% decrease in

manufacturing accidents and 41% reductions in overall deviations, according to (Dufton, 2009)

The Lean and Six sigma method which has proved to dramatically increase the benefits in the industry is mostly impacted by the factors aiding in implementation of Lean Sigma, similarly, it is also negatively impacted by the group of factors which demote the implementation. A Literature review by (Sreedharan V et al., 2018) has put forth various critical success factors in implementation of Continuous Improvement, Lean, Six sigma and Lean Sigma. Another study by (Stankalla et al., 2018) has reviewed the critical success factors in six sigma implementation in small and medium sized enterprises across 6 different countries and stated that linking the six sigma to the business strategy and the top management's commitment are the top critical success factors in either of the small and medium sized enterprises.

And also stated that in these industries linking the six sigma to the customer is also beneficial. Whereas, (Navarro, 2014) has posted five major roadblocks, the so called barriers in implementing LSS in small business were: Insufficient management time to support lean, Not understanding the potential benefits of applying lean, Underestimating employee attitudes/resistance to change, Insufficient workforce skills to implement lean and Backsliding to the old inefficient ways of working.

Considering the culture as one of the facilitator, an article by (Steve, 2010) conducted a cross sectional study on usage of six sigma in Europe and concluded that the change in the organizations is mostly impacted by their national culture. In a research article (Ilaria, 2018) on corporate and national factors which serve as barriers in Lean projects, the results has shown that Performance orientation and Egalitarianism of the gender are the two main national culture factors and uncertainty avoidance, orientation of the future and institutional collectivism are the cultural factors with respect to individual that are influencing the lean culture.

(Bhaskar, 2020) concluded that introduction of lean in the organization is done only if all the managers are aware of eight basics of LSS in the sector of manufacturing. A systematic review (Albliwi et al., 2015) have stated 50 benefits of using LSS in

manufacturing industry by reviewing 37 research articles and 19 case studies from 11 different countries. The top 5 benefits were: increased profits and financial savings; increased customer satisfaction; reduced cost; reduced cycle time; and improved key performance metrics.

There is again very less research on narrowing down or confining the research to a particular country's scope of LSS implementation and comparing differently sized industries like small, medium and large scale in a specific country. While comparing the LSS implementation in developed countries like United States, United Kingdom, Ireland etc., to developing countries like India, Bangladesh, Pakistan and other Asian countries, many factors are to be considered like the cultural differences, mindset, finances, government's role etc., (Zhang et al., 2012) carried out a study on critical success factors in LSS implementation on national and Multinational organizations in Pakistan and found out that the LSS implementation in Pakistan was at early stage and didn't specify what has created a difference in implementation pattern in Pakistani organization. Another study by (bin Wan Ibrahim et al., 2017) hypothesized that lean implementation in Malaysian pharmaceutical SME's is at infancy. Support of the management, commitment of the employee's, local government support and knowledge of lean in employees were identified as the major critical success factors and further concluded that implementation of Lean in local pharmaceutical SME's will be beneficial in reducing the costs and efficiency can be increased which cannot impact the GMP guidelines that are existing.

The major differences between the developed countries with the developing one's in terms of implementation of LSS are: there is sufficient staff and good implementation of LSS in developed nations but in the case of developing countries there is no proper fund from investor, lack of staff and there is disbelief that LSS is implemented only in the large scale industries. According to Mehdi's overview of LSS in developing countries (Mehdi, 2012) the implementation of LSS needs a excellent top-level management and concluded that in developing countries the CEO's were hesitant to invest on training its employees on the LSS tools. But, in

order to remain competitive in the market, training of employees is most important for successful LSS implementation.

There are enough number of research studies on the implementation of Lean and Six sigma separately, but very few on Lean six sigma as a single entity, mainly in the pharmaceutical manufacturing sector. Besides, comparing the Pharmaceutical manufacturing industries in a developed country like Ireland and a developing one, namely India, in the LSS perspective gives this thesis a unique position by being the first one to do so by dealing with the study gaps in the above-stated research articles.

#### 1.4 Significance of the study

This study helps every personnel in the pharmaceutical manufacturing department to understand each other's perspective towards LSS. Likewise, the top-level managers can understand the extent of knowledge the employees have and the entry-mid level employees can simultaneously get to know what are the benefits, challenges, facilitators and barriers in the LSS implementation.

This study and its results will be of great help to all the Pharmaceutical professionals, and researchers and, serve as an add on to the literature in the areas of LSS implementation in pharmaceutical manufacturing companies in India and Ireland. It helps to gain knowledge on elements, tools, way to implement LSS, identifying the critical success factors and the barriers. Also, it aids in finding out the areas that need further improvement and the areas that are performing well, which will ensure successful LSS implementation.

#### 1.5 Research Objective

The main aim of this research was to carry out a qualitative research on comparison between implementation methods and tools used in LSS in both India and Ireland.

**The macro level objectives were:**

- To compare the extent of LSS implementation and different tools used in India and Ireland.
- To compare the differences in LSS implementation and tools in Large Vs Small-medium sized pharmaceutical manufacturing sectors in India and Ireland.

**Micro level objectives:**

- To find out the factors which help in implementing the LSS.
- To identify the factors that deteriorate the LSS.
- To list out the possible solutions to the factors that pull back the improvement in LSS.

## 1.6 Structure of the research

The research has 5 chapter's, as shown below:

**Table 1: Research Chapters**

<b>Chapter 1</b>	<b>Introduction</b>
<b>Chapter 2</b>	<b>Literature Review</b>
<b>Chapter 3</b>	<b>Research Methodology</b> Method Selected: Qualitative method.
<b>Chapter 4</b>	<b>Results and Discussion</b> This chapter includes findings and summarizes the qualitative research and also includes discussion and interpretation of the results.
<b>Chapter 5</b>	<b>Conclusion</b> Includes conclusions, recommendations and limitations of the research wok.

## Chapter 2: Literature Review

### 2.1 Introduction:

This literature review aims to synthesize, organize and structure the stock of knowledge relating to lean and six-sigma implementation in Irish and Indian pharmaceutical industries. The primary focus of this review is on theoretical developments and empirical studies in the practice of lean six-sigma. The term “six-sigma” was coined by Bill Smith, an engineer at an American company named Motorola. This six-sigma concept was introduced in the year 1986, and just after 1 year of its introduction, Motorola was awarded the Malcolm Baldrige National Quality Award in the year 1988. Both Lean and Six Sigma have gained acceptance as industry-recognized business improvement methods and their popularity has grown significantly (Nonthaleerak and Hendry, 2006)

However, there is not enough literature review on LSS applications in the pharmaceutical industry when compared to other industries such as automobile, textile industry, etc. The Six Sigma approach is planned for accomplishing continued consumer loyalty through its persistent spotlight on client needs (Lande et al., 2016) Lean Six Sigma consolidates the standards of the lean venture and lean assembling with Six Sigma to improve execution and methodically evacuate waste. (Schroeder et al., 2008).

The literature review was performed utilizing different approaches such as common web search, searching secondary literature in the library, collecting related literature from the paper, peer reviewed scholarly journals, reading through articles, publications along with thesis, wide internet search. EBSCO database host and Google scholar had been searched to determine qualified grey literatures in July 2019. The hunt was restricted to publication dates, past 20 years, but there was no geographical and language limitation in the system of selection. Grey literature continues to be more specifically conceptualized in broad and narrow ways. (Luzi, 2000) conservatively defines it a document type produced at most government levels, academics and business in electronic and print form; they're protected by

intellectual property correct, that are to be looked after by library holdings. The following search terms have been used; Lean 6 Sigma in pharmaceutical industries, Lean 6 Sigma implementation, Facilitators & barriers of Lean 6 Sigma. The hunt was restricted to the very first 12 pages of results, as qualified papers have been identified as soon as the very first page but needed varieties of documents on the search phrase. The literature review's concentration and goal comprehend the LSS research which is performed, highlight the main improvements in the literature and in order to identify gaps where further analysis is needed.

In particular, 1,000 articles were collected from grey and written literature explaining the search words. The researcher analyzed these articles and tested their qualifications and relevance to the subject of the study. While interest in studies in the LSS field has risen over the last decade or so, the literature is low in terms of diversity and depth. It contains material in the literature Conceptual frameworks for implementation of the LSS.

A description of the following will be addressed in this chapter: Six Sigma, Lean Manufacturing, LSS Methods, LSS for Pharmaceutical Industry, LSS Implementation, Differences in LSS Implementation of India and Ireland and various tools used and LSS Implementation Facilitators and Barriers.

## 2.2 Six Sigma in Pharmaceutical Industry:

The latest analysis of William Hanna Al Kunsol (Alkunsol William Hanna et al., 2019) reveals that all factors in Lean Six Sigma have an Effect on the business of pharmaceutical manufactures price, with no additional time to process and wait. The defect had the highest impact, led by motion, inventory, transport, sustainable growth, over-production and unused ability, respectively.

It suggests that the pharmaceutical business has a lot to purchase from the six sigma. The six-sigma efficiency of pharmaceutical firms in the area of production and delivery of ideally appropriate drugs continues to increase on a regular basis (Noori and Latifi, 2018). This can be claimed that six Sigma was a set of systems

and strategies intended to solve challenges or to develop processes. (Weinstein, 2009) stated that six Sigma would also be used to increase efficiency and performance. Six sigma is helping to improve business processes and profitability in many industrial companies (Gutierrez et al., 2014).

Examples of pharmaceutical firms implementing six sigma include Eli Lilly, Johnson & Novartis and Johnson. While the pharmaceutical industry is heavily controlled to ensure that businesses conform with all regulatory authority requirements, many essential products are failing to reach current market and customer expectations, because new development takes years to be introduced. Today, current developments in the pharmaceutical sector are the ideal time to turn to six Sigma principles. Standard monitoring methods such as a map, a quarterly map and a Gantt chart have been used before, but this approach does not work with six sigma (Psychogios and Tsironis, 2012) This is not an effective method. Six Sigma is a continuous improvement methodology that uses the model to reduce defects. (Bicheno, 2004) Defines the study of quantities and increases power of DMAIC.

## 2.3 Introduction to lean methods

### What is lean?

Lean is a business improvement approach that centers around process improvement in new item advancement, assembling, and circulation so as to cut lead times, improve quality and client responsiveness, bringing about improved incomes, decreased speculation and costs. Spearheaded by Toyota during the 1950s and generally received across ventures, lean's targets incorporate utilizing less human exertion, less stock, less space and less time to deliver great items as proficiently and financially as could be expected under the circumstances while being exceptionally receptive to client request (Lawal et al., 2014). It is considered an essential attribute of a successful manufacturing endeavour. (Pearce and Pons, 2013).

The idea of lean administration was consistently resuscitated with the changing occasions and requirements of the business. With this dynamism in the industrial environment, various proponents of lean assembling made huge commitments in the field of lean management (Schrecker, 2016)

#### Lean in Manufacturing:

Taiichi Ohno, a Japanese engineer, proposed the need to create a more effective and profitable manufacturing system that would render it successful and in the Western world (Dahlgaard and Mi Dahlgaard-Park, 2006) with Lean Output. Lean management is a positive technique that, if taken fully into account, requires strategies and steps towards a framework that can contribute to improvements, particularly in the business sector (Papadopoulou and Özbayrak, 2005). Activities that use lean are often specifically defined as determinants, methods and strategies used to enhance the efficiency of an enterprise. Six Sigma's DMAIC methodology is supported by lean production with staff, clients and waste minimisation principles (Hamrol et al., 2019)

Many reports also discussed the objectives of Lean Manufacturing: to minimize processing times, to reduce inventories, to increase customer performance by increasing customer response time and to minimize or eliminate non-value - added steps, and to benchmark production efficiency.

Some analysts and journalists have split Lean output into six or seven components. However, various authors have identified various items; seven wastes have been identified by (Shingo and Dillon, 1989) while eight potential residues have been identified by (Weinstein, 2009) There have been different points of view on the types of waste: overproduction, waiting times, movement, over-processing, transport, defects and over-processing.

#### Lean applications in pharmaceutical industry:

Pharma companies continue to face challenges of globalization, complex supply chains and hyper-rivalry - all while interest for medications keeps on expanding.

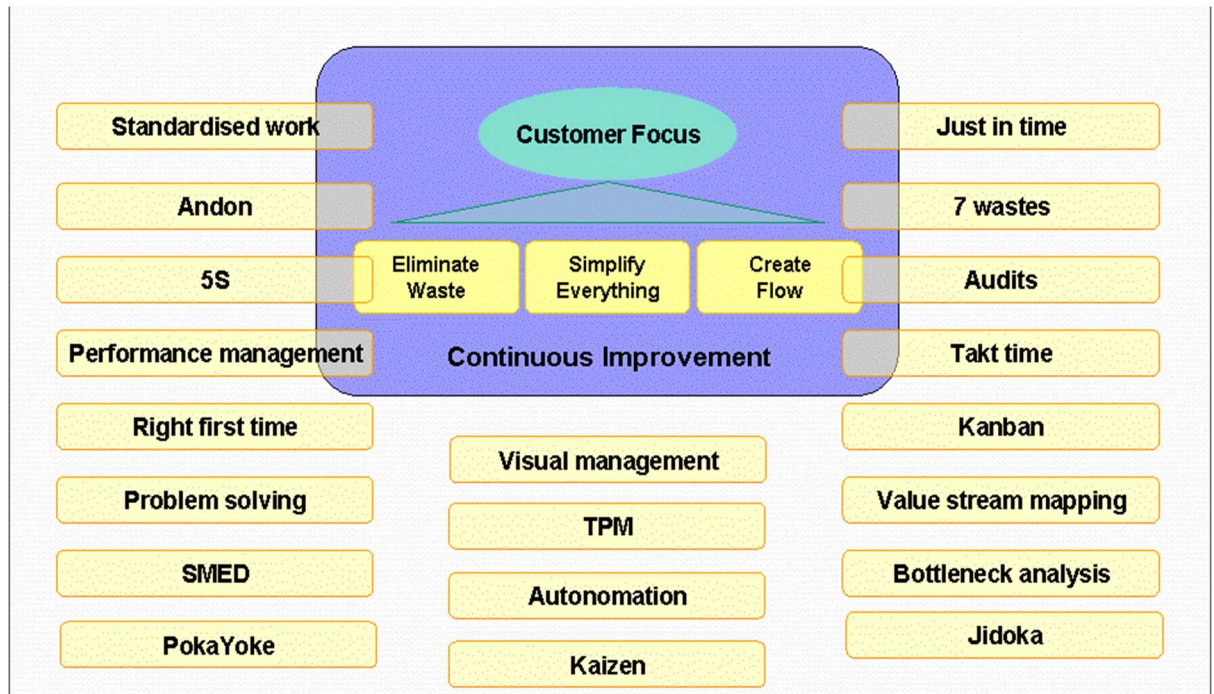
Subsequently, the need for greater throughput, higher quality and reduced costs has become a top priority.

In the course of the most recent two decades, lean projects have become a well-known way to deal with tending to these challenges in the pharmaceutical industry, as evidenced by the number of published case studies; conferences devoted to the topic and published articles. Unfortunately, the industry has seen minimal overall improvement in becoming more “lean,” as shown by the absence of improvement in inventory turns performance. Lately, execution over the industry has slacked that of the earlier decade with gains not seeming by all accounts to be sustainable due to a widespread lack of understanding of lean’s strategic value at the senior leadership level, and how it should be optimally applied. (Consulting, n.d.) The use of operational Lean tools is a minimum, but not sufficient condition for the development of Lean principles as a Lean infrastructure for which a culture of continuous improvement and Lean leadership are also necessary. Worldwide pharmaceutical organizations are acquiring manufacturing principles, which have long been used in other industries, to reduce the time and money it takes to release their products. Lean manufacturing is essentially evacuating non-value adding activities or waste from the production system. (Mostafa et al., 2013).

## 2.4 Tools of LSS:

Operational lean tools can be classified according to the five principles of Lean (Womack and Jones, 1996), also known as the VVFPP-model: 1) Customer value tools to evaluate what customers value, need and desire, 2) process mapping and root-cause analysis tools (RCT) to map and evaluate processes and analyze for improvements, 3) visual management tools (VMT) to communicate through visual signals instead of text or written instructions, 4) pull control tools (PCT) to control the flow of work by only releasing materials onto the work floor as the customer demands them, i.e. only when they are needed, and 5) Kaizen improvement tools (KIT) to facilitate continuous improvement (Lin et al., 2015). Visual management tools, for instance, are intended to make processes as simple as possible, resulting in higher

process improvement performance (Mostafa et al., 2013). Good housekeeping tools such as 5S are intended to develop productive standardized workplaces to reduce waste, increase efficiency and as a result decrease waiting times (Rivera and Chen, 2007).



