

Study the Influence of Lean Principles which Enhances the Operational Excellence in the Pharmaceutical Industry

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Abstract

Today most of the pharmaceutical companies particularly the small molecule domain, faces unprecedented challenges of escalating costs, delivering the quality products and innovations within the short term period with increasing competitive pressure from other companies. In other industries, process improvement approaches such as Lean, Six Sigma etc., have delivered the benefits in speed, quality and cost of delivery. In this paper, specific attention is given to the three key points from management point of view is that Very high productivity, Very short lead times and Exceptional product quality for any drug product. Currently, pharmaceutical industry has been slow to adopt the lean manufacturing unlike many sectors where it has been successfully deployed. In fact, Lean and cGMP go hand in hand as quality is sustained at a higher level with lower costs due to lean principles that are applied. This research study attempts to sketch out the scope and implementation ways to implement lean management principles existing in the pharmaceutical manufacturing and thereby improve the quality of products and services. This study adds to the literature by providing background information regarding the current status of lean involvement in quality system in the pharmaceutical manufacturing sectors.

Keywords: Cost of Delivery, Lean, Product Quality, Short Lead Times, Very High Productivity

1. Introduction

In olden days, Lean strategies have been developed to eliminate or reduce waste and thus improve operational efficiency in a manufacturing environment. However, in practice manufacturers encounter difficulties to select appropriate lean strategies within their resource constraints and to quantitatively evaluate the perceived value of manufacturing waste reduction.

In case of pharmaceutical sector, many pharmaceutical organizations had shown a willingness to simplify operations, processes and reduce costs via lean implementation. Nowadays, Pharma industries are under tremendous pressure to improve its competitive business: R&D methods, manufacturing efficiency and whole supply chain performance. These organizations are struggling to find ways to cut costs.

In any industry where success is increasingly driven by satisfaction scorecards, reliable access to key talent is essential for meeting the demand for quality service.

Over the last decade lean implementation has become the vital driver of operational change, eliminating waste and improving process. It is important to note that lean is heavily based on the mindset of the people and practices that continuous improvement can be found through the power of respect for people. The culture of the company is crucial in designing the business system that motivates people to want to improve, teaching them the tools, methods and principles and motivates them to apply those tools every day.

Lean scope and implementation improves the manufacturing process and business strategy and it involves the employees at all levels.

Today Industry trends shows that many pharmaceutical manufacturers are following some of the manufacturing principles in the way for significant improvement of operational efficiency and quality, while facilitating compliance. To ensure a solid position on the market and competitive advantage they are looking to increase the efficiency of their operational and manufacturing process

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- optimizing resources, improving efficiency and short lead times with best product quality.

Even if the change is good and beneficial, its lack of acceptance by the relevant stakeholders can bring in the uncertainty in the consequence of the change. Nowadays, Pharma industry faces the dilemma between pursuing the competitive advantage of cutting edge technology and the risk of uncertainty associated with it. So, the Implementing lean is a journey, not a process

2. Research Objectives / Importance of the Study

This research study involves in the “Study the involvement and Implementation of Lean aspects in Pharmaceutical Industry”. This research study is to find out the scope and implementation of lean principles in the Pharmaceutical environment which in turn not identified and not applied as an effective tool in the business processes.

The following core objectives were taken into consideration during the research study,

- Proper selection of the lean methods for the implementation and Identify the Lean factors which determine the complete quality system management of the selected pharmaceutical firms. (Quality Focus)
- What are the management principles / factors already exist with the pharmaceutical industries but the implementation aspects are very weak. (Lean Tools / Goals)
- Whether lean management principles can be applied effectively?

Based on the study, Suitable suggestions will be made for implementation of lean in the pharmaceutical firms to enhance the high productivity; short lead times thus by reduce the cost.

Note: All the above factors are covered in the survey questionnaire.

3. Research Questions/ Hypotheses

3.1 Statement of the Problem

This study emphasis on the finding out the “Scope and implementation of lean principles in the pharmaceutical industry” and thereby improve the productivity and operational efficiency.

Nowadays, many pharmaceutical companies are

relying on the management concepts to improve the business processes. However, in most cases companies took only few steps towards the identifying and implementation of lean principles before but on later stage they are falling back into old habits. As a result, the Pharmaceutical industries lag in efficiency behind other major manufacturing industries such as the automotive and consumer goods sectors.

3.2 Hypothesis of the Study

At present, it was found that there is a lack of coordination between management function and proper quality enforcement in the systems. In order to meet the strict quality requirements, management function and quality enforcement have to be coordinated, have to move in tandem but not to be separated.

