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DOI: http://ijmer.in.doi./2021/10.06.183

INTERNATIONAL JOURNAL OF MULTIDISCIPLINARY EDUCATIONAL RESEARCH
ISSN:2277-7881; IMPACT FACTOR :7.816(2021); IC VALUE:5.16; ISI VALUE:2.286
Peer Reviewed and Refereed Journal: VOLUME:10, ISSUE:6(10), June:2021
Online Copy of Article Publication Available: www.ijmer.in
Digital certificate of publication:http://ijmer.in/pdf/e-Certificate%20of%20Publication-IJMER.pdf
Scopus Review ID: A2B96D3ACF3FEA2A
Article Received: 10th June - Publication Date:30th June 2021

OBSTACLES IN LEAN IMPLEMENTATION IN PHARMACEUTICAL INDUSTRY

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ABSTRACT
Lean manufacturing remains to be under utilised set of tools and techniques till date for the pharmaceutical industry. The report introduces what lean manufacturing is, followed by the detailed approach on what does the lean scenario in pharma sector looks like. It focuses on the manufacturing constraints and liabilities provided in the sector to the companies and explores further with the help of literature review of numerous research papers as well as by the example of a particular pharma industry to know what are the obstacles preventing lean implementation in the aforementioned sector and then the result after 60 days of implementation is presented.

Keywords: Lean Management, Pharmaceutical Industry, Lean Tools, Lean Aspect.

INTRODUCTION
Lean manufacturing is the "set of tools that assist in the identification and steady elimination of waste". While eliminating the waste, quality improves as well as the production time and cost reduces.There are multiple tools and techniques that have been developed over a time period of years and years and are still developing in this domain of lean. Few of the lean tools that are required specifically in the case of pharmaceutical industry are 5S, Kaizan, continuous flow, just in time and Jidoka.

1.1 Understanding the pharmaceutical sector
India secures the rank 3 in pharmaceutical production by volume and it ranks 14th by value, the ranks are enough to emphasize the need of 'proper by every ounce' manufacturing in the sector. India is renowned as the biggest provider of generic drugs on a global level. Indian pharmaceutical sector has the supply of over 50% of global demand for different vaccines. The domestic pharmaceutical industry includes a network of 3,000 drug companies and ~10,500 manufacturing units. As cited in Indian Economic Survey 2021, the inhouse market in our country is expected to grow 3 times in the coming 10 years. In 2021, India's domestic pharmaceutical market is expected to be worth US$ 41 billion, rising to US$ 65 billion by 2024 and US$ 120-130 billion by 2030.

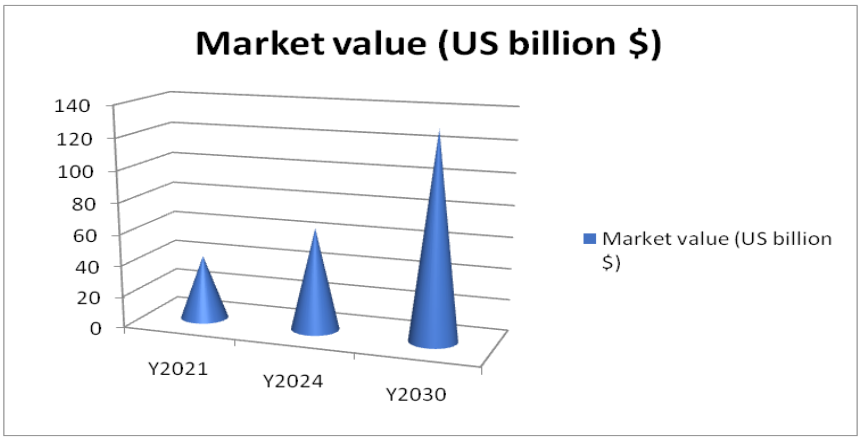

Figure 1: Projected worth of pharma industry.

1.2 Problem statement
Most pharmaceutical companies, particularly those in the small molecule spaces, confront hurdles in terms of rising costs delivering really high-quality products and innovations in a timely manner, and dealing increasing competition from other firms. The growth of lean in pharmaceutical sector has been slow and many issues including sturdy regulations for quality development and safety are to be considered responsible.GMP standards bind the industries into following a certain path that also cannot be avoided and therefore lean gets on the back seat. For a better study, a pharmaceutical industry in the Indore region is studied, say company XYZ. The obstacles and success factors after implementation of lean are analyzed and represented. The solutions for currently persisting loopholes are identified and related solutions are suggested.