**Figure 1:** Lean tools (Lean Tools, n.d.)

**5S:** This method guarantees consistent cleaning with increased performance. Enhancements of 5S Type (removing needless products) Glisten (to keep the workspace clean), to put things in order (to keep everything in place), to standardize and maintain (to ensure continuity) Standardized attempts to eliminate the surplus stock of first-line bosses. (Beger, 1997).

**Bottle neck Analysis:** The assessment of the neck of the bottle concerns the length of the process. You decide the biggest cycle by setting a limit. This assessment raises important concerns in the treatment of light-impaired systems. If the neck cycle of the bottle could be the efficiency and capacity would be increased. (Colin, 2017).

**JIT:** Just in time, with the correct amount, period and warranties Customer's optimum price of commodity to operate quicker (Plenert, 1997).

**The 5 Why's:** It is a tool for finding the root cause of problems utilized by organisations. DMAIC is also used as part of the process of study. The problem is written down and why the root cause is repeatedly identified (Gangidi, 2019).

**Kaizen:** It's a Japanese term that implies continuous development. It's a key lean tool (Beger, 1997). The aim is to involve and train all workers in operations and to lead them in their mission or to "continuous progress."

**FMEA:** Failure of modes and effects at the early stages of each item or process Companies may find and fix vulnerabilities by research (FMEA). FMEA was developed in the 1950s to analyze components, modules and subsystems for the purpose of determining the triggers and impacts of failure modes. FMEA employs Lean Six Sigma professionals to improve the efficiency of their systems, facilities and goods across barriers until they can be identified. (DEAR Cloud Inventory Management, 2019).

**Value stream mapping:** It represents the entire production process visually in order to eliminate all non-value - added activities, highlight value-added process activities and identify waste.

## 2.5 Methodology of LSS:

### Concept and Process of Six Sigma and Lean:

Concept of Lean and Six Sigma was brought up in order to give response against the demand in market share. (Jiju, 2019) comment that it deals with six principles that are as follows:

#### **Critical to quality:**

Customers use to examine the products quality along with its price in order to cater their own needs. It has been seen that enterprises have to understand recent

demands of their customers and needs before launching any product so that they can establish their business and product in a right way. However, additive features in product with reasonable price all time grab extra attention of customers about the product.

**Defect:**

When the products are delivered to customers in defective way, it hampers not only customers' contentment level but it also creates negative impact on organisation's identity. (He et al.,2017) opine that issues in delivery service or in manufacturing procedure eliminate products effectiveness and it creates hindrance on organisational business procedure.

**Process capability:**

(Formby and Dave, 2016) mention that marketing executives often takes feedback from the customers regarding their products in their trail phase in order to understand their products efficiency. Additionally, it is found that accurate products have to be delivered to customers as per their want. Customers want to get realistic products with systematic manner so that it can manage customers' wants.

**Variation:**

Different products of same organisation or same products from different organisations are thoroughly examined by customers so that they can get best service with reasonable price. Product variation it required to match customers' satisfaction and it guides the organisation to increase their recognition in recent merchandise community.

**Stable operations:**

Main goal of organisation is to conduct stable business procedure and robust processes in order to increase their customers' satisfaction level. He et al., (2017) state that implementation of secure stable reliable processes raises transparency in

business that improves service users' experience. However, it seen that customers' needs and trends are continuously changing in nature, due to which enterprise have to keep them updated about new features and digital technology factors to meet their customers demand.

## 2.6 Design for Lean Six Sigma:

Higher authority has to prepare design in such as way so that they can meet all essential needs or requirement of their customers along with capability of their procedure.

It has been noticed that this principle is implemented by the enterprises to minimise their non-desirable variations such as extra cost of production and it enhances product quality. Enhancement of service users' satisfaction is quite important in the business procedure so that the enterprise can execute their business in competitive market in a lucrative way. Using of statistical tools by digital technology changes mindset of entrepreneurs and therefore, it creates a positive impact on their workplace culture (Antony et al., 2016). Quality management tools such as TQM, Kaizen Events often guides the enterprise to get a vivid overview about their business structure. It also assists higher officials to examine external environment so that they can use right methodology to improve their business status.

The idea of "Six Sigma" was initiated as a reaction to lost piece of the overall industry which caused the organisation to understand that and increment in quality was important. Bill Smith, presents another quality control framework named Six Sigma. The usage was effective and after that the other pharmaceutical business ventures are trying to adopt this process for improving the overall business improvement. According to the report of The Governance Blog. (2017), Lean can be demonstrated as the process or approach of enhancement of the business operations that centres around process improvement in new item advancement, assembling, and circulation so as to cut lead times, improve quality and client responsiveness, bringing about improved incomes, decreased speculation and costs. With this dynamism in the industrial environment, various proponents of lean assembling made huge

commitments in the field of lean management. As per the statement of Sieckmann et al. (2018), the main motive of the “lean production” is to “intensify the relationship with the consumers”, “improve the market share of the company”, “increase the lead of the company in the market” and many more. There are five different stages of lean production are discussed below and all are equally essential for implementing or improving the business processes of the multination companies (Wagner et al. 2017).

### **Value**

It is one of the most essential as well as initial phase of the process of “lean production”. This stage is analysed based on the perspective of the consumers. According to the report of The Governance Blog. (2017), in this stage, two things or components are verified by the organisations such as value of the consumers and specific product that are offered by the company. At the time of offering any product the responsibility or the duty of the company is to check the demands of the consumers and based on that they should manufacture product. Consumer’s behavioural pattern is not static and the duty of the companies is to analyse and check the requirements of the consumers or client so that they can offer products.

### **Map**

It is the second essential phase and needs be analysed in a detailed manner so that the company can easily able to map the demands of the clients and the offered product of the company.



**Figure 2: Lean implementation stages**

(Source: The Governance Blog. 2017)

### **Flow**

Also, make the continuum of item development, administrations, and data from start to finish. Dispense with bunch testing. Thus, it is important to eliminate pointless stock development. In this stage the management and the statistical team of the companies are trying to make a state transition diagram or the path module diagram so that they can easily able to track their present status and the future status. According to the report of The Governance Blog. (2017), in addition to that, analysing the status in every stage is mandatory to check the progression status or graph or map of the company. If the company is able to meet the user's needs and as per the needs if the company is stated manufacturing products then the graph will increase in an exponential manner.

## **Pull**

As per the requirements or needs of the clients, and remove the requirement for sales assumptions. Consumers will not come towards any company so to grab the consumer's attention; the responsibility of the company is to analyse and offer products so that it assists the consumers in their daily life. Various techniques to advertise the products are also incorporated in this stage.

## **Perfection**

This process is the final stage of the "Lean Production" methodology. There is no such ultimate process of minimizing the overhead expenses, time of the project implementation and execution, others. According to the report of The Governance Blog. (2017), so at the time of executing all the stages, the responsibility of the companies is to make an optimised process which eliminates all the additional expenses, reduces the time of the project, meets the demands of the clients and many more. In this stage, the management of the firms are trying to make a simple and optimised structure of the process, leave a place for further improvement and change the design of the framework as per the situation or condition (Venugopal and Saleeshya, 2019).

### **2.7 LSS In Pharmaceutical Manufacturing:**

Lean Management is an intellectual approach that consists of a set of measures and procedures that, as a whole, have the potential to contribute to a lean and therefore particularly competitive situation within an organization. Lean Management is an intellectual approach Brand growth, manufacturing chains, shop floor management and, to a lesser extent, after-sales facilities are the primary areas of operation concerned. The multi-dimensional architecture of Lean Manufacturing, which is a source of extensive literature on the topic, may be implemented in multiple ways to put together various approaches. Since their rapid growth in pharmaceutical production, many businesses have opted for Lean Management to meet goals such as a decrease in the delivery time for products to be released on the market, a

decrease in technology waste, an improvement in communication with end-users and an increase in productivity, both in manufacturing and testing laboratories. (Nenni et al., 2014)

Effective usage of LSS in the pharmaceutical industry has led several businesses to have a right impact on their implementation in terms of rising excess production and waiting period. Both the efficiency of the facility, contact with customers and development are continually enhanced in the facility. (Reoskar and Pohekar, 2013). Although commitment was authorized, Katarina and Vojislav (2010) stated that, in order to encourage radical improvements, LSS ideologies are now being implemented in pharmaceutical and medical equipment. The LSS approach lowers costs and facilitates the manufacture of pharmaceutical or medical devices for scientific growth, thus promoting enforcement, by using the LSS theory to increase operational performance and consistency (Shaked, 2015).

The first step in accepting the Lean Six Sigma is to understand the need for change, regardless of its improved quality. Where non-value - added processes are regarded, the real cost of production is obvious (Lertwattanapongchai and William, 2014). According to Jiju (2015), there are several possible limitations, in particular the lack of availability of the data that is most required and that may create frustration if even a small part of an expensive and data-based approach is actually introduced. Several consultancy companies are reported to be controlled, even though it is obvious. That, despite alleging inaccurate or overrated consumer experience, they have no clear knowledge of the lean six sigma model programs and resources.

In the last few years, a few pharmaceutical firms have started to change Six Sigma to every process, time and expense. Due to the very complex procedure, it takes 12 months for the manufacturer to recognize and authenticate the packaging content. GSK decreases and improves the period time from 12 to 5 months using the LSS Method (GlaxoSmithKline, 2004). Savings are really significant. Types of healthcare firms who have embraced Six Sigma and Lean Methodology include Eli Lilly, Johnson & Johnson and Novartis (Stuckrath 2006).

Provides a systematic framework to the evaluation of clinical progress and functional change methods, completely interlinked procedures and compatibility with positive economic results, highly interlinked. (Deepak et al 2010).

## 2.8 LSS Implementation:

The introduction of Six Sigma and Lean focuses on role, policy, economy, ties, services, disciplines and implications, Schroeder et al. (2008) has been published.

Furterer, (2004) has mapped out the variables of the Lean Six Sigma execution that depend on its components. Six Sigma is a methodology that continually reduces minimum errors across a systematic method that meets user requirements and relies on the DMAIC estimation, analysis, enhancement and control (DMAIC) norm.

Such similarities indicate that LSS is a fresh solution to and effective application of the central effectiveness of public order (Zhang & Xu, 2008). Six Sigmas output variables, a true case study in factories and services, have disclosed the results of this research carried out by Alsmadi, Lehaney, and Khan (2012) and have shown that Six Sigma's minor implementations have applied primarily to the usage of classical devices, whereas modern technology and methods have been utilized less commonly. Effective adoption of the LSS will require committed leadership in a quality-driven organizational culture (Koning et al., 2008) Technical supportive system and teamwork (Psychogios & Tsironis, 2012).

Delgado et al. (2010) Work on the growth of Slovenia, concentrating on common challenges, complexities and severe issues with the application of Six Sigma. The variables were defined on the basis of the Six Sigma literature. The key criteria for the achievement of the six Sigma specification are "Six Sigma" and "Infrastructure," accompanied by the "Economic Transition.

## 2.9 Advantages of using Six Sigma and Lean in manufacturing industry:

Right usage of resources in the production areas often guides the enterprise to decrease extra cost on wastage and it also reduces garbage disposal issues. it

allows the organisation to produce quality products in front of their target customers so that their products can cater the basic needs and therefore, it enhances their identity in recent competitive community. Formby and Dave (2016) comment that adopting strategy like quality by design often brings innovative products in front of their target customers' and it creates a positive impact on their quality standards. It has been found that these six-sigma allows the modern enterprises to focus on continuous improvement along with excellence in order to increase their service users' satisfaction level. Furthermore, it guides the enterprise to focus on government regulations while making their business procedure in order to decrease the chance of governmental penalties and another chaotic attitude (Antony et al., 2016).

Here is the list of advantages that are associated with the lean production in the pharmaceutical industries.

## **Advantages**

### **Reduction of waste materials**

As per the report of Planettogether.com. (2020), it assists the management and the administrative departments of the business ventures are easily able to reduce the waste and improve their productivity. As the pharmaceutical organisations deals with huge budget and having big totals of "stock" and "waste", this technique takes out "obsolete or matured stock".

### **Improved association ship with the consumers**

In any business organisation, consumers always play a vital role and the minimum duty of the venture administration cells is to meet the user's needs. In this highly competitive market, there are many pharmaceutical companies so for lasting in the marketplace for a prolonged time duty of the companies is to meet the demands of the consumers and provide them with proper medicines so that they can secure their life from outer viruses and diseases. As per the report of Planettogether.com. (2020), rather than exclusively aiming on the necessities "everything being equal", "lean

spotlights predominantly on steadfast buyers”. So with the help of this statement, it can be stated that instead of focusing on the manufacture process, if the management started thinking of process diversification and meeting the needs of the consumers then it will help them to improve their business operations and overall revenue will also increases.

### **Lean infrastructure**

A lean framework incorporates the following sections: “building”, “instruments”, “supplies”, “gear”, and “work to satisfy close term stock interest”. On the other hand, here is the list of advantages that are associated with the lean production in the pharmaceutical industries.

#### **2.10 Facilitators in LSS:**

While globalization has opened up more markets unimagined, it has driven companies to remain competitive with its associated global competitiveness alongside scarce resources (Eirin et al. 2016). Industries have used LSS to help eliminate waste and improve effectiveness. To achieve this, they are using LSS. Although the implementation of six sigmas and Lean Manufacturing was widely acknowledged by key players in the industry, the need for a detailed study of the reasons for diminishing or hindering its efficacy was then recognized as a problem for researchers (Denton and Paddy, 1997; Jeyaraman and Teo, 2010). This segment discusses observations on the challenges and facilitators involved in the implementation of the LSS in line with the above. The word "facilitators" used here applies to variables that facilitate the introduction of the LSS. Any of the factors listed are as follows:

- Commitment to management
- Change adaptability
- Training
- True usage of tools and equipment

**Commitment to Management:**

LSS management commitment is one of the most important factors for LSS-influenced organizations. "Six Sigma is seen by some organizations as a forward-looking logistical direction that only adds to the cost, without significant financial benefits," said Raghunath and Jayathirtha (2013). It's hard to achieve its success. There are two areas where top-level LSS management assistance is needed. Firstly, the capacity and scope of Six Sigma requires a significant obligation on the organization. This requires support from senior management to address departmental barriers. Secondly any change in an organisation, either deliberately or merely because of conflict, will generate a form of opposition. If the government is behind this change, the resistance must be battled and defeated (6sigma, 2013).

**Change Adaptability:**

As stated earlier, any shift in an organization, either intentionally or simply out of disinterest, would encounter some kind of opposition. There has also been recognition of the adaptability of transition as a crucial consideration for the implementation of the LSS. "Change is usual and individuals need to be educated to make changes in order to stay afloat," notes Brian, Mohamad, and Chloe (2017). If not, they can lose significance during continuous transition. Nevertheless, despite its success, staff are expected to adapt to the change and not feel at risk from the LSS.

**Training:**

Most of others do not recognize LSS. Throughout this context, LSS is not known to be too complicated; training staff can address this in order to improve their knowledge of the program. The LSS is too complicated to do. Abdullah and Patrick (2016) state that training has been described as a key element in the effective adoption of the LSS in any organization.

### **True Usage of Tools and Equipment:**

Nethland (2015 ) claimed in the study that it established certain lean methods, such as 5s, Kaban, JIT, value stream mapping and troubleshooting and overall output maintenance, the independent usage of tools and practices that are inadequate to disseminate, that it allows the implementation of procedural instruments effective and necessary to disseminate lean values.

### **2.11 Barriers in LSS Implementation:**

Here, barriers are those that slow down or hinder the implementation of the LSS. While there is no universal consensus among scientists on the barriers to LSS, we established a range of important topics in this report. They will not, however, be consist of:

- Lack of resources
- Lack of training
- Towards Internal Resistance
- Society and Business
- Towards Bad Performance

### **Lack of resources:**

Finance is the key to the progress of LSS. Raghunath and Jayathirtha (2013), writing on its importance, have noticed that the Six Sigma initiative would consume loads of company money, such as financing, human resources, time, etc., in the light of their research into barriers to the adoption of Six Sigma by Small and Medium Enterprises. Unable to meet the financial criteria of the LSS, the LSS concept was underestimated during the implementation of the project. Stephen, Ann and Kevin (2009) argued that the challenges to the LSS were "mixed with heavy support" when they wrote about it. In the report. Jeyaraman and Teo (2010) argued as follows:

In order to make significant expenditure, the LSS needs the business. Curriculum materials, mathematical registration methods, Demand for support,

acknowledgment and other services Creation and conservation of Mythology. To make things easier the financial ability of the company is essential to the effective execution of the LSS. Boost the probability of an effective application of the LSS Managing.

