

Sketching Out the Hidden Lean Management Principles in the Pharmaceutical Manufacturing

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ABSTRACT: In Recent times, pharmaceutical companies are faced with the demanding tasks such as adjustments to the unstable and turbulent market in times of economic crisis as well as to meet the customer needs. The pharmaceutical industry, manufacturing in a current Good manufacturing practice (cGMP) environment has been slow to adopt the lean manufacturing unlike many sectors where it has been successfully deployed. One of the major concern for many pharmaceutical manufacturers looking to implement a lean methodology is how to integrate the Lean methods into its current good manufacturing practice (cGMP) environment, where the main aim to deliver a safe and effective medicinal product. 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 hidden lean management principles existing in the pharmaceutical manufacturing and thereby improve the quality of products and services through the focused implementation of the lean principles.

Index Terms: Lean methods, Quality, cGMP, Costs

I. INTRODUCTION

Nowadays, several large pharmaceutical organizations had shown a willingness to simplify operations, processes and reduce costs via lean management practices. Today, the Pharma industries are under tremendous pressure to improve its competitive business: R&D methods, manufacturing efficiency and whole supply chain performance. These organizations are scrambling to find ways to cut costs. Healthcare providers are continuously feeling the pressure to manage costs and launch new product in the market. Lean strategies have been developed to eliminate or reduce waste and thus improve operational efficiency in a manufacturing environment.

In any Healthcare industry where success is increasingly driven by satisfaction scorecards, reliable access to key talent is essential for meeting the demand for quality service. At the same time, the difficulty of ensuring a reliable supply of quality products and professional talent is challenging the status quality of traditional talent acquisition strategies. Over the last decade lean management 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 principle 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 of improvement and motivates them to apply those tools every day.

Lean therefore, must go beyond just the manufacturing process and business strategy and it involves at employees at all levels.

Current Industry trends shows that many pharmaceutical manufacturers are following some of the lean manufacturing principles in the way for significant improvement of operational efficiency and quality, while facilitating compliance. Few of the Lean principles are existing in the Pharma environment without the proper focus by the management. To ensure a solid position on the market and competitive advantage they are looking to increase the efficiency of their operational and manufacturing process - optimizing resources, improving efficiency, reducing waste and controlling inventory.

Uncertainty is a corollary of change. 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. Every new implementation / process change brings with it some concomitant uncertainty due to the change in the existing business workflow and processes. Nowadays, Pharma industry faces the dilemma between pursuing the competitive advantage of cutting edge technology and the risk of uncertainty associated with it.

Pharma Manufacturing firms are one of the prime strategic functions of any business. Whether or not manufacturing operations achieve their strategic potential and contribute to the competitive position of the business depends on how they are managed (Kasul & Motwani, 1995).

II. OBJECTIVES / IMPORTANCE OF THE STUDY

This research study involves in the “**Sketching out the Hidden Lean Management Principles involved in the Pharmaceutical Manufacturing**”. The research study is to find out the hidden lean management principles in the Pharma 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,

- Discussion about organizational structure and quality management system followed in the selected pharmaceutical firms in Hyderabad, Andhra Pradesh.
- Factors influencing quality system management in small, medium and large pharmaceutical firms.
- What are steps implemented to improve the quality / productivity to larger extent in the surveyed pharmaceutical firms?
- How the whole system functions towards the product quality with respect to cost and productivity?
- Identify the factors which determine 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. (Tools / Goals)
- Where lean management principles can be applied effectively.
- What is the business process and workflow?
- Comparison of the cGMP in the Pharma environment and lean principles and identify the areas for the improvement.
- To offer suitable suggestions for improvement, conclusions in the implementation of the lean management principles in the pharmaceutical firms to enhance the operational efficiency, improve the productivity and reduce the cost.

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

III. UNDERSTANDING THE ASPECTS OF LEAN IN PHARMA INDUSTRY

3.1 STATEMENT OF THE PROBLEM

Many Pharmaceutical companies began lean manufacturing projects or even embraced complete supply chain transformation programs several years ago. However, in most cases companies took only few steps towards lean manufacturing before 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. Faced with a similar but more extreme challenge 20 years ago, manufacturers from other industries learned how to make significant, sustainable improvements to their profitability by taking a holistic look at their overall cost structure.

Pharmaceutical firms mainly focused on the required quality and compliance standard of pharmaceutical manufacturing are often cited as limiting factors in creating greater efficiency, many companies do better. Although the pharmaceutical industry tends to view itself as unique—which in some ways it is—pharmaceutical companies can learn several lessons from the companies that made the difficult but essential transformation to lean manufacturing.

Many Pharma companies started from the false assumption that implementing lean processes would automatically lead to a reduction in overstaffing. In fact, lean processes only address the lack of process optimization. In fact lean processes require leadership from the top level of the company and at each subsequent level. Many companies initially believed that becoming a lean manufacturer would take about two years. However, they discovered that lean manufacturing is such a different method of operation that achieving full implementation takes four to five years.