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RESEARCH METHODOLOGY

The literature review of 12 research papers was analysed and conducted out of which 8 were related to finding loopholes in lean implementation in SME's and 4 were specifically linked to pharma sector. The papers outlined different prospects of lean implementation and obstacles related to same have been shown below.

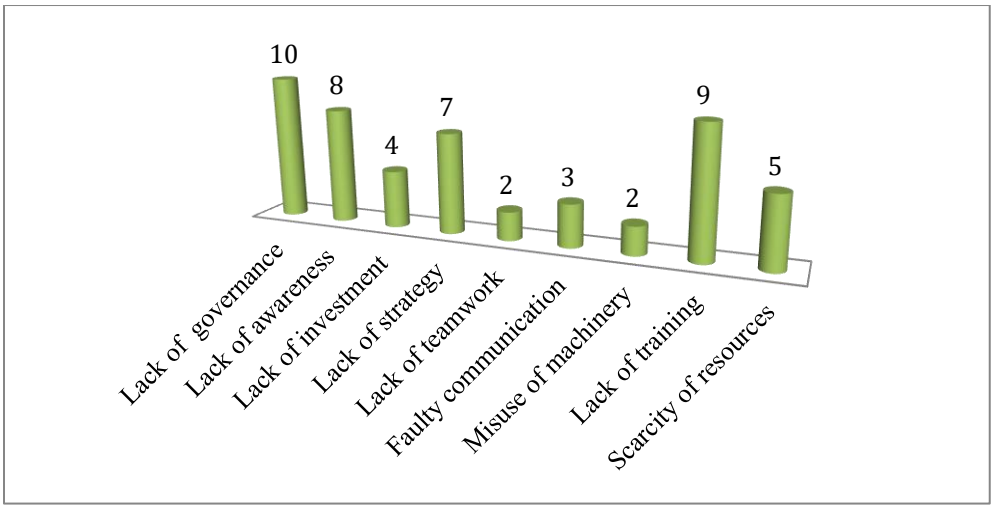

Figure 2: Frequency of lean obstacles in reviewed papers.

The company XYZ is a pharmaceutical company in Indore region of Madhya Pradesh with about 200 employees. In order to research on obstacles faced while implementing lean, personal interviews of company professionals and surveys were conducted, along with data collection and calculation from the company itself in order to compare what is the scenario 'before' and 'after' the problems have been solved and solutions implemented.

ASPECTS	DATA PROVIDED
Manufacturing ability	75%
Design and procedure that is solid	75%
Short lead time	25%
Quality of product	75%
Current status of lean manufacturing	45%
Acceptance of lean implementation	80%
Awareness amongst employees	70%

Table 1. Lean aspects in company XYZ.

The above data was primarily used to get a crux of where lean stands in the company and try to understand what loopholes have been hampering the same.Further to test awareness amongst the employees, the sources of awareness were identified via surveying through google form and following data has been represented through it.

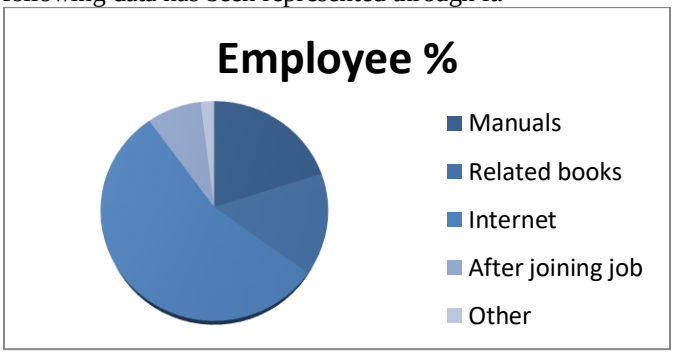

Figure 3: Sources of awareness

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RESULTS AND DISCUSSIONS

With the study from data collection of company XYZ and the literature analysis of selected papers, there have been certain issues that are hurdles in lean implementation. Pharmaceutical companies are primarily focused on high productivity, short lead times, necessary quality, and compliance standards, which are frequently identified as limiting issues in increasing efficiency, and many organisations do better.