### **Lack of Training:**

It is an autonomous approach to focus less on LSS training. This is important for the completion or loss of the initiative, both in terms of preparedness for the work ahead with the workers and the management. "The choice of less capable Black Belt employees was linked to the challenges of six sigma projects," Kumar and Kaushish (2014) found. In a related analysis, Raghunath and Jayathirtha (2013) noted that lack of preparation and coaching has been the greatest challenge to date for the adoption of Six Sigmas in small and medium-sized enterprises. The lack of training is associated with the lack of understanding of the requirements of the LSS. Writers, including (Raghunath and Jayathirtha 2013, Kumar and Kaushish 2014), emphasized the value of providing significant resources and time for training for the maximum benefit of LSS.

### **2.12 LSS In Ireland:**

According to (Antony et al., 2019) the results of the study found that the bulk of the drug error occurred at the administrative stage in Norwegian hospitals and that this stage would therefore be aimed at change. The study showed that Lean and Six Sigma were not used as full methodologies in the Norwegian health care setting, while PDCA was regarded as a common change technique. LSS is intended to be an important method that can be used to resolve medication problems and specific product mistakes. This is therefore a possible opportunity to improve LSS in the Norwegian healthcare sense as a tool for the elimination of these errors. In fact, the complexities and problems of LSS will be taken into consideration before beginning the LSS initiative for health professionals. The aim of the Lean and Six Sigma methodology and its methods and professional knowledge as well as preparation will be known by the leaders of the management team (including all professionals

participating in the opioid process). In turn, the facility will evaluate the aspects of preparation before beginning the LSS project and assess if the institution is equipped and implement the LSS.

According to (Laureani et al., 2013) Lean Six Sigma is also fairly early in the healthcare market compared to the usage of its output. Health care is now subject to lower budgets and reduced staffing, as well as increased activity in Ireland and many countries as a result of an aging population. Lean six sigma offers healthcare a chance not to try higher expenditures or additional money, not to reduce the number of programs or facilities, but to change the way the work is done.

According to (McSweeney and Moore, 2015) think at 'making something for fewer' in a innovative way. CSO has adopted a lean six-sigma approach to problem-solving in the face of a major downturn in human capital and demands for quality enhancement. -How and how we have implemented CSO-Examples of effective lean projects: how we have achieved this and the gains we have made in terms of cost savings and efficiency of quantitative progress-Examples of where lean projects have been concerned-leaning / implementing concerns regional statistical institutions, such as importing, should be identified.

According to (O'Reilly et al., 2017) The findings of the study identify three main practices in the Lean Six Sigma sector, namely the key role of experienced LSS experts who understand / adapt to the university environment; (ii) management commitment and development of resources through a cascading deployment plan; and (iii) the role of the LSS approach in methods.

According to (Wiele et al., 2010) Approximately half of the respondents use Six Sigma, as shown in the results. Such organizations are typically major U.S. international companies that have hired Six Sigma for at least three years. Diffusion occurs inside the company. Multinational firms are behaving in such a way as to extend the activity to the Irish division, to manufacturers and, eventually, to other local businesses by following Six Sigma at US headquarters. It also highlights,

however, the role of traditional dissemination mechanisms. In response to economic competition for cost-effectiveness factors, the company embraces Six Sigma.

According to (Orlando Silva, n.d.) The Lean and Six Sigma systems, which include multiple methodologies, are the key outcome of a cycle of improved efficiency and consistency that has emerged in a number of contexts and periods. Specific results were provided by the initial strategy for the conduct of isolated Kaizens in the fields, sectors and procedures, which led to the necessary change in the organizational culture to be introduced in the organization of the companies.

### 2.13 LSS In India:

According to (Karwande et al., 2018) In the pharmaceutical industry, Indian pharmaceutical producers merged R&D and medicament formulation to represent a balanced growth rate with the world's pharmaceutical MNC's. The most prevalent requirements in private companies were to improve service levels customer interest, expense savings and lead time with innovative product tests, raising human resources and strengthening the quality of work. All this is part of the low-cost generics churned out by a host of Indian pharmaceutical companies and intensified rush by a factor of competitiveness. As a consequence, the global pharmaceutical giants have concentrated on enhancing the efficiency of Indian product producers, adhering to GMP and satisfying market demand that has led to "operational excellence" in most firms. In R&D, engineering and production, much of the lean methodology, methods and product enhancements have been streamlined to conform to the contract requirements. 50 percent increase in cost-efficiency and productivity was reported by MNC pharmaceutical firms, 10 years and 57 percent by Indian-born pharmaceutical companies.

According to (Patel, n.d.) The vision of our Lean Six Sigma Team is that several organizations in India will follow six sigma DMAIC methodologies, because they realize what a big profit and program time difference. Moreover, this will create healthy competition between Indian companies. Of starters, once a company did something good to boost the productivity of other companies, it will also strive to

achieve better by encouraging employees. In addition, the founders of the companies seek to distinguish themselves from what had previously existed in the sectors.

According to (Zhang (corresponding et al., 2012) Lean 's six sigma work is at the first level. Lean Six Sigma has also proven valuable for drug or company concerns as well as for major or small businesses. It is quite useful for specific sectors with small changes as needed by the demand. Research on the SME sector to integrate Lean Six Sigma, on which financial efficiency is an obstacle, is suggested.

According to (Al-Shourah and Alzu'bi, 2018) Six Sigmas have been observed by humans for a long time, but their hunting is still early. The long history has relieved the concerns of researchers and expanded experimental involvement in a variety of different ways, as demonstrated by the new six Sigma articles. It is a real illusion, but it seems to be the feature of the empiric studies of Six Sigma. Six Sigma is often considered to be a rather useful drug. The popularity of Six Sigma, as evidenced from the growing series of articles on Six Sigma, has relaxed the fears of researchers in a variety of ways.

#### 2.14 Conceptual Framework:

I will be using the materials and studies identified in the literature review to identify the main differences in LSS implementation among India and Ireland. I will also find out what are the top barriers, benefits and facilitators in LSS implementation, By finding out the tools used in both the countries, I can also figure out which size of the industry among small, medium and large has a wide range of usage of the LSS tools, I will figure out the solutions for the factors that are causing deterioration of LSS.

#### 2.15 Literature Gap

At the time of executing the research, various journals and scholarly articles and publications are considered by the researcher and all are completely based on the theoretical aspects. As a result, the practical implementation of the research is not

shown in this literature or in this research. Besides, multiple gaps are also encountered by the researcher are “improper assumptions”, “current status of the external environment”, “insufficient time”, are also creating lots of hurdles in the literature which affects the quality of the research.

## Chapter 3: Research Methodology

### 3.1 Introduction

In this chapter we will discuss approach and research philosophy, design, Strategy, data collection, ethical research, data analysis method. According to Ahmed Ibrahim Nouri research defined as a practical way to address questions and test theories for generating new information or validating established knowledge. Quarantine measures or qualitative measures or both can answer questions of research. One of the benefits of the systematic analysis approach is to become informed of the research scope and the theoretical context in a particular field.

The methodology employed to coordinate this research will also be addressed in this chapter. The chapter discusses the way research data has been collected so as to obtain answers to the questions of study, research design, materials and methods used in the collection of data, data analysis, rationale of the methodology chosen, type of data analysis, and ethical concerns discussed during research.

### 3.2 Overview of Philosophy and Approach

According to Hari Lal Bhaskar philosophy in Lean six sigma is a scientific theory guided by systemic data focused on waste management, process variance reduction and consumer experience. (Bhaskar, 2020). He also describes Lean six sigma is a formal approach to solve problems and it is very important to have a comprehensive manufacturing analysis to understand each element of Lean Six Sigma.

The word philosophy of science applies to a set of beliefs and conclusions about knowledge creation. Even if this sounds pretty abstract, that is just what you do in research: build expertise of a particular domain. The advancement of information that you pursue may not be as drastic as a modern psychological philosophy of inspiration, but you also are gaining new awareness even while coping with a particular issue of a certain organisation. (Mark NK Saunders, n.d.)

Clarification of research philosophy is the starting point for research methods to be determined. There are few research philosophies Critical realism, Pragmatism, Interpretivisms, Positivism, and Postmodernism. (Mark NK Saunders, n.d.)

- Positivism is defined as research with a social reality that is understandable. It often requires theoretical analysis and consists primarily of testing an inference that has already been seen.
- Realism is described as performing science, in which the scientist accepts the facts as a fact, assuming that things are autonomous from the human mind. Realism is therefore primarily linked to objective methods of study.
- Pragmatism is characterized as research that can be carried out by one or more methods, and it is research itself that is the most important, not research philosophy.
- Interpretivism refers to practice in which proof is acknowledged by the researcher through review. Many of the assumptions come from his or her own interpretation and point of view. Therefore, this type of work may be defined as autonomous. Interpretation relies primarily on the contextual expertise of the analysis.

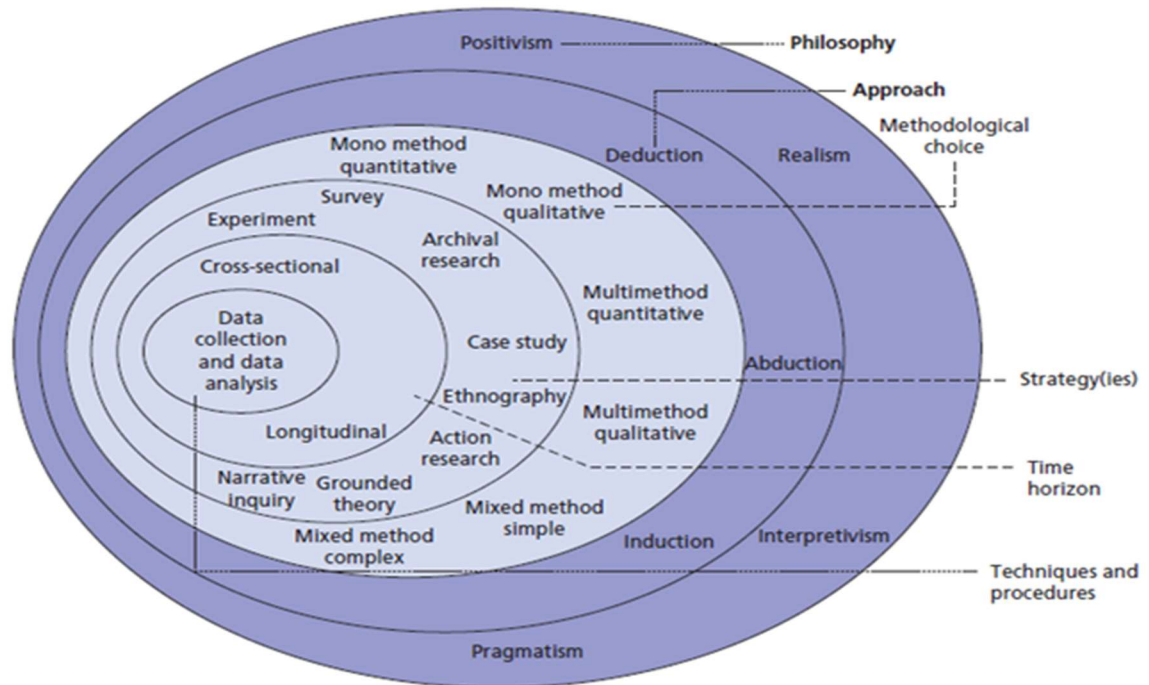


Figure 3: Research philosophy (Research philosophy, n.d.)

From above diagram the outer most layers are positivism philosophy which plays major role. This research thesis will follow the Interpretivisms philosophy. In which small sample size, depth of content and quality of content will be playing major role. The research depends on the expertise and technical awareness of the researcher's definition. The topic matter of the research will also be examined on the basis of the opinions of the respondents and the perception of the obstacles and facilities of the LSS that have been implemented within the pharmaceutical industry and the analysis submitted to the recommendations and viewpoints of the participants. The philosophy of interpretivism helps this research to accomplish its objectives.

### 3.3 Research approaches:

According to Ketokivi and Mantere there are three research approaches which are Abductive, Inductive, and Deductive approaches.

- Deductive Approach: A hypothesis has already been developed that needs to be tested in the analysis. This starts with a theory that can be proven or rejected after the study. It goes from the general to the individual.
- Inductive Approach: Only at the conclusion and generalizing from specific to general is the hypothesis determined.
- Abductive approach: The Abductive Research Approach addresses incomplete observations or unknown facts. Methodology of research the Abductive Method generalizes the relationship between the general and the person.

The approach to this research is an inductive that allows articulating the theory. The research would begin with a questionnaire with a group of pharmaceutical industry staff in Ireland and India on their understanding of the challenges and LSS facilitators in order to analyse the data gathered define trends and use the results of the data review to formulate a hypothesis. This method uses research questionnaires to understand the scope of study.

### 3.4 Research Design:

The manner in which a study proposal is designed as research issues and priorities is called research design, which is a detailed framework about how questions posed during analysis will be addressed and the data sources involved. According to Kothari research architecture, the requirements for data collection and review are structured to combine process economy with study relevance. (Kothari, n.d.).

This thesis used an inductive methodological method for analysis. Quantitative and qualitative are the two common forms of analysis concepts. According to Creswell 2009 Quantitative data are typically used for gathering questionnaires or reports, which exist in different graphical type which measurements. By comparison, qualitative analysis also involves, with few and detailed surveys, analytical questions, findings, and focus groups and is typically correlated with interpretative theory. (Young and Babchuk, n.d.).

A qualitative method has been selected to gain in-depth information and perspective into the participants' point of view about the LSS facilitators and challenges they have encountered throughout their organisation, and it is the strongest strategy for identifying and discussing what people ascribe as a human issue.

The essence of the data collected during the investigation may be explanatory, descriptive, evaluative exploratory or combination of both. (Mark NK Saunders, n.d.).

Data from this research will illustrate the question of exploratory research and the study questions discuss the subject in differing degrees of scope. It is simply intended to explore research issues and will not offer final and conclusive solutions to current issues. Typically, this form of work is conducted to study an undisclosed issue. Exploratory analysis is carried out to determine the nature of the issue and not to include conclusive information. It makes it simpler for us to understand the problem. The exploratory research architecture does not seek to give definitive and definite answers to the research questions, but instead examines the research subject with varying degrees of depth. 'Exploratory work is the initial study and the foundation for more definitive work. It has been noted that the architecture of the study, the measurement technique and the data collection process can also be calculated.

The research explorer selected and used by the researcher will involve the use of surveys by employees of pharmaceutical companies, knowledgeable and expert in the field of LSS, which will provide researchers with a better understanding of the barriers and facilitate the implementation of LSS by Irish and Indian Pharmaceutical Companies.

### 3.5 Research Strategy:

The overall plan for performing a research project is a research approach that directs researchers to prepare, execute and track the analysis. Analysis approaches inform the researcher how, through interviews, questionnaires or mathematical techniques, to gather and analyze data instances. The study approach priorities are influenced

by research aims and questions which are often related to the theory chosen.(Saunders et al., 2009). He also says that we must point out that there is no inherently higher or lower research strategy than any other and the most important aspect, therefore, is not the mark attached to the plan, but that this will help you to address your questions and achieve your goals. Your choice of research strategy will be based on your research questions and objectives, the extent of existing knowledge, the time and other resources you have and your own philosophy (Saunders et al., 2009).

It may be an entity, community, person or method of study. Case studies can provide information and are used when they exist in day-to-day activities. This analysis technique is primarily used by interpreters but also by positivists; the data collection approach may include focus questionnaires, thoughts and different types of findings for case studies according to (Saunders et al., 2009) Multiple cases can involve case study research strategy and case Study Approach will provide insight into analysis and improve applicable analysis Awareness of the study of a term that could be an entity, process or event, usually in the real-life context.

Although there are various styles of testing approaches, the researcher's methodology is a case study; this is mainly related to interpretative reasoning and inductive logic. This research topic examines and compares the extent of LSS implementation and different tools used in India and Ireland. It is the best path to the field of research, gathers in-depth knowledge on LSS implementation, different tools used in small- and large-scale industries, and collects data through the questionnaires survey. Various employees at various pharmaceutical firms in India and Ireland should provide their personnel knowledge, providing the study subject of several case studies.

### 3.6 Recruitment:

Recruitment has been taken over 4 weeks from 20 Feb 2020 to 20 March 2020. In this research researcher used questionnaires were sent through LinkedIn and emails to employees of different pharmaceutical companies in India and Ireland. Remind

emails were sent to few of them after 5days as a follow procedure. 25 employees from different pharmaceutical and biopharmaceutical manufacturing companies from India and Ireland were contacted from them 17 were responded and from those 17 11 filled the questionnaire. The researcher sent Emails and messages to participants which contains the details of study as seen in appendix A.