Bringing about the lean principles in Pharma is easier said than done. For any implementation – people, technology and processes that form the backbone of business are receptive to the inherent change. In particular, the Pharma industries may limit the degree to which this industry can adopt lean supply practices. Mostly, regulatory authorities do not necessarily share the view that lean manufacturing and GMP standards are comparable. Absolute supply security is such a high priority in the pharmaceutical industry that full implementation of lean manufacturing is nearly impossible to achieve.

First step towards the lean is to understand and accept the need for change. Despite its focus on quality, it is the fact that pharmaceutical industry has failed to keep up with other industries in terms of manufacturing efficiency and productivity, the main reason for this being high costs and burden involved in revalidating any process change, even though changes were made in the spirit of improvement.

From the historical perspective, pharmaceutical manufacturers who had high profits margins had not enough economic stimuli to introduce changes. It is estimated that the world wide potential cost savings from efficiency improvement in pharmaceutical industry could be as high as 90 billion dollars per year.

In the past, pharmaceutical industry for which the principles of good manufacturing practice are mandatory, has slowly been embracing lean manufacturing, in contrast to other sectors that adopted it relatively quickly and successfully.

Therefore, this study emphasis on the finding out the hidden lean principles in the pharmaceutical industry and thereby improve the productivity and operational efficiency.

3.2 HYPOTHESIS OF THE STUDY:

3.2.1 UNDERSTANDING THE LINK BETWEEN LEAN AND PHARMA ENVIRONMENT:

Lean's dual objectives, to reduce or eliminate waste and to create value, differ from cGMP objective which is to ensure that controls are in place to deliver a safe and effective medicinal product. In most cases, cGMP and lean management principles do overlap in the pharmaceutical manufacturing environment. So, effective lean management principles to be identified in the Pharma environment and utilised to improve the operational efficiency.

Most of the industries are concern about the product quality with respect to cost and productivity. While considering important research issues, it was found that there is a definite role for management in quality control and quality assurance in implementing lean principles. Only if quality control and quality assurance are strictly adopted, the management goals such as name of the company, sales and profits could be achieved since due to effective quality systems the company would be producing quality products.

Also through quality control and quality assurance cost reduction could be obtained. Moreover only through proper adoption of quality practices, price of products can be competitive, sales and market share also may increase. At present, it is found that there is a lack of coordination between management function and proper quality enforcement. 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.

Lean and cGMP aspects could exist when two groups interact:

- 1) Existing quality principles involved in the optimization of the processes and
- 2) Implementation efficiency of the Identified management principles.

Sometimes it takes decades to implement 100% of the identified management principles. Quality management system does not depend upon the capital investment and percentage of operating expenditure on quality control / quality assurance.

As more and more of the lean methodology implementation in the health care business is preceded this way, the concept of a technology implementation to the customer and acceptance of the system will be difficult but it takes long pathway to accept in the society.

IV. 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.

4.1 Study Area: The study area refers only Hyderabad city, Andhra Pradesh.

- 4.2 Sampling Procedure & Data collection: The data were collected through different sampling technique (refers to different ways of sampling approach) and Primary data through an interview schedule was used as a tool for collecting the data.
- 4.3 Frame work of Analysis: Percentage Analysis.
- 4.4 Data Analysis and Interpretation.

Sampling Procedure: *Sampling was carried out in Hyderabad city, Andhra Pradesh, INDIA. The data was collected through various sources like 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, Histogram graphical representation was made to interpret the results from the collected data.

The current study reveals that the customers awareness of the healthcare market innovations, trend in markets were studied and represented below,

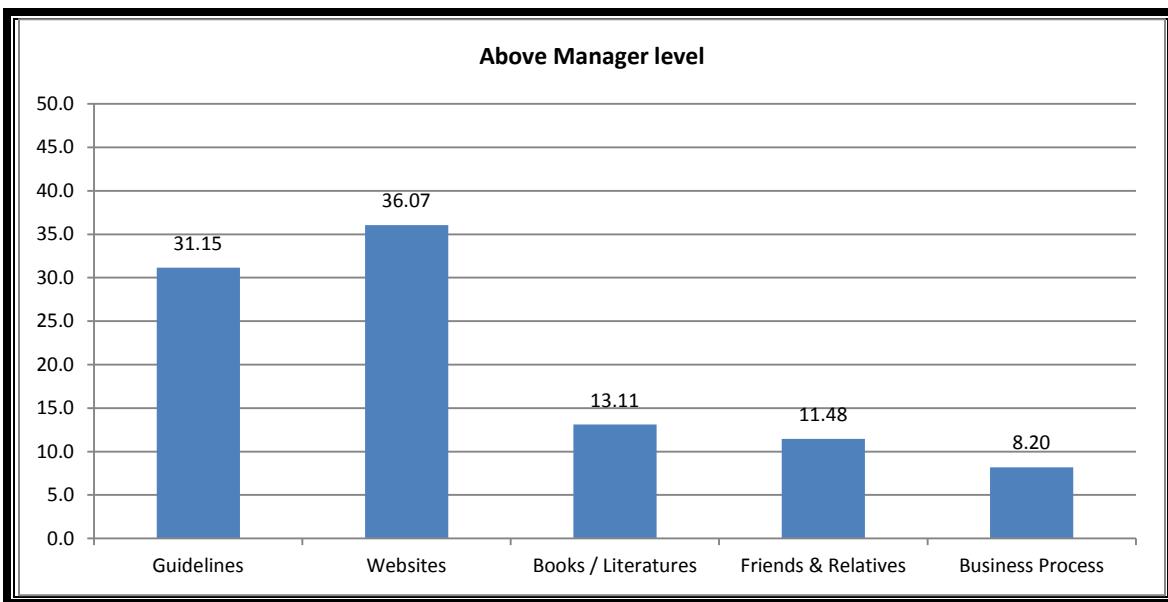
Table1. Source of awareness on LEAN aspects in Pharma industry: (*Lean aspects are Operational efficiency, Reduce cost, Quality, creating value etc*)