The following are the hypotheses which are to be tested in the present study.

- Quality system level (Lean aspects) in a company is dependent on the commitment of the management towards quality.
- Quality system management does not depend upon the capital investment and percentage of operating expenditure on quality control / quality assurance.

Level of quality system management is not related to the size of the firms, capital investment, turnover, personnel cost incurred, ISO certification, area of selling and vendor evaluation.

In most cases, lean management principles do overlap in the pharmaceutical manufacturing environment. So, effective lean management principles to be identified in the Pharmaceutical environment and utilized to improve the operational efficiency.

4. Research Methodology

- Study area
- Sampling procedure & data collection
- Frame work of analysis
- Data analysis & interpretation

Research is a careful investigation or enquiry especially through search for new facts in any branch of knowledge. Descriptive research has been used which involves surveys and fact findings.

- Study Area: The study area refers only Bangalore city, Karnataka.
- Sampling Procedure & Data collection: The data were collected through different sampling technique (re-

fers to different ways of sampling approach) and Primary data through an interview schedule was used as a tool for collecting the data.

- Frame work of Analysis: Percentage Analysis.
- Data Analysis and Interpretation.

4.1 Sampling Procedure

Random Sampling was carried out in Bangalore city, Karnataka, India. The data was collected through various sources like Management Guides Websites (response through internet) and Friends & Relatives, direct interviews.

During study, the data was collected as a whole and then segregated into various parts. Then, the collected data was organized and reviewed. Relevant data were taken into consideration and few data was kept for the reference purpose. Questionnaire with personnel interview conversation was done much relevant to the study. The collected data was considered and tabulated in the final stage of the report. Further, graphical representation (Histogram& Bar Diagram) was performed to interpret the results from the collected data.

The current study reveals the lean implementation aspects along with awareness within the employees were studied and represented below,

The following sources was reviewed / applied to understand the scope of lean aspects

Direct Interviews / Discussions conducted before / during the research study –

General discussions were performed across the peoples (above / below – Manager Level) just to understand the scope and awareness about the Lean aspects.

General discussion was made with the people to understand how the various sources help in understanding the Lean aspects.

Few aspects was considered e.g. Awareness from Management Guides which covers leading Management

books¹, Website – Through online search, Books / Literatures – During the study / Research articles, Business Process – While working in any management organisations.

4.2 Histogram Representation: Figures

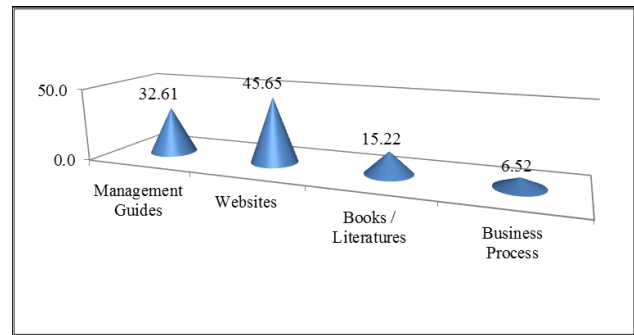


Figure 1. Above manager level.

4.3 Inferences

From the above data represented in the Figure 1, Above manager level data shows that (45.65%) of the respondents became aware through website and (32.61%) of the respondents through some of the management guidelines. Other awareness areas like books and literature (15.22%) and Business processes shows (6.52%) with reducing trend. If we look into the area of business process, this shows the less percentage of (6.20%) from the respondents.

4.4 Below Manager Level

Figure 2 shows that data shows that (31.52%) of the respondents became aware through website and (48.91%) of the respondents through some of the management guidelines. Other awareness areas like books and literature (14.13%) and Business processes shows (5.43%) with reducing trend.

Table 1. Available scope of the LEAN aspects in pharmaceutical industry (Lean aspects are Very high productivity, Short Lead Time, Product Quality value etc)

Sources of Awareness	Above Manager level		Below Manager level	
	No: of respondents	Percentage (%)	No: of respondents	Percentage (%)
Management guides	15	32.61	45	48.91
Websites	21	45.65	29	31.52
Books / Literatures	07	15.22	13	14.13
Business Process	03	6.52	05	5.43

Source: Secondary data

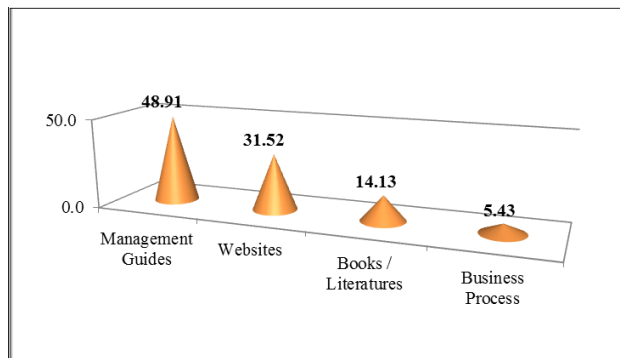


Figure 2. Below manager level.