### 3.7 Sampling:

According to (Fisher and To, 2012) the aim of Sampling is to pick a subset of people from the population to achieve results that represent the characteristics of the population as a whole and Numerous types of uncommon samples are usable, including limitations, simplicity, purpose and snowball sampling. The purposeful sampling was used for this study. When selecting the unit to be tested, selective selection focuses on the researcher's discretion and the key objective is to focus on a particular community of concern that responds better to the study.

For this research different pharmaceutical and biopharmaceutical manufacturing companies from India and Ireland were selected purposive sample (11) of employees have knowledge on Lean Six Sigma utilization and different tools used in their industry were selected and participated in questionnaires filling. Out of 25 people 17 were responded and 11 were filled the questionnaire through emails and LinkedIn. Among 11 participants 6 of them were from Ireland and 5 of them were from India. Among them 3 were directors of the company remaining were supervisors, interns, technicians, Quality analyst and head of formulations.

### 3.8 Role of the Researcher:

According to(Saunders et al., 2009) this study has taken on the role of an external study in which a full-time student is expected to perform. The researcher described the pharmaceutical company as the environment in which the work is carried out and the agreed access of the workers. A qualitative and quantitative questionnaire survey is the approach chosen by the researcher for which a set of question has been developed as shown in Appendix A.

The subject guide was intended to perform the study properly, which was reviewed and accepted by the supervisor. In order to achieve entry, the researcher adopted the following methods and carried out the study.

- When touch was made, the investigator told him / her that he / she knew the pharmaceutical firms.
- A detailed justification was given for the reasons for the inquiry and the form of access needed, as set out in Appendix A.
- All points and opinions of the Participant have been noted.

### 3.9 Ethical Issues:

The legal issues that occur with data protection about the identity of personnel are examined only with the data produced by the employees. There will be no declaration or holding with any identifying characteristics, such as place, association, sex, role, etc. In training, the participants explained what is required of the study with comprehensive questionnaire explanations. Both participants will be presented with an informed consent form and the questionnaire will be completed.

### 3.10 Conclusion:

This chapter presents the methodology used by the scientist to respond to the research issue of the LSS application and the various tools used by pharma and biotechnology manufacturing companies in India and Ireland.

This chapter describes the steps taken to conclude this project and the conclusions are discussed in the next chapter.

## Chapter 4: Findings and Discussion

### 4.2 Overview

This section of results and discussion, includes the analysis of the data obtained from the research surveys. Both the inductive and deductive approaches were followed to achieve its desired aim. The analysis is done using Microsoft excel and google docs in the end with the help of constructivist thinking. The main aim of the study was to compare the extent of the LSS implementation and tools in Small-Medium Vs Large scale pharmaceutical manufacturing industries across India and Ireland.

A cross- sectional analysis was done on the results, for this analysis the questionnaire of 23 questions was grouped into 4 subcategories namely,

- i. Demographics and Personal information: This section includes the information obtained from questions 1, 5, 6, 7, 8 and 13. Areas covered as per these questions were demographics, their present role, number of years of experience, size of their industry, similar role experience in India/ Ireland and years of experience with LSS.
- ii. Knowledge on LSS: It includes the questions 2 and 12 which analyze the person's knowledge and their certification in LSS.
- iii. LSS Implementation in the industry: This section has got questions 3, 4, 14, 15 and 16. It briefs about scope of LSS implementation in the participant's organization, tools being used and their recommendations on additional tools to be used by their organization.
- iv. Opinions: This section is huge and remains crucial in analyzing the results. Questions 9, 10, 11, 17, 18, 19, 21, 21, 22 and 23 belong to opinions. It gathers the opinions from the participant about the success factors/ facilitators, barriers,

benefits of LSS, their level of agreement about cultural impact and benefits that LSS has done to their organization.

#### 4.1 Research Findings and Discussion

(Shah et al., 2008) conducted a research on implementation patterns and had two outputs, they were: The first move is to increase the possibility of adopting Six Sigma by introducing some technique from a larger range of Lean method. Moreover, practices frequently combined under quality management predict and differentiate the Six Sigma group of plants from those not implemented. Second, the results of regression show a considerable difference in the Six Sigma implementer group's performance compared to the non-implementer group.

Another studied which got hugely benefited from the LSS was a case study at Indian Auto Ancillary Conglomerate at which different phases of the studies, the LSS toolbox data analyzes identified and validated the root causes of the problem. Using the LSS methodology, drilling errors were reduced during injection molding and defects per million opportunities were reduced from 38,000 to 5600. The application of this methodology had a significant financial impact (a saving of about INR 1.4 million per year) on the bottom line of the company.(Gijo et al., 2018)

##### i. Country wise participants:

The main aim of this research was the comparison of LSS implementation in India and Ireland. Hence, the participants were selected from both the countries. The country wise representation of the participants is shown in the **Figure 4**, which shows 5 people were from India and 6 were from Ireland, which is nearly equal. There are few studies which create comparison between two countries, (Lee et al., 2013) compared South Korea and UK in terms of LSS implementation status and other factors which are related to adoption of LSS and concluded that UK was 3 times ahead of South Korea in LSS implementation. Another study (Ahmad et al., 2017) conducted a comparison between Japanese and Malaysian automotive

service centers practicing Lean and researched that Malaysian automotive services couldn't compete with Japanese centers.

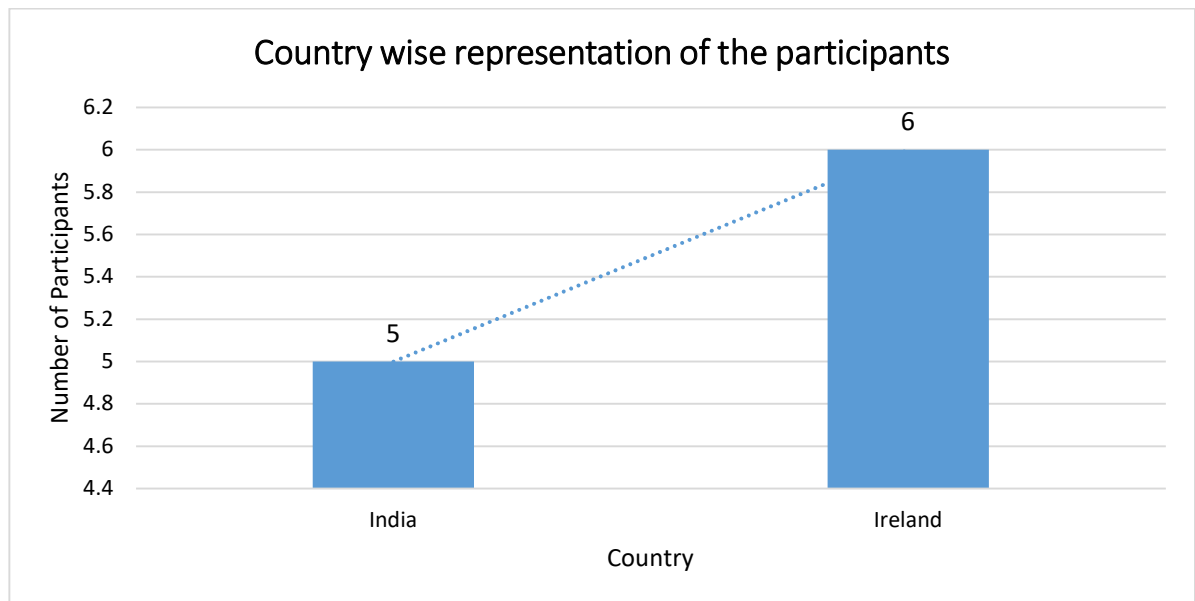


Figure 4: Country wise distribution of the participants

ii. Knowledge on LSS:

For choosing the population for the study, it is always important that the participants have basic knowledge on the area of research in which they are participating. Likewise, the question “are you aware of LSS?” filters the study population. In this research, testing the knowledge on LSS is a binary question with YES/NO options, and this was their last question if the participant answers NO. Hence, there was a participant who answered it NO, and the filtered sample size for further research was 10 as shown in the **Figure 5**.

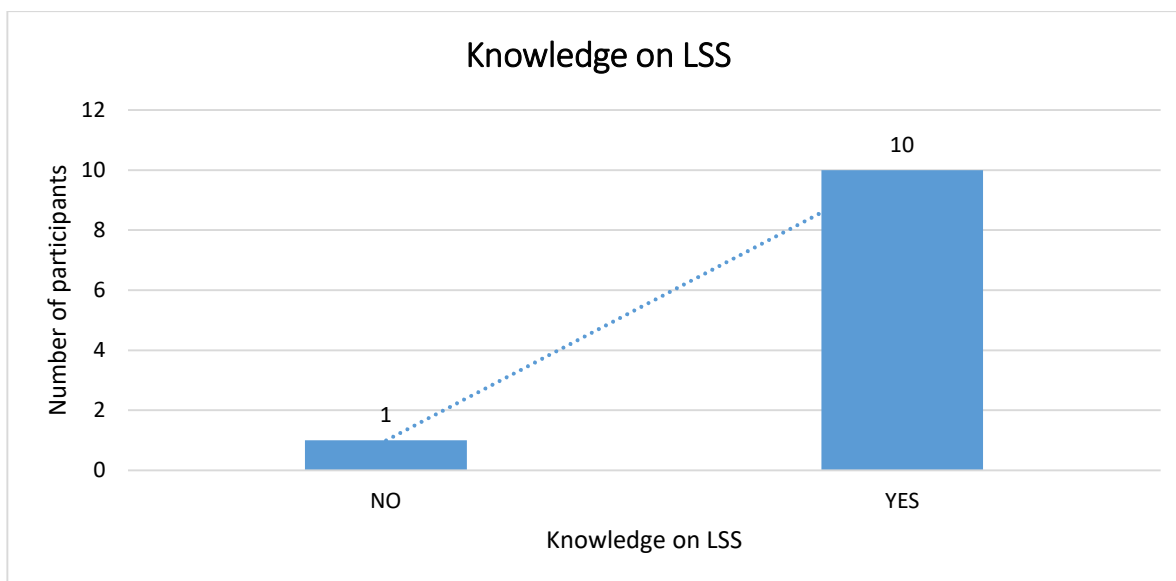


Figure 5: Knowledge on LSS

iii. The Designations of the participants:

This research includes participants from pharmaceutical and biopharmaceutical manufacturing industries and includes the designations from entry level to senior most director level. The designations of participants were:

Table 2: Designations of the participants

Designations
Head of Formulation and Process R&D
Director
Technician
Head of formulations
Supervisor
Intern

Director
Director of Quality
Manufacturing
Quality assurance associate

iv. Level of experience:

These participants have different levels of experience, as shown in **Figure 6**. In our study the highest number of participants belonged to the entry-mid entry level group, followed by the senior level.

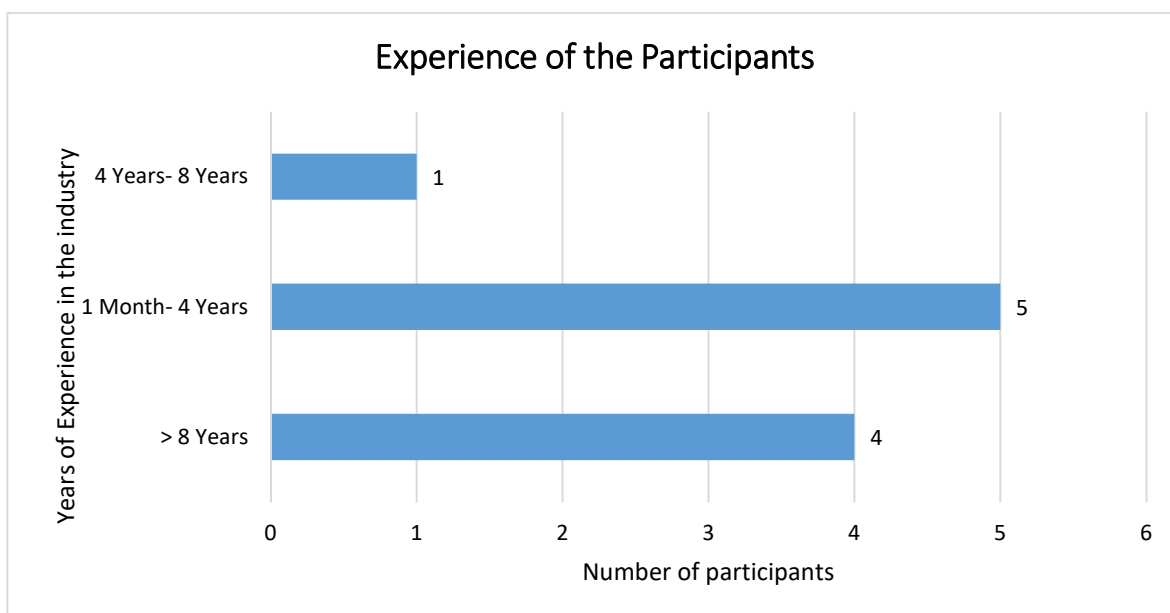


Figure 6: Experience of the participants

v. Experience with LSS:

And as in **Figure 7** total population 40% of them had 3-7 years of experience working with LSS, followed by 30% population each in >7 years and 1-3 years of experience.

#### Experience working with LSS methods/ tools

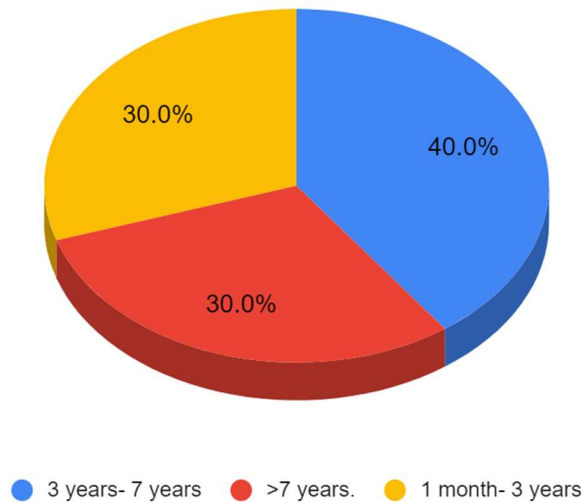


Figure 7: Experience working with LSS

#### vi. Size of the organization:

One way of estimating the size of the industry is by the number of employees, in our study **Figure 8** we classified the industry size into 3:

- a. Small industry: 10 to 50 employees
- b. Medium industry: 51-500 employees
- c. Large industry: >500 employees

The maximum number of employees in this study were equal in number in both Medium and Large-scale industries. And the minimum was recorded with small scale industry. In comparison among India and Ireland, the complete data of small-scale industry belonged to Ireland, none were reported in India. India has the maximum count of large industries, followed by medium scale industries, were as Ireland has the highest number of medium scale industries. In a study (Banik, 2017), it was concluded that small scale industries (SSI) were important in development of the Indian economy and also helps in economic sustainability. For this sector of small-

medium industries, it is very essential for the government in providing them with financial assistance and resources in order to maintain a stable economy.

(Anandakrishna and V, 2013a) conducted a research study among small and medium enterprises to find out the barriers in implementation of the six- sigma, and hypothesized that Six-sigma was hugely confined to large scale industries with more resources, and also added that the same methodology can be equally followed by SME's in acquiring its bottom line benefits, In order that these SME's need to get educated regarding these methods, they must firstly overcome the barriers and begin to focus on the benefits of Six-sigma.

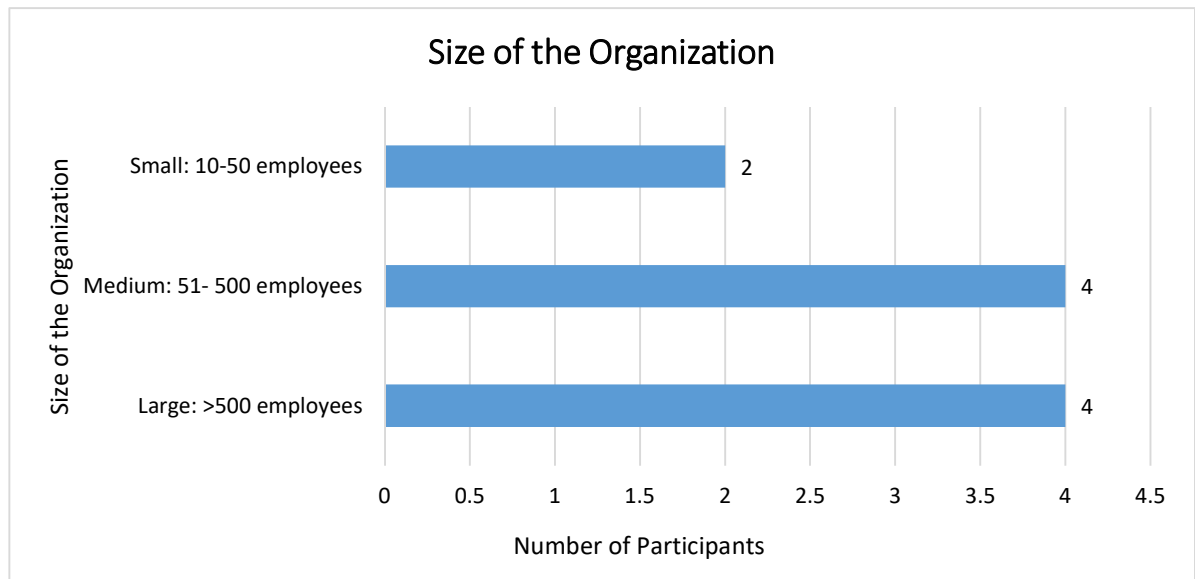


Figure 8: Size of the Organization

vii. Extent of LSS implementation in the organization:

There are enough number of studies which aim at larger industries and a very limited research is present on SME's (small and medium enterprises). (Alkhoraif et al., 2019) has conducted a systematic review on SME's and their critical success factors and added that his literature can serve as guide for SME owners and managers.