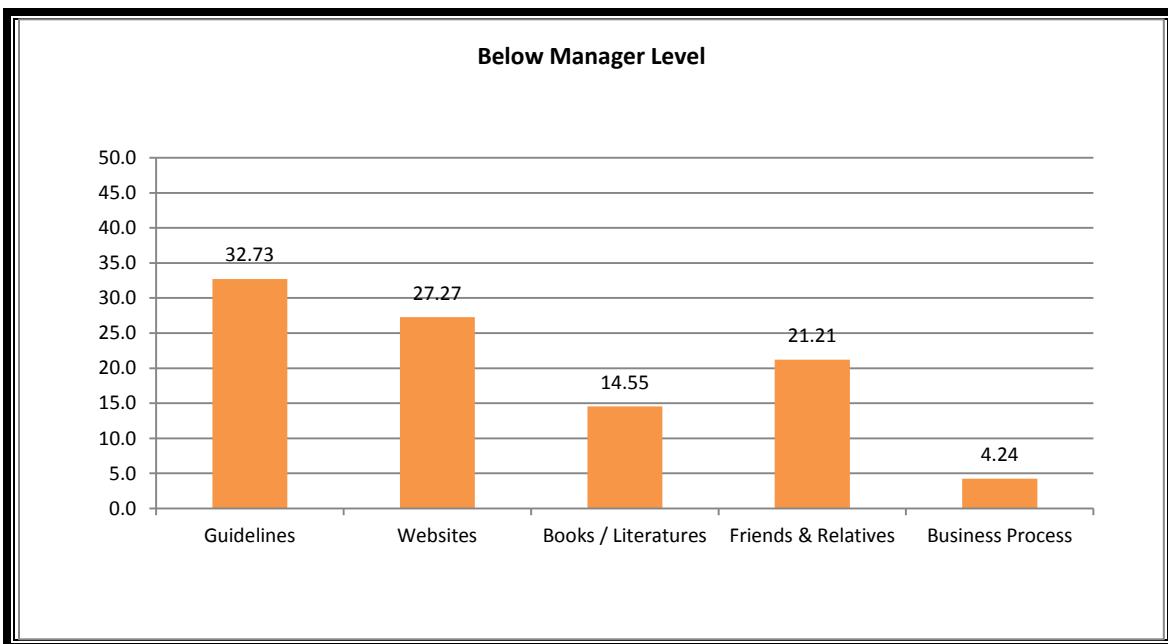
Sources of Awareness	Above Manager level		Below Manager level	
	No: of respondents	Percentage (%)	No: of respondents	Percentage (%)
Guidelines	19	31.15	54	32.73
Websites	22	36.07	45	27.27
Books / Literatures	08	13.11	24	14.55
Friends & Relatives	07	11.48	35	21.21
Business Process	05	8.20	07	4.24

Source: Primary data

Histogram representation: ANNEXURES

Table1. Source of awareness: LEAN aspects in Pharma industry. (Y axis refers the % awareness)





INFERENCES:

From the above data represented in the table 1, (**Above manager level**) data shows that (36.07%) of the respondents became aware through website and (31.15%) of the respondents through some of the guidelines. Other awareness areas like books and literature (13.11%) and friends & relatives shows (11.48%) with reducing trend.

If we look into the area of business process, this shows the less percentage of (8.20%) from the respondents.

Below manager level data shows that (32.73%) of the respondents became aware through Guidelines and (27.27%) of the respondents through some of the website. Other awareness areas like books and literature (14.55%) and friends & relatives shows (21.21%) with reducing trend.

If we look into the area of business process, this shows the less percentage of (4.24%) 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 management tools and aspects.

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

To identify the HIDDEN LEAN MANAGEMENT PRINCIPLES in the cGMP environment, the following review was conducted in the various pharmaceutical firms and outcomes are tabulated below,

Table 2 Awareness on the primary focus of cGMP aspects in the Pharma manufacturing:

cGMP