If we look into the area of business process, this shows the less percentage of (5.43%) from the respondents. So, in current scenario of the competitive world, the pharmaceutical firms were not concentrating in the implementation of the lean management principles and methods. Hence, the implementation of the lean management principles is not the part of the business process.

The above data clearly indicates that the pharmaceutical firms are growing in the Industrial sector in many ways but they are not concentrating in the implementation of the lean aspects and management tools and aspects.

Based on the data, pharmaceutical firms should look into the scope of the management aspect to implement the lean management principles to enhance the operational excellence with more productivity.

5. Research Study / Survey - Through Questionnaire / Direct Interview

About 6 pharmaceutical Industries were surveyed through Questionnaire / Direct interview with the senior / middle level peoples in Bangalore city, Karnataka to understand the lean management principles involvement in the Pharmaceutical manufacturing environment (Which links the operational excellence).

The following management aspects are identified which in turn improves the operational excellence.

The major aspects which are identified in pharmaceutical environment as well as LEAN management principles are,

Very High Productivity, Robust Design, Manufacturing Capability, Validated process, Lead time, Product Quality

and Implementation of LEAN tools etc.

The above factors will immensely contribute to the Pharmaceutical industry in many ways for the operational excellence with balanced productivity and Quality.

5.1 Method of Survey

To understand current scenario in the Pharmaceutical industry, the survey questionnaire was prepared as per the research study requirement. Then, the selected Pharmaceutical firms were identified and visited. The survey questionnaire was distributed to the middle level management peoples and taken back with the comments. Further, the direct interview was performed at each senior level and information was collected and scrutinized as per the study requirement.

This study includes many stages:

- Defining the Lean Practices based on criteria such as the inclusion of practices that workers could observe, interact with and use on a daily basis;
- Defining the attributes for each practice, emphasizing the dimensions which were typical of their implementation in Lean Practices in pharmaceutical environments;
- Defining a set of evidence and sources of evidence for assessing the existence of each lean attribute – the sources of evidence included direct observations, analysis of documents, interviews and a feedback meeting to validate the assessment results with company representatives.

This study supports the identification of improvement opportunities in pharmaceutical performance based on the analysis of their interfaces.

Some peoples were not properly effectively during the course interview but few suggestions were taken as a part of research study.

Overall the responses / information's / suggestions received from the Pharmaceutical companies were found to be adequate for the research study and tabulated in Table 2.

To identify the Lean Aspects which improves the Operational Excellence in the Pharmaceutical Industry, the following survey and review was conducted in the various pharmaceutical firms and outcomes are tabulated (Table 2).

Note: The research survey (questionnaire / discussion) was conducted in the pharmaceutical companies with the Quality related peoples / teams (senior / middle level) in the various departments. Direct interview / discussion are conducted with questionnaire (above aspects) with 6 out of selected 11 medium and largest pharmaceutical firms.

Table 2. Survey related to lean concepts and aspects in the pharmaceutical manufacturing

Survey Questionnaire Focussed on the below aspects related to LEAN	COMPANIES SURVEYED FOR THE STUDY*					
	A	B	C	D	E	F
% Acceptance of LEAN implementation	75	50	75	50	75	25
% Robust Design & Process	25	50	50	50	25	50
% Manufacturing capability	75	50	75	50	75	75
% Very High Productivity	75	50	75	50	75	50
% Short Lead Time	25	25	25	50	25	50
% Validated process	25	50	25	50	25	50
% Product Quality	75	50	75	50	75	75
% Current level of Implementation of LEAN	25	25	25	25	50	25

Note:

- * ABCDEF refers to the various Pharmaceutical companies surveyed around Bangalore city, Karnataka.
- % refers to the Average data: Scale used in the Survey Questionnaire relates to the current quality system , Very Less - 25%, Moderate - 50%, Good - 75% Excellent - 100%

Source: Primary data, % calculated from 100%, hence data collected for comparison only.

(Name of the surveyed organization names not mentioned, but supporting questionnaire data is available). Source: Primary data, % calculated from survey.