The idea of finding out the extent of LSS implementation in this study comes from the literature gap created between number of studies on Larger and SME's. This

scope of implementation of LSS in an organization was classified into four in our study:

- a. LSS is followed throughout the organization.
- b. Only few departments follow LSS.
- c. Only in the participants department
- d. No implementation of LSS in the industry.

As per the results, the option “B” “only few departments” stand at the highest at 37.5%, followed by “entire industry practices LSS” and “No LSS at the organization” equally as in **Figure 9**. The scope and extent of implementation of LSS varies among the countries, as in **Figure 10**. In the data received, India has the highest percentage saying LSS is implemented throughout the organization followed by few departments and no implementation. In contrary, In Ireland LSS was practiced in “only few departments” and “only in participant’s department” equally.

Another study from west Ireland (Iyede et al., 2018) found out that LSS is still unknown in few SME’s, whereas large scale industries have adopted it fully. In a study by (Antony et al., 2005) the findings were that many SME’s were not aware of the six sigma and in addition do not have enough resources to start a project. He added that six sigma was not so popular in these SME’s. A pivot table **Table 3** was created using extent of implementation in the organization, size of the organization and the country (India/ Ireland).

Row Labels
[-] India
[-] Few departments only
Large: >500 employees
Medium: 51- 500 employees
[-] Implemented in the entire organization
Large: >500 employees
[-] Ireland
[-] Few departments only
Medium: 51- 500 employees
[-] Implemented in the entire organization
Large: >500 employees
[-] No implementation at all
Small: 10-50 employees
[-] Only in your department
Small: 10-50 employees
<b>Grand Total</b>

Table 3: Pivot Chart between Size of the Organization, extent of LSS implemented in the organization and the Countries.

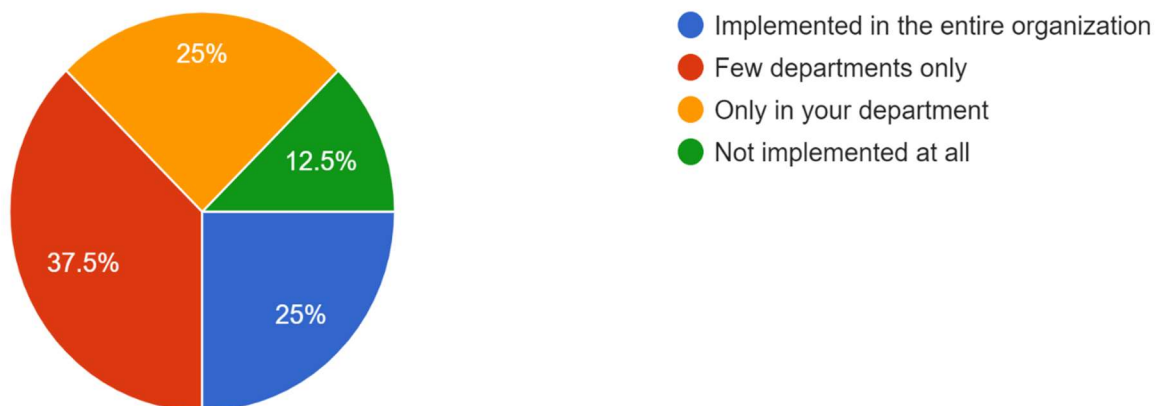


Figure 9: Extent of overall LSS implementation.

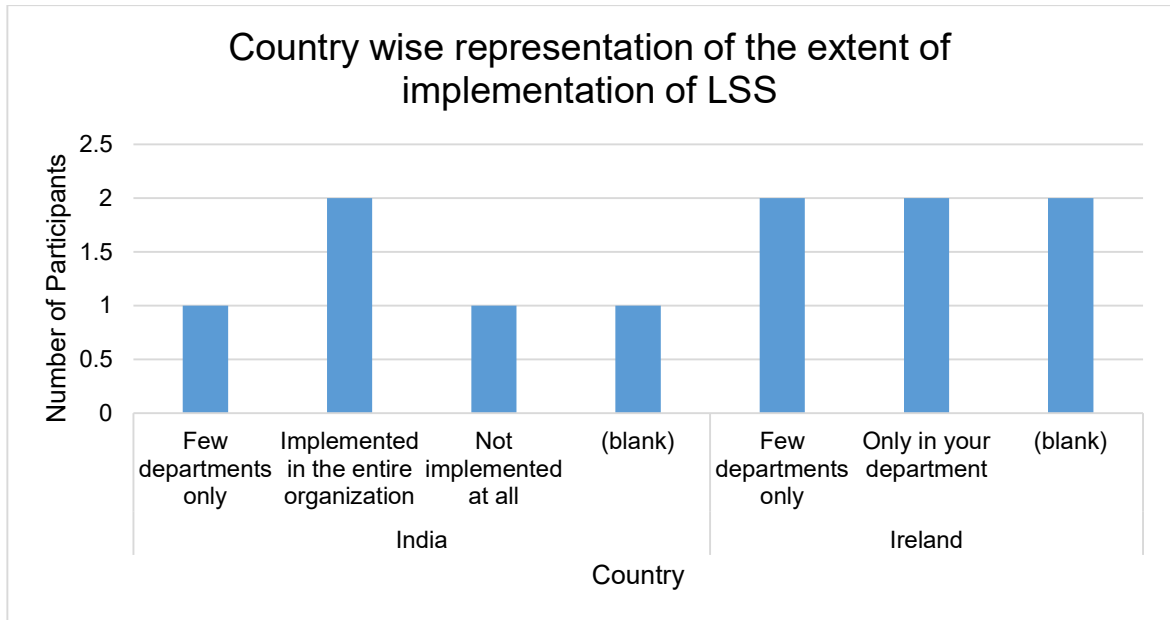


Figure 10: Extent of LSS implementation in the organization in each country

#### viii. Reasons for lack of LSS implementation:

For the organizations, in which the LSS is partially implemented or not implemented at all, the reasons for not implementing the LSS were answered as:

- May be lack of facilities or time,
- Time & resources deficits,
- Depends on applicability- where ever it is necessary it is implemented.

#### ix. Comparison of experience between the India and Ireland:

For this research the comparison between India and Ireland remain crucial, one being the developed and the other as a developing country. The participants who have got experience in both the countries serve as asset to the research, their self-experienced differences among the countries were reported. As in **figure 11**, 20% of the research population, i.e.; 2 participants have got experience in both the countries.

From the responses of participants who have an additional experience in the second country India/Ireland, the major differences between both of the countries were:

**Participant 1:** there isn't huge corporate culture gap, but surely there are national culture differences, India is under vigorous development unlike last century in terms of pharma sector, the small-scale industries may not be able to enough funds and resources from the government in India, unlike Ireland.

**Participant 2:** State of the industry. Levels of maturity. Corporate culture

Cultural differences and ownership of the activity was assumed to be the difference by another participant who had no exposure in the second country.

In developing nations like brasil, (Scheller et al., 2018) a research study carried out found that the lean and six sigma were carried out and practiced as separate methods instead of one, and also added that there are many critical factors and failure factors that influence the implementation of both the individual approaches like training and changes in the organization.

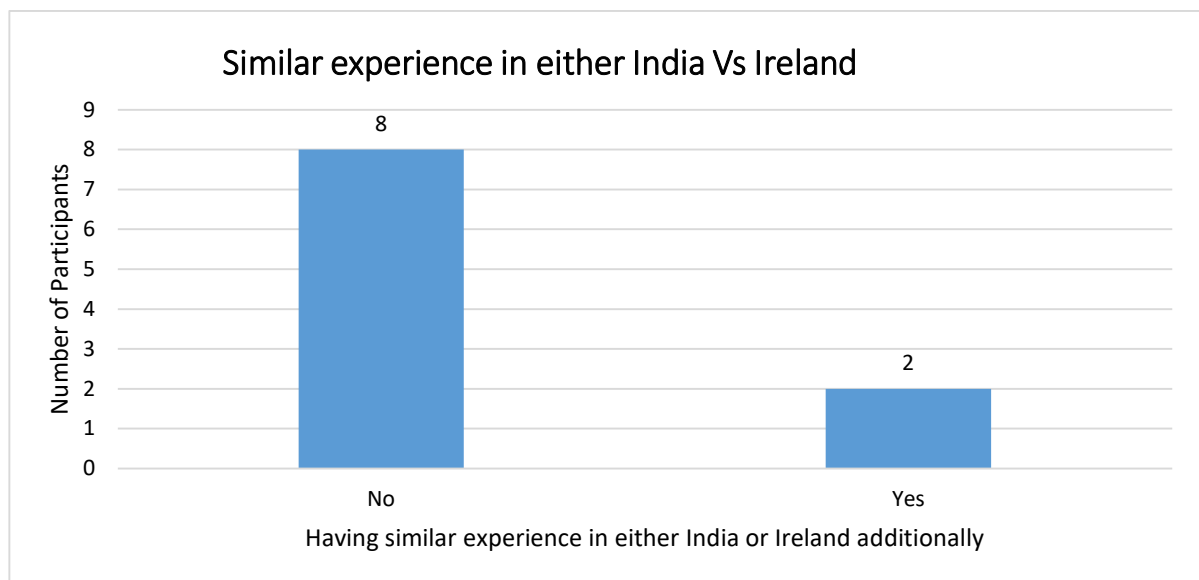


Figure 11: Number of participants having experience in both India and Ireland.

x.      Impact of culture in LSS implementation:

The results in a study by (Jacobs, 2015) have shown that few national culture factors like Orientation of the performance and Gender Egalitarianism, can have an huge impact on success of lean management and also helps to maintain a healthy lean culture. In our study, 50% of the study population have agreed that national culture has an impact for successful implementation of LSS, whereas 40% have strongly agreed and 10% has neutral opinion as shown in the **Figure 12**.

Apart from the general discussion on national cultural differences, agreement on the national or corporate or organizational cultural differences between both of these countries, causing differences in implementation of LSS is 60% strongly agreed followed by 40% of agreed population, with no other mixed opinion as in **Figure 13** In the same study as above (Jacobs, 2015) concluded that some cultural factors in an individual perspective, uncertainty avoidance, orientation in the future and the institutional collectivism supports and helps to overcome the human and cultural barriers.

Similarly in a paper (Alkhoraif and McLaughlin, 2016) mentioned that few philosophers have said that culture is primarily defined by language, but corporations do not have one. And also added that in spite of living in a globalized world, the business's operation is largely influenced by national and local culture.

(Dahlggaard and Mi Dahlggaard-Park, 2006) concluded that lean and six sigma has much focus on training in the tools and techniques and less on getting to know the human factor, i.e.; building of the right company corporate culture.

Agreement that national culture has impact in successful implementation of LSS

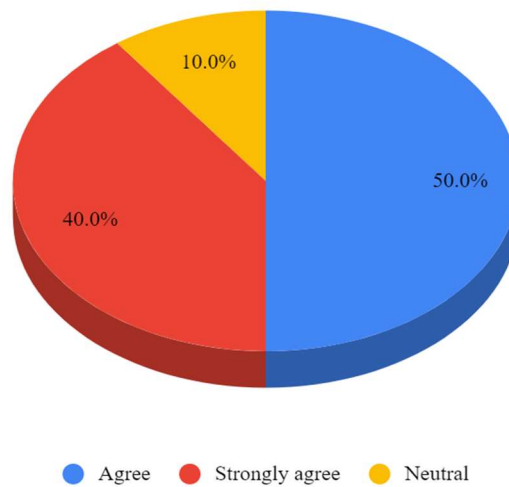


Figure 12: Agreement of national culture's impact on successful LSS implementation.

Agreement that cultural differences between India and Ireland causes differences in the implementation of LSS.

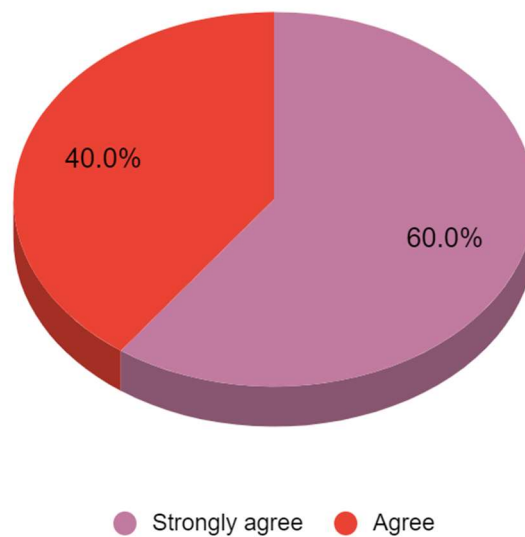


Figure 13: Agreement on cultural differences between India and Ireland cause difference in the way of LSS implementation.

xi. LSS certification:

Among the participants, 60% were not LSS certified, 20% were Master black belt holders and 10% each for black belt and yellow belt as shown in the **Figure 14**.

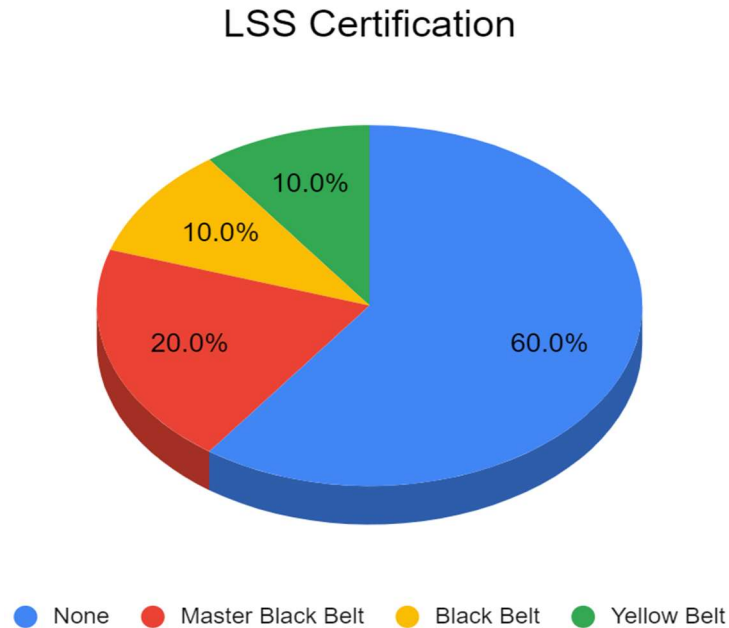


Figure 14: Participants holding LSS certification

xii. Comparison of LSS implementation and its tools used in India and Ireland.

The macro objective of comparison between both the countries in terms of LSS tools is explained in **Figure 15** which clearly shows the country wise usage of tools. The most commonly used tool in both the countries were FMEA followed by process map. Ridge cost analysis was reported by none.

In India the root cause analysis, FMEA and fish bone were widely used, whereas value stream mapping, ridge cost analysis and 8 types of waste were the hardly used tools. But in Ireland, the process map and FMEA were the highly used tools and the least used one was ridge cost analysis. The applicability of the tools is always dependent on the circumstances of the industries and may vary from time to time.

But comparatively Ireland has shown advancement in usage of more tools than India.