3.1 Solutions

Regulatory agencies may not always agree that lean manufacturing and GMP standards are interchangeable. Safety is prominent which makes freedom of lean reluctant. Lean principles such as robust design, proven process, and lead time are not well adopted and improved. The main reason for this is a lack of training and a lack of well-defined business processes. Redesigning the manufacturing process by re implementing lean would reduce inventory and waste. The senior management should be trained in lean, which thereby trains the middle management and then further the employees are trained by middle management. A logical order of steps from literature review was introduced to open the bottlenecks and steps of Plan-Develop-Execute-Sustain -Monitor was introduced. Markets, rivals, suppliers, and customers must all be evaluated, as well as internal and external aspects such as products, processes, staff, facilities, and resources. Both internal and external issues should be assessed from a social as well as an economic standpoint and from an environmental one.The pharmaceutical industry is heavily regulated, due to its focus on quality development, cost and productivity. Lean's dual goals of reducing or eliminating waste and creating value contrast from cGMP's goal of ensuring that controls are in place to deliver a safe and effective pharmaceutical product of good quality. In most circumstances, the ideas of cGMP and lean management intersect in production environment for pharmaceuticals. Therefore, they should each be compared with each other and accordingly implemented under proper guidance. Pharmaceutical manufacturing has been a batch wise process generally since long, therefore it has not experienced the benefits of continuous processing. This needs to be slowly considered and practiced to reduce time and thereby enhance production, by identifying bottlenecks and working on their release.

3.2 Outcomes

After 2 months of applying selective solutions, the industry observed significant changes in the outcomes as described in table 2. Application of jidoka and kanban significantly helped the industry transition into lean. Jidoka refers to partial automation of machinery, instead of full. This helped the company to cut down unnecessary cost. Due to post COVID implications, the company agreed to very briefly imply JIT, or Just in time to curb the problem of overproduction.

SN	Activity	Goal	Achieved
1	Reduction in process lead time	5 days	4 days
2	Reduction of throughput time	4 days	3 days
3	Redesign suggested	300m	284m

Table II. Two monthly reports after lean implementation.

3.3 NPT analysis

NPT stands for nonproductive time, which means time killing of unused time. Before implementing lean tools, the NPT was significantly observed in planning,dispensing, packaging, pending decisions and approval delays. The graph shows before and after comparison in which nonproductive time is significantly reduced in the time period of 60 days.

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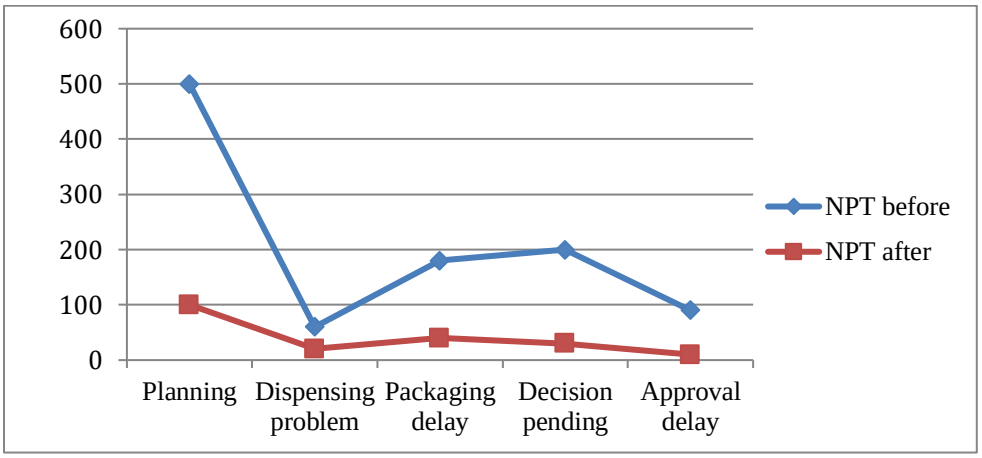

Figure 7: NPT analysis after implementation of lean.

IV. CONCLUSION

Lean manufacturing is based on very simple principles, identifying value added processes and those which do not add value to a company and which the customer is unwilling to pay. Lean methods can be introduced quite quickly promising high potential for improvement in pharma. They act as a booster for efficiency optimisation in product development. The research done previously suggests that though pharma industries are willing to take up lean manufacturing as and when they are becoming more and more aware of it, there are regulationalboundations and slow inclinations of interests due to high focus on quality and safety in this industry. But the experience of company XYZ as we see is good enough post lean implementation acting as a proof of advantageous aspect of lean manufacturing.

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