6. Analysis and Data Interpretation

Existence of lean principles in pharmaceutical industry,

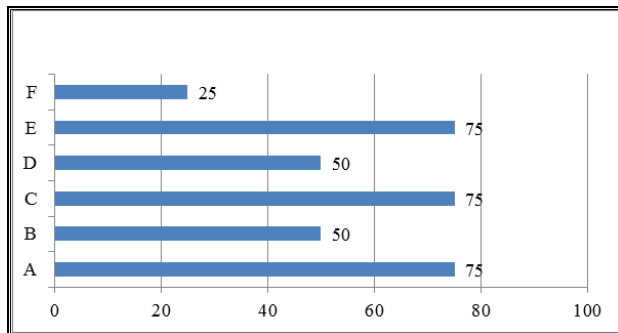


Figure 3. Acceptance of LEAN aspects..

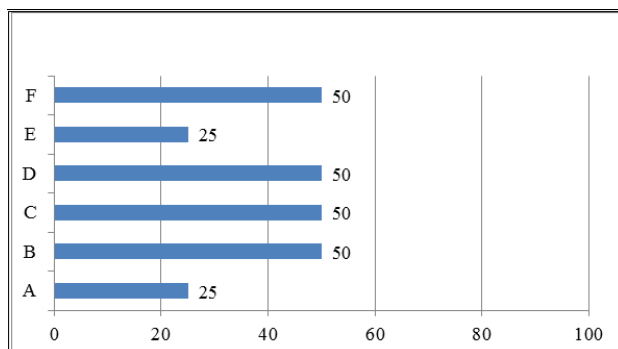


Figure 4. Robust design and process.

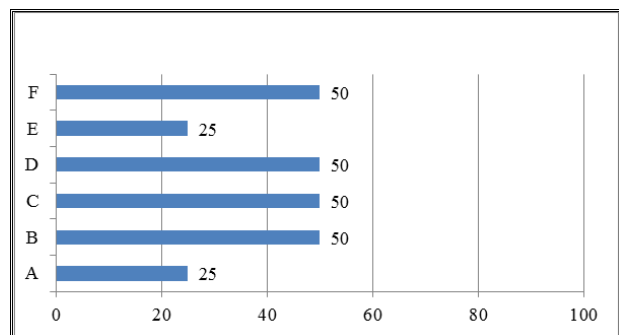


Figure 5. Manufacturing capability..

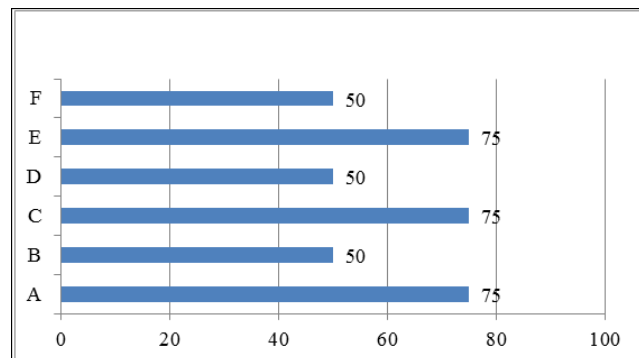


Figure 6. Very high productivity.

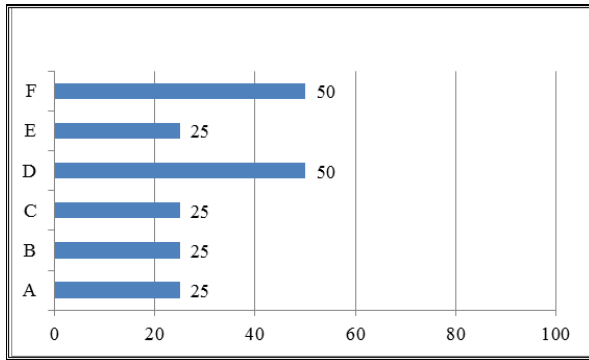


Figure 7. Short lead time..

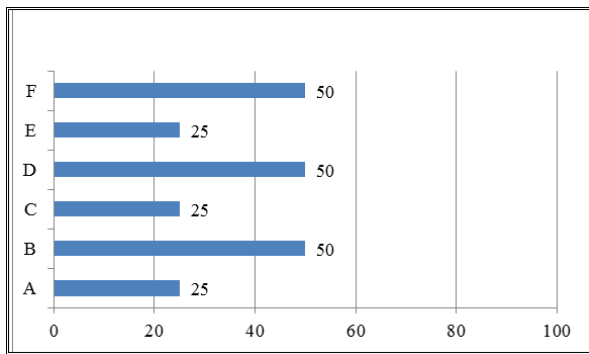


Figure 8. Validated process.