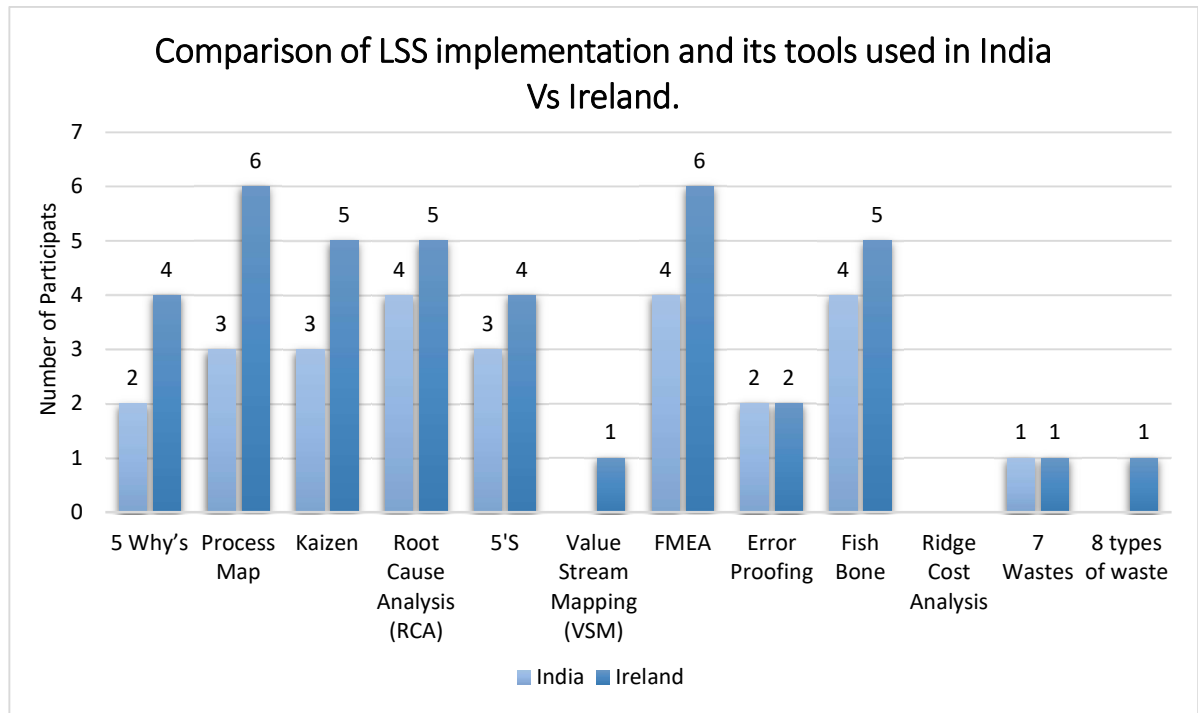


Figure 15: Comparison of LSS implementation and its tools used in India Vs Ireland.

Among the 11 participants, no small-scale industry employees were reported in India, when the usage of tools were separately plotted in the graph as in **figure 16**, based on the size of the industry, more tools were used in the large-scale industries when compared to the medium scale industries. Fish bone, FMEA, Root cause analysis and process map were used widely by the large-scale industries. Process map was confined to large scale industries only in this research.

8 types of waste, Ridge cost analysis, Value stream mapping weren't used by any of these industries. (Kumar et al., 2006) has reported a case study from Indian SME in which lean tools like current state map, 5s methods, TPM along with six sigma

DMAIC methodologies were used to increase the bottom-line results and customers compliance.

(Desai et al., 2012) found out that the CSF's and tools were almost same for differently sized industries in India.

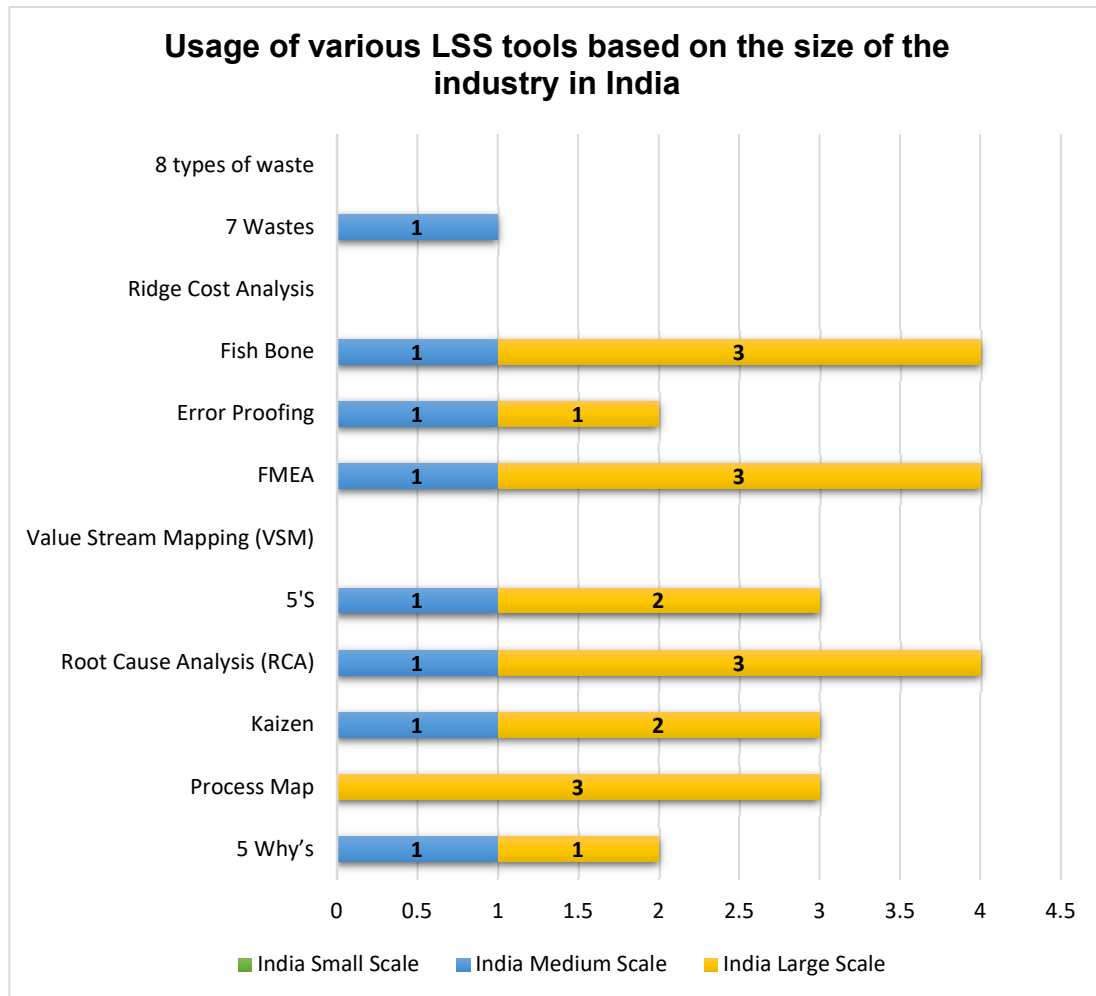


Figure 16: Usage of various LSS tools based on the size of the industry in India

In Ireland, the medium scale industries were ahead in usage of more tools when compared to large- and small-scale industries. Fish bone, FMEA, RCA, Kaizen, Process map were the tools spread over large scale industry. Unlike India, process map was even reported in small and medium sized industries. There were ample

small-scale industries reported and were using FMEA, Kaizen and Process map as in **figure 17**.

(Laureani et al., 2013) conducted a study on tools used in Irish hospitals and reported that process mapping, seven wastes, 5S and logic tree/root cause were mostly used. The other studies used were control charts, checklists and theory of constraints.

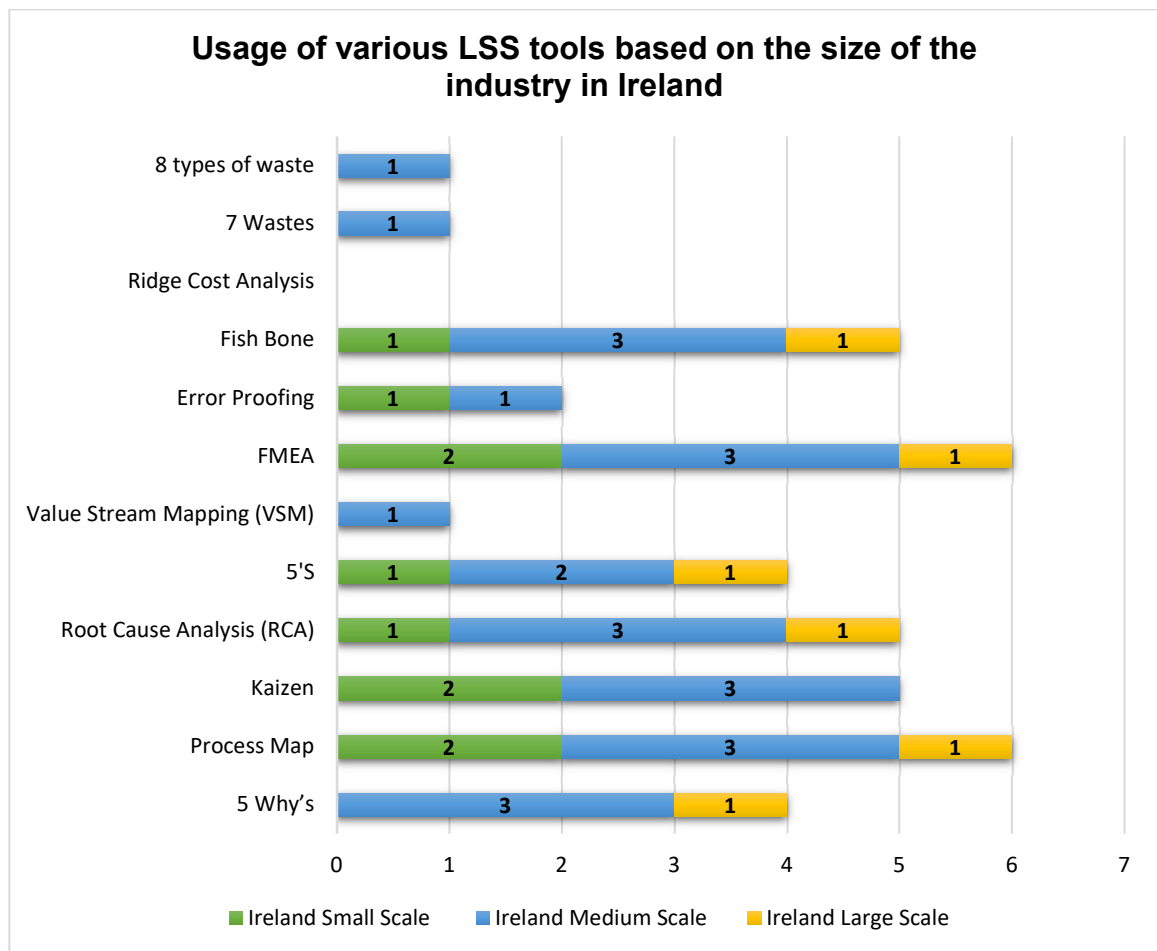


Figure 17: Usage of various LSS tools based on the size of the industry in Ireland

Comparing the same size industries in both the countries as in **figure 18**, small scale and medium scale industries in Ireland were more prominent than small scale and medium scale industries in India respectively. Large sized one's were more in India

than in Ireland. Overall, in the 6 types of industries as in the graph below, majority of the tools were successfully implemented in the medium sized industries in Ireland.

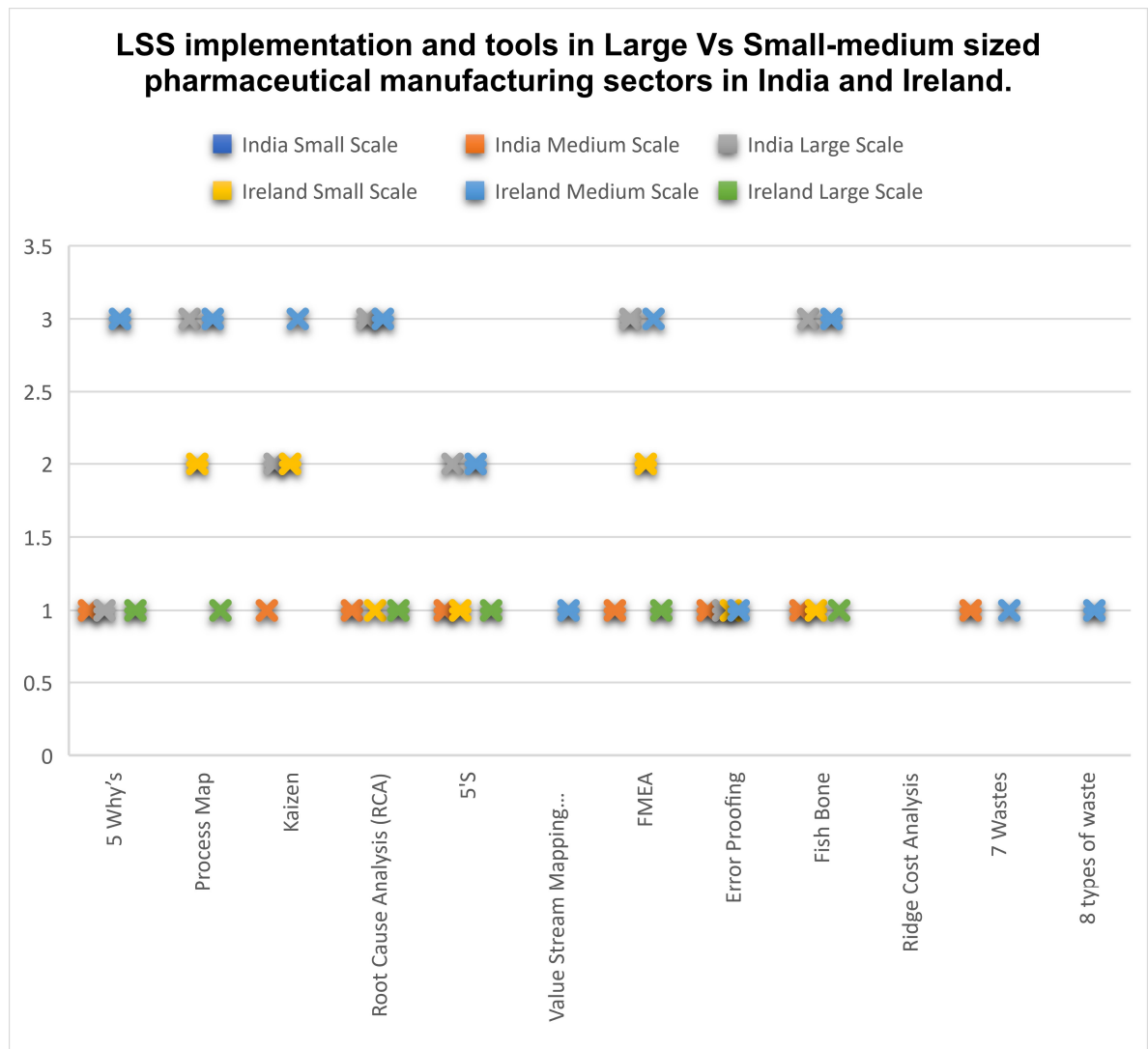


Figure 18: LSS implementation and tools in Large Vs Small-medium sized pharmaceutical manufacturing sectors in India and Ireland.

**xiii. Justification for the usage of current tools and future recommendations:**

The justification for usage of current tools and why not other tools were answered differently among the participants, their responses were:

1. These tools were sufficient to cover our manufacturing activities
2. To remove non value task
3. To understand current state, to simplify processes, to ensure adequate controls are in place
4. Standard tools are used. Proven track record that these tools work. We do not exclude any particular tools.
5. The tools used have given the desired outcome
6. The tools are sufficient
7. self sufficient
8. I think they are well for our industry size
9. Tools will be packed based on their application

Apart from the tools being used, the additional requirements what their industry needs were answered as:

1. Continuous processing with Process Analytical Tools
2. Design for Six Sigma. TRIZ
3. Error proofing answered by 2 participants
4. Pareto charts, control charts

#### xiv. Experience of LSS benefits:

With a set of polling questions, the first one was on the level of agreement with LSS benefiting the company out of which 80% of the population strongly agreed and 20% with moderate agreement as in **figure 19**.

Second one was on the agreement with LSS implementation in reducing the waste, 60% of the participants showed strong agreement and 40 % with considerable agreement as n **figure 20**.

Third on the list as in **figure 21**, was on the agreement for LSS implementation in reducing the financial burden of the industries, this question had quite mixed opinions with 60% modest agreement, 30% of strong agreement and 10% of the research population had neutral opinion.

Fourth comes the agreement on increased customer satisfaction and product quality with LSS implementation as in **figure 22**, 70% with balanced agreement and 30% with strong agreement.

Agreement with LSS implementation benefiting the company

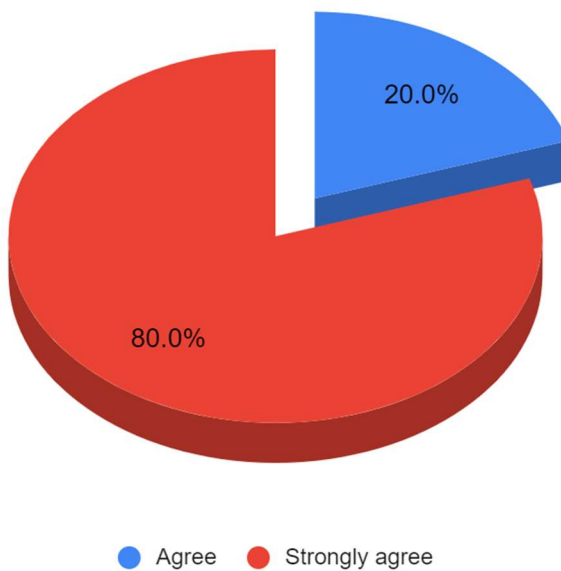


Figure 19: Agreement with LSS implementation benefiting the company

Agreement with LSS implementation is helpful in reducing the waste

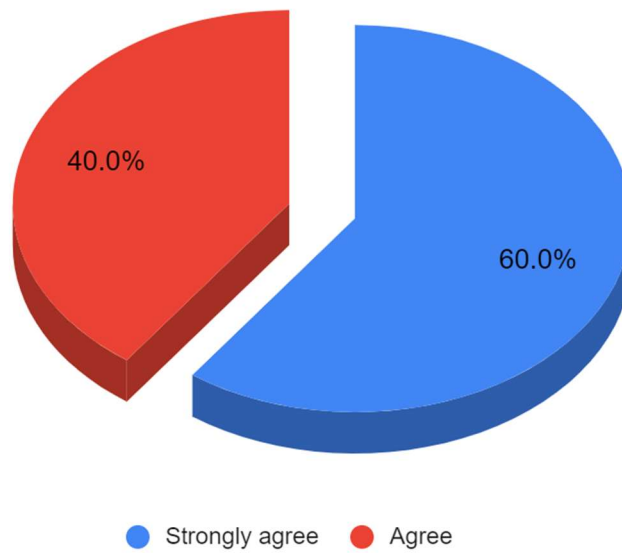


Figure 20: Agreement with LSS implementation helpful in reducing the waste.

Agreement with LSS implementation in reducing the financial burden

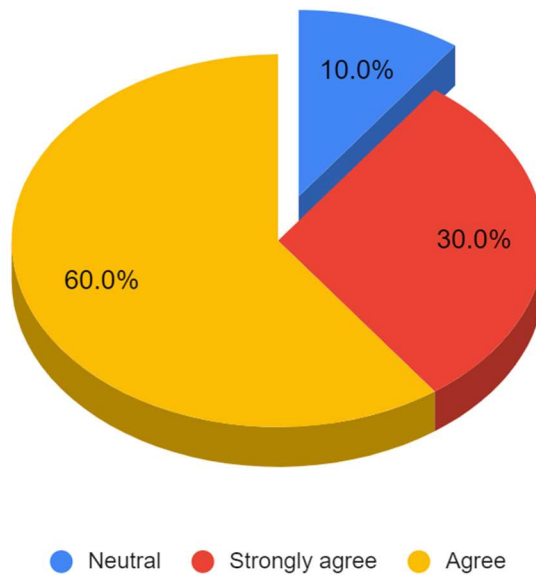


Figure 21: Agreement with LSS implementation in reducing the financial burden

Agreement with LSS implementation increasing customer satisfaction and product quality

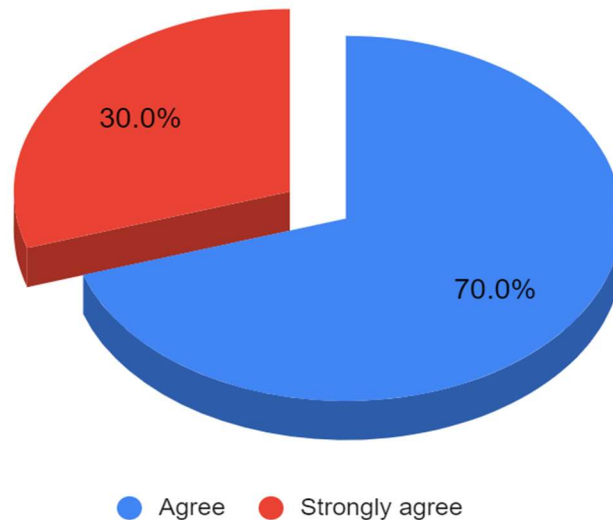


Figure 22: Agreement with LSS implementation increasing customer satisfaction and product quality.

#### xv. Facilitators/ CSF's:

There are certain factors which strongly help in implementation of LSS, these factors are sector of the industry in which LSS is implemented, size of the industry, locality, financial assistance etc., this thesis aims at finding out the top 5 important factors which help in LSS implementation/ facilitators. The participants were asked to rank their preferences 1-5, in which the top most would be ranked one and the least prioritized one is ranked 5.

According to the ranks obtained, the statistical analysis was done in such a way that the factor ranked 1 was given a score of 5, 2<sup>nd</sup> rank- score 4, 3<sup>rd</sup> ranked- score 3, 4<sup>th</sup> ranked -score 2 and fifth ranked- score 1. All these scores were summed up and the overall total has given the scene to identify the prioritized facilitators. when plotted against the graph as in **figure 23**, the top 5 facilitators were:

1. Management commitment and capability

2. Linking LSS to business strategy
3. Training
4. Organizational culture and ownership and
5. Leadership style.

(Antony et al., 2005) in this study, the researcher added that management involvement and participation, linking of six sigma to the customers and business strategy were the most CSF's reported in his study on SME's.(Laureani et al., 2013) Support from top management and regular communication with investors were identified as CSF's in a study on LSS at Irish hospitals.

(Iyede et al., 2018) found out that top management commitment, understanding of LSS methodologies, techniques and tools, integration of LSS to business strategy, organizational cultural change, and training were the top most CSF's in a study at western Ireland.

(Desai et al., 2012) studies CSF's in India, and stated that management participation and involvement, organizational infrastructure and linking six sigma to the business strategy were considered the top most factors like our study.



Figure 23: Top 5 facilitators in Lean Six Sigma Implementation.

#### xvi. Barriers:

There are certain barriers which deteriorate the LSS implementation, in a study by (Jiju, 2019) found out that the LSS at Norwegian hospitals was at infancy and also added that lack of top-management support, lack of training, lack of awareness of the benefits of LSS were the barriers in his study.

In another study (R. Jadhav et al., 2014) there were 24 lean barriers identified, and the researcher also added that successful lean implementation will not be purely based on the selection of appropriate tools and techniques but will also depend on the top managements involvement and leadership, attitude of the workers, resources and culture.

Lack of the top executive supports, organizational strategy, costly LSS projects, improper prioritization of LSS projects and cost effectiveness were the top most barriers in western Ireland. (Iyede et al., 2018).

In a systematic study by (Albliwi et al., 2014) studied 34 common failure factors in LSS implementation and found out that lack of top management, commitment, lack of communication improper training were marked as failure factors.

(Dhiraj and Deepak, 2014) and (Anandakrishna and V, 2013a) stated that It is an autonomous approach to focus less on LSS training. This is important for the completion or loss of the initiative, both in terms of preparedness for the work ahead with the workers and the management. "The choice of less capable Black Belt employees was linked to the challenges of six sigma projects found.

In a related analysis, (Anandakrishna and V, 2013b) noted that lack of preparation and coaching has been the greatest challenge to date for the adoption of Six Sigmas in small and medium-sized enterprises. The lack of training is associated with the lack of understanding of the requirements of the LSS. These authors emphasized the value of providing significant resources and time for training for the maximum benefit of LSS.

Among a list of barriers as in **figure 24**, the top 5 reported in this study were:

1. Lack of leadership from the top executives.
2. Poor execution
3. Fear of change in organizational culture
4. Failure to recognize the need for change and
5. Lack of resources.

#### Possible Solutions:

As the micro level objective states to figure out the solutions that cause deterioration of LSS implementation, the main step to find out the barriers is to analyze all the possible barriers that may occur in the project. Many industrialists think that LSS

project can get succeeded on having good finances and resources, but surprisingly the projects with good finances and resources have failed due to poor execution and lack of leadership. So, the proper leadership from top executives is equally important as the above two. And there are enough number of survey's conducted which say that the CEO's weren't willing to spend money on the required amount of training and resources which is considered the main factor that collapses the entire project. Even though the training investment is costly, but the result after that is fruitful. The false belief among many small and micro enterprises that LSS is only meant for larger companies must be addressed and counseled.



Figure 24:Top 5 barriers in LSS implementation

#### xvii. Benefits:

Although there are good number of well-known benefits about the use of LSS, the top 5 as in **figure 25** in our research were as follows:

1. Improvement in business and quality

2. Standardization
3. Helps in gaining experience in quality management.
4. Organizational growth and
5. Ensuring compliance.

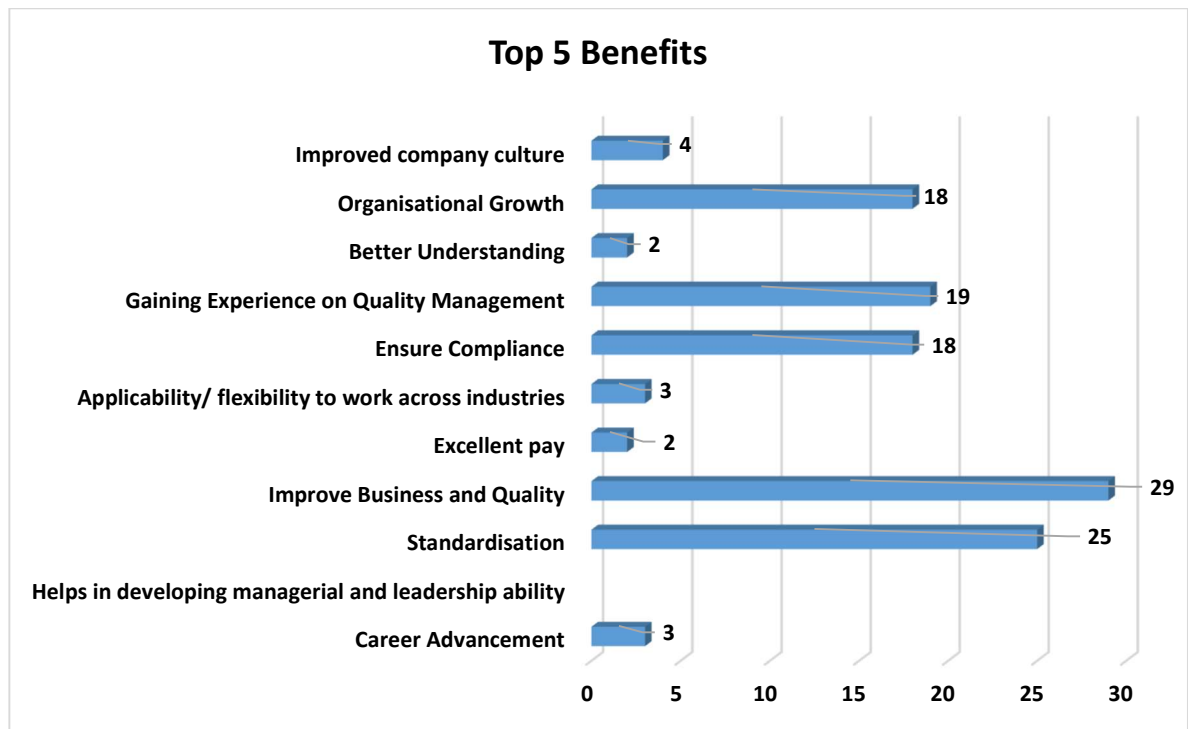


Figure 25: Top 5 benefits in LSS implementation

## Chapter 5: Conclusion

### 5.1 Research conclusions:

The findings and analysis of this research has addressed the study's objectives and also helped to reach its goals, which were: to compare the extent of LSS implementation and different tools used in India and Ireland, to compare the differences in LSS implementation and tools in Large Vs Small-medium sized pharmaceutical manufacturing sectors in India and Ireland, to find out the factors which help in implementing the LSS, to identify the factors that deteriorate the LSS and to list out the possible solutions to the factors that pull back the improvement in LSS.

At the end, the findings of this thesis were:

- The extent of implementation of LSS in India and Ireland was almost the same, there was not much difference as many other studies said while comparing a developed and developing nation.
- The usage of tools is always dependant on the requirement of the projects, size of the industry etc., tools implemented in India and Ireland were compared and their patterns were analysed and found out that Ireland has a wide range of LSS tools in use when compared to India, irrespective of the size of the organization.
- Process map, FMEA and Fish bone were widely used and the least used tool was ridge cost analysis.
- When the size of the organizations was taken into consideration, Ireland had more SME's than in India, while India had more large-scale industries.
- In India especially in the large-scale industries, LSS is implemented in the entire organization, while in Ireland, the equal number of participants opted saying that LSS is implemented in few departments and only in their

departments. But, in both the countries, LSS implementation is still at infancy or not yet established in few small-scale industries or lower.

- There is a very strong agreement that the cultural differences among both the countries is causing a huge variation in the pattern of LSS implementations.
- The major differences between India and Ireland in terms of LSS were answered by the participants who had similar experience in both the countries, according to the opinions received, we can conclude that:
  - there isn't huge corporate culture gap, but surely there are national culture differences, India is under vigorous development unlike last century in terms of pharma sector, the small-scale industries may not be able to get enough funds and resources from the government in India, unlike Ireland.
  - There is a false belief in certain small-scale industries in both the countries that LSS is only meant for companies with huge resources and more staff.
  - State of the industry, ownership of the activity, the levels of maturity also varies among the countries.
- For the question on justification for the usage of current tools and why not the others, there were mixed opinions reported and were understood as:
  - The present tools were sufficient to cover their manufacturing activities and there is a proven track record that these tools work.
  - The tools being used were aiding to remove the non-value-added task, they help in understanding the current state, to simplify processes, to ensure adequate controls are in place.
- The recommendations on other tools that the participant's company need to implement were:

- Continuous processing with Process Analytical Tools
- Design for Six Sigma. TRIZ
- Error proofing answered by 2 participants
- Pareto charts, control charts
- Majority of the study participants agreed that their organization has been benefited from the LSS in terms of waste reduction, reduction in the financial burden, increased customer compliance and quality of the products.
- The top facilitators in LSS implementation in our study were:
  - Management commitment and capability
  - Linking LSS to business strategy
  - Training
  - Organizational culture and ownership and
  - Leadership style.
- Where is the top 5 barriers were:
  - Lack of leadership from the top executives.
  - Poor execution
  - Fear of change in organizational culture
  - Failure to recognize the need for change and
  - Lack of resources.
- And the benefits reported on the top 5 list were:

- Improvement in business and quality
- Standardization
- Helps in gaining experience in quality management.
- Organizational growth and
- Ensuring compliance.

## 5.2 Limitations of the study:

- The major limitation of this study was the research sample, it was quite difficult to get the data from the participants due to their busy schedule. Even though only 11 people responded, the data doesn't go invalidated.
- Secondly, the scope of this research was a narrow one, and was only confined to LSS implementation in pharmaceutical manufacturing sector.

## 5.3 Strengths of the research:

Due the narrowed scope the research was well shaped and sharp to point instead of being vague. A critical in-depth study was carried out from all perspectives from the samples and their opinions were reported.

## 5.4 Recommendations:

- It is expected that pharmaceutical companies will invest a lot in the production of the benefits of the LSS. Likewise, the companies are advised to invest on the training, although the project may initially prove to be capital-intensive, studies have shown that it has long-term financial value.
- The findings of this analysis have shown that money alone doesn't yield the LSS. The management will participate and commit itself to LSS for quicker results, as well as expenditure in preparations.

- The misconception of LSS is only meant of large-scale industries must be stopped and even the small-scale industries should try implementing the LSS and experience its benefits.
- A similar study can be conducted in various departments across different sectors and countries in order to know the scope of LSS.
- Due to the time constraint and sample size, we couldn't establish beneficial tools which can be confined to a particular department. Like, a group of tools or methods in LSS, that work for a particular industry, which can be guide of the respective department.

### 5.5 Final conclusion and reflections:

From the analysis of the data and findings in the research, it can be concluded that the LSS implementation in India and Ireland is almost the same, while Ireland had more SME's when compared to India and India had more large-scale industries. FMEA, Fish bone and process map remained as the mostly used tools, and Ridge cost analysis was the least preferred one. The top 5 facilitators, barriers and benefits were reported.