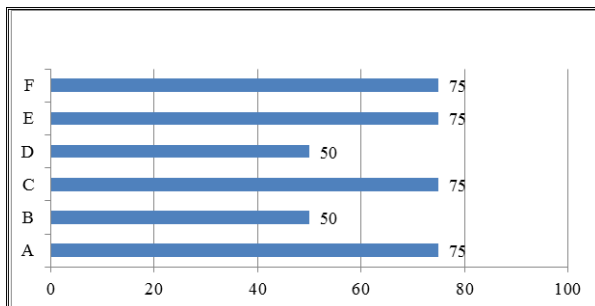


Figure 9. Product quality.

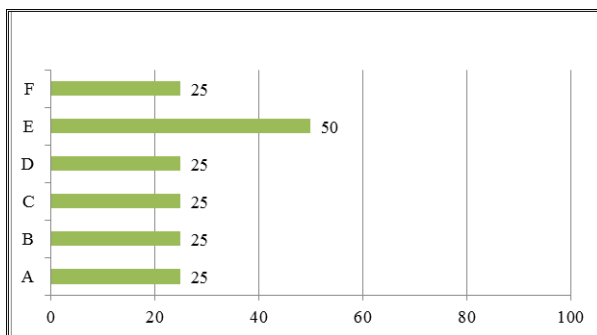


Figure 10. Current level of implementation LEAN.

7. Results / Discussion / Recommendation from the Outcome of Research Survey

From the above data represented in the graphs, it shows that many of the Pharmaceutical industries follow the good manufacturing practices but there was lot of scope for the implementation of the LEAN management principles to improve the operational excellence. Till today, the Pharmaceutical firms were mainly concentrating in the core aspect of ensuring the Product Quality through product development. Based on the initial survey / discussion, it was observed that there was lack of awareness about the lean principles in the various pharmaceutical industries. Most of the industries are concerned about the product quality with respect to cost and productivity.

Inference from the above survey:

Identification + implementation of lean = improved operational performance

Effective quality management systems for the companies are the integral part of the company because it enables them to provide quality products. Based on the survey data analysis, it was observed that most of the companies are focus in ensuring the product manufacturing. Some of the companies are in robust design and validated process but existing process validation data helps them in improving product quality.

Core lean aspects like Robust design; validated process, Lead time like lean principles are not much implemented and improved. The main cause for the same is due to the lack of training and business process was not clearly defined.

8. Limitations of the Study

Around 6 pharmaceutical industries are surveyed and studied. The most important factor to be viewed in the survey was the lack of understanding and weak implementation of the lean practices implementation around 25% in the Pharmaceutical sectors.

Most of the pharmaceutical companies focus on the product quality thereby looking into the other aspects like reducing the cost, creating value etc. The management should realize that Operational Excellence will be achieved only through the effective quality management system through the implementation of the Lean Methods And Practices.

In current scenario, many companies are following some process steps to achieve the best quality products. Based on the survey it was clearly understood that identified lean principles or methods to be implemented effective with proper understanding to improve operational excellence to ensure that system will yield the desired results.

9. Conclusion

Change is inevitable and the only constant in today's world. Every Pharmaceutical industry has to implement the quality management systems in line with the management principles and sustain in the ever changing environment. Pharmaceutical field is no exception to this.

During the course of the study, it was found that there was a lot of scope for the implementation of the lean management principles in pharmaceutical industry which was not clearly identified and implemented.

- Based on the research study & data, it was clearly states that in the recent years more focus given to the product quality and operational excellence. Moreover, some % of people was not aware completely about the scope of lean method and nature of the impact. But, if we look into the % business process for the awareness of the lean management it was found to be less and this would be the area for the scope of improvement.
- Many of the people in the industry were not involved in the quality system implementation activity. Based on the management guidelines and training activities most of the lean principles to be implemented. Further, the higher management people are not completely transparent on their policies and procedures to implement the lean management principles in the pharmaceutical environment.
- Based on this research study, primary data review & research survey we have derived that employee knowledge on the lean management to be improved and senior level people should implement the lean management principles. A well-designed LEAN implementation enhances the operational excellence tremendously.

The lean management principles derived from this research study are represented above which is to be implemented effectively in the Pharmaceutical environment to enhance the Operational Excellence - High productivity, short lead time with operational excellence and improve product quality.

10. Outcome of the Research Study

A Continuous effort is essential to identify and implement the LEAN practices and principles in the Pharmaceutical sectors to ensure the Operational Excellence.

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