## References:

- Ahmad, M.F. *et al.* (2017) 'Comparative Study of Lean Practices between Japanese and Malaysia Automotive Service Centres'. In THE 2ND INTERNATIONAL CONFERENCE ON APPLIED SCIENCE AND TECHNOLOGY 2017 (ICAST'17). Kedah, Malaysia, p. 020022. DOI: 10.1063/1.5005355.
- Albliwi, S. *et al.* (2014) 'Critical Failure Factors of Lean Six Sigma: A Systematic Literature Review'. *International Journal of Quality & Reliability Management*, 31(9), pp. 1012–1030. DOI: 10.1108/IJQRM-09-2013-0147.
- Albliwi, S., Antony, J. and Lim, S. (2015) 'A Systematic Review of Lean Six Sigma for the Manufacturing Industry'. *Business Process Management Journal*, 21, pp. 665–691. DOI: 10.1108/BPMJ-03-2014-0019.
- Alkhoraif, A. and McLaughlin, P. (2016) 'Organisational Culture That Inhibit the Lean Implementation'.
- Alkhoraif, A., Rashid, H. and McLaughlin, P. (2019) 'Lean Implementation in Small and Medium Enterprises: Literature Review'. *Operations Research Perspectives*, 6, p. 100089. DOI: 10.1016/j.orp.2018.100089.
- Alkunsol William Hanna *et al.* (2019) 'Lean Six Sigma Effect on Jordanian Pharmaceutical Industry's Performance'. *International Journal of Lean Six Sigma*, 10(1), pp. 23–43. DOI: 10.1108/IJLSS-01-2017-0003.
- Al-Shourah, A. and Alzu'bi, D. (2018) 'The Integration of Lean Management and Six Sigma Strategies to Improve the Performance of Production in Industrial Pharmaceutical'. *International Journal of Business and Management*. DOI: 10.5539/ijbm.v13n8p207.
- Anandakrishna, R. and V, D. (2013a) 'Barriers for Implementation of Six Sigma by Small and Medium Enterprises'. *International Journal of Advancements in Research & Technology (ISSN 2278-7763)*, 2.
- Anandakrishna, R. and V, D. (2013b) 'Lean and Six Sigma Approach for Manufacturing SMEs'.
- Antony, J. *et al.* (2019) 'An Exploratory Study into the Use of Lean Six Sigma to Reduce Medication Errors in the Norwegian Public Healthcare Context'. *Leadership in Health Services*, 32(4), pp. 509–524. DOI: 10.1108/LHS-12-2018-0065.
- Antony, J., Kumar, M. and Madu, C. (2005) 'Six Sigma in Small- and Medium-Sized UK Manufacturing Enterprises: Some Empirical Observations'. *International Journal of Quality & Reliability Management*, 22, pp. 860–874. DOI: 10.1108/02656710510617265.

Banik, S. (2017) 'SMALL SCALE INDUSTRIES IN INDIA: OPPORTUNITIES AND CHALLENGES'. 6.

Bhaskar, H.L. (2020) 'Lean Six Sigma in Manufacturing: A Comprehensive Review'. *Lean Manufacturing and Six Sigma - Behind the Mask*. DOI: 10.5772/intechopen.89859.

Bicheno, J. (2004) 'The New Lean Toolbox: Towards Fast Flexible Flow'.

Consulting, R.S., Director, Clarkston. *Lean Laggards: Exploring the State of Lean in Pharma*. *Pharma Manufacturing*. Available at: <https://www.pharmamanufacturing.com/articles/2018/lean-laggards-exploring-the-state-of-lean-in-pharma/> (Accessed: 16 October 2019).

Dahlgaard, J.J. and Mi Dahlgaard-Park, S. (2006) 'Lean Production, Six Sigma Quality, TQM and Company Culture' Mi Dahlgaard-Park, S. (ed.). *The TQM Magazine*, 18(3), pp. 263–281. DOI: 10.1108/09544780610659998.

Desai, D.A., Antony, J. and Patel, M.B. (2012) 'An Assessment of the Critical Success Factors for Six Sigma Implementation in Indian Industries'. *International Journal of Productivity and Performance Management*, 61(4), pp. 426–444. DOI: 10.1108/17410401211212670.

Dhiraj, K. and Deepak, K. (2014) 'A REVIEW OF SIX SIGMA APPROACH: METHODOLOGY, OBSTACLES AND BENEFITS'. p. 5.

Duffton, S.W.C.K.D.A.A.M. (2009) *Learning from Lean Sigma*. Available at: <http://www.pharmtech.com/learning-lean-sigma> (Accessed: 8 May 2020).

Gijo, E.V., Palod, R. and Antony, J. (2018) 'Lean Six Sigma Approach in an Indian Auto Ancillary Conglomerate: A Case Study'. *Production Planning & Control*, 29(9), pp. 761–772. DOI: 10.1080/09537287.2018.1469801.

Gutierrez, L., De Leeuw, S. and Dubbers, R. (2014) 'An Integrative Model for Lean Six Sigma Implementation in Logistics Services Environments'. *Review of Business and Economic Literature*, 58, p. 211.

Hamrol, A. et al. (2019) *Advances in Manufacturing II: Volume 3 - Quality Engineering and Management*. Springer.

Hayes, R. (2013) 'Improving Operations and Performance: How Rottapharm Is Using Lean Six Sigma Principles'. *European Pharmaceutical Review*, 18, pp. 54–56. Available at: <https://www.europeanpharmaceuticalreview.com/article/20869/six-sigma-how-rottapharm-is-using-lean-six-sigma-principles/> (Accessed: 8 May 2020).

Ilaria, D. (2018) *The Moderating Effects of Corporate and National Factors on Lean Projects Barriers: A Cross-national Study: Production Planning & Control: Vol 29, No 12*. Available at:

<https://www.tandfonline.com/doi/abs/10.1080/09537287.2018.1494345?src=recsys&journalCode=tppc20&> (Accessed: 13 May 2020).

Iyede, R., Fallon, E.F. and Donnellan, P. (2018) 'An Exploration of the Extent of Lean Six Sigma Implementation in the West of Ireland'. *International Journal of Lean Six Sigma*, 9(3), pp. 444–462. DOI: 10.1108/IJLSS-02-2017-0018.

Jacobs, M. (2015) *Cultural Impact on Lean Six Sigma and Corporate Success: Causal Analyses Considering the Effects of National Culture and Leadership*. Gabler Verlag DOI: 10.1007/978-3-658-07340-4.

Jiju, A. (2019) *An Exploratory Study into the Use of Lean Six Sigma to Reduce Medication Errors in the Norwegian Public Healthcare Context | Request PDF*. ResearchGate. DOI: <http://dx.doi.org/10.1108/LHS-12-2018-0065>.

Karwande, R. *et al.* (2018) 'Implementing Six Sigma for Manufacturing Sector in India -a Model Based on a Steel Industry'. *Industrial Engineering Journal*, 11, pp. 20–34. DOI: 10.26488/IEJ.11.8.1137.

kothari, kothari. 'RESEARCH METHODOLOGY'. *Chapter Two*, p. 34.

Kumar, M. *et al.* (2006) 'Implementing the Lean Sigma Framework in an Indian SME: A Case Study'. *Production Planning & Control*, 17(4), pp. 407–423. DOI: 10.1080/09537280500483350.

Lande, M., Shrivastava, R.L. and Seth, D. (2016) 'Critical Success Factors for Lean Six Sigma in SMEs (Small and Medium Enterprises)'. *The TQM Journal*, 28(4), pp. 613–635. DOI: 10.1108/TQM-12-2014-0107.

Laureani, A., Brady, M. and Antony, J. (2013) 'Applications of Lean Six Sigma in an Irish Hospital'. *Leadership in Health Services*, 26(4), pp. 322–337. DOI: 10.1108/LHS-01-2012-0002.

Lawal, A.K. *et al.* (2014) 'Lean Management in Health Care: Definition, Concepts, Methodology and Effects Reported (Systematic Review Protocol)'. *Systematic Reviews*, 3(1), p. 103. DOI: 10.1186/2046-4053-3-103.

Lean Tools. *Lean Manufacturing Tools, Principles, Implementation. Lean Manufacturing Tools*. Available at: <https://leanmanufacturingtools.org/> (Accessed: 21 May 2020).

Lee, J. *et al.* (2013) 'A Comparative Study of the Implementation Status of Lean Six Sigma in South Korea and the UK'. In pp. 1489–1502. DOI: 10.1007/978-3-319-00557-7\_120.

Lin, Y.-P., Gullan, P. and Cook, L. (2015).

Luzi, D. (2000) 'Trends and Evolution in the Development of Grey Literature: A Review'. *International Journal on Grey Literature*, 1, pp. 106–117. DOI: 10.1108/14666180010345537.

Mark NK Saunders, M.N.S. (PDF) 'Research Methods for Business Students' Chapter 4: Understanding Research Philosophy and Approaches to Theory Development. ResearchGate. Available at: [https://www.researchgate.net/publication/330760964\\_Research\\_Methods\\_for\\_Business\\_Students\\_Chapter\\_4\\_Understanding\\_research\\_philosophy\\_and\\_approaches\\_to\\_theory\\_development](https://www.researchgate.net/publication/330760964_Research_Methods_for_Business_Students_Chapter_4_Understanding_research_philosophy_and_approaches_to_theory_development) (Accessed: 17 May 2020).

McSweeney, K. and Moore, K. (2015) 'Innovating to Do More with Less - the Story of Lean Six Sigma in the Central Statistics Office, Ireland'. *Statistical Journal of the IAOS*, 31(4), pp. 587–592. DOI: 10.3233/SJI-150929.

Mehdi, M.A. (2012) 'Lean Six Sigma: An Overview for Developing Countries'. p. 12.

Mostafa, S., Dumrak, J. and Soltan, H. (2013) 'A Framework for Lean Manufacturing Implementation'. *Production & Manufacturing Research*, 1(1), pp. 44–64. DOI: 10.1080/21693277.2013.862159.

Navarro, N. (2014) *Five Obstacles to Implementing Lean in Small Business* | Everett Community College. Available at: <https://www.everettcc.edu/ccec/enewsletters/five-obstacles-implementing-lean-small-business> (Accessed: 8 May 2020).

Nenni, M.E., Giustiniano, L. and Pirolo, L. (2014) 'Improvement of Manufacturing Operations through a Lean Management Approach: A Case Study in the Pharmaceutical Industry'. *International Journal of Engineering Business Management*, 6, p. 24. DOI: 10.5772/59027.

Nonthaleerak, P. and Hendry, L. (2006) 'Six Sigma: Literature Review and Key Future Research Areas'. *International Journal of Six Sigma and Competitive Advantage*, 2. DOI: 10.1504/IJSSCA.2006.010111.

Noori, B. and Latifi, M. (2018) 'Development of Six Sigma Methodology to Improve Grinding Processes: A Change Management Approach'. *International Journal of Lean Six Sigma*, 9(1), pp. 50–63. DOI: 10.1108/IJLSS-11-2016-0074.

O'Reilly, S. et al. (2017) 'A Continuous Improvement Journey in the Higher Education Sector: A Case Study of a University in Ireland'. In *Proceedings of the Fourth International Conference on Lean Six Sigma for Higher Education*. Fourth International Conference on Lean Six Sigma for Higher Education. Purdue Scholarly Publishing Services, pp. 7–15. DOI: 10.5703/1288284316371.

Orlando Silva, O.S. (PDF) *LEAN SIX SIGMA – MULTIPLE CASE STUDY*. ResearchGate. DOI: <http://dx.doi.org/10.7198/geintec.v7.i4.1105>.

Papadopoulou, T.C. and Özbayrak, M. (2005) 'Leanness: Experiences from the Journey to Date'. *Journal of Manufacturing Technology Management*, 16(7), pp. 784–807. DOI: 10.1108/17410380510626196.

Patel, R. 'Modeling Lean Six Sigma in the Small Packaging Industry in India'. p. 128.

Pearce, A. and Pons, D. (2013) *Implementing Lean Practices: Managing the Transformation Risks*. *Journal of Industrial Engineering*. DOI: <https://doi.org/10.1155/2013/790291>.

Psychogios, A. and Tsironis, L. (2012) 'Towards an Integrated Framework for Lean Six Sigma Application: Lessons from the Airline Industry'. *Total Quality Management & Business Excellence - TOTAL QUAL MANAG BUS EXCELL*, 23, pp. 1–19. DOI: 10.1080/14783363.2011.637787.

R. Jadhav, J., S. Mantha, S. and B. Rane, S. (2014) 'Exploring Barriers in Lean Implementation'. *International Journal of Lean Six Sigma*, 5(2), pp. 122–148. DOI: 10.1108/IJLSS-12-2012-0014.

Research philosophy. *Research Philosophy - Research Methodology. Research-Methodology*. Available at: <https://research-methodology.net/research-philosophy/> (Accessed: 14 May 2020).

Rivera, L. and Chen, F.F. (2007) 'Measuring the Impact of Lean Tools on the Cost-Time Investment of a Product Using Cost-Time Profiles'. DOI: 10.1016/j.rcim.2007.02.013.

Saunders, M.N.K., Lewis, P. and Thornhill, A. (2009) *Research Methods for Business Students*. 5th ed. New York: Prentice Hall.

Scheller, A., Sousa-Zomer, T. and Cauchick-Miguel, P. (2018) 'Lean Six Sigma in Developing Countries: Evidence from a Large Brazilian Manufacturing Firm'. *International Journal of Lean Six Sigma*. DOI: 10.1108/IJLSS-09-2016-0047.

Schrecker, T. (2016) *Surviving Globalism: The Social and Environmental Challenges*. Springer.

Schroeder, R. et al. (2008) 'Six Sigma: Definition and Underlying Theory'. *Journal of Operations Management - J OPER MANAG*, 26, pp. 536–554. DOI: 10.1016/j.jom.2007.06.007.

Shah, R., Chandrasekaran, A. and Linderman, K. (2008) 'In Pursuit of Implementation Patterns: The Context of Lean and Six Sigma'. *International Journal of Production Research*, 46(23), pp. 6679–6699. DOI: 10.1080/00207540802230504.

Shingo, S. and Dillon, A.P. (1989) *A Study of the Toyota Production System: From an Industrial Engineering Viewpoint*. CRC Press.

Sreedharan V, R., Sunder M, V. and Raju, R. (2018) 'Critical Success Factors of TQM, Six Sigma, Lean and Lean Six Sigma: A Literature Review and Key Findings'. *Benchmarking: An International Journal*, 25, pp. 00–00. DOI: 10.1108/BIJ-08-2017-0223.

Stankalla, R., Koval, O. and Chromjakova, F. (2018) 'A Review of Critical Success Factors for the Successful Implementation of Lean Six Sigma and Six Sigma in Manufacturing Small and Medium Sized Enterprises'. *Quality Engineering*, 30(3), pp. 453–468. DOI: 10.1080/08982112.2018.1448933.

Steve, C. (2010) *Using Six Sigma in Europe: A Cross-Cultural Perspective. iSixSigma*. Available at: <https://www.isixsigma.com/regional-views/europe/using-six-sigma-europe-cross-cultural-perspective/> (Accessed: 13 May 2020).

Taylor, D. (2015) 'The Pharmaceutical Industry and the Future of Drug Development'. pp. 1–33. DOI: 10.1039/9781782622345-00001.

bin Wan Ibrahim, W.M.K., Rahman, M.A. and bin Abu Bakar, M.R. (2017) 'Implementing Lean Manufacturing in Malaysian Small and Medium Startup Pharmaceutical Company'. *IOP Conference Series: Materials Science and Engineering*, 184, p. 012016. DOI: 10.1088/1757-899X/184/1/012016.

Weinstein, L.B. (2009) 'Best Practices in Lean Six Sigma Process Improvement: A Deeper Look'. *Benchmarking: An International Journal*, 16(4), pp. 562–563. DOI: 10.1108/14635770910972469.

Wiele, T. van der., Iwaarden, J. van. and Power, D. (2010) 'Six Sigma Implementation in Ireland: The Role of Multinational Firms'. *International Journal of Quality and Reliability Management*, 27(9), pp. 1054–1066. DOI: 10.1108/02656711011084837.

Womack, J. and Jones, D. (1996) *Lean Thinking : Banish Waste and Create Wealth in Your Corporation*. DOI: 10.1038/sj.jors.2600967.

Young, T.T. and Babchuk, W.A. 'Contemporary Approaches to Qualitative Research: Andragogical Strategies for Teaching and Learning'. p. 7.

Zhang (corresponding, Q. et al. (2012) *Lean Six Sigma: A Literature Review*.

Zhang, Q. et al. (2012) 'INTERDISCIPLINARY JOURNAL OF CONTEMPORARY RESEARCH IN BUSINESS CRITICAL SUCCESS FACTORS FOR SUCCESSFUL LEAN SIX SIGMA IMPLEMENTATION IN PAKISTAN'. *Hygiea Internationalis An Interdisciplinary Journal for the History of Public Health*, 4, pp. 117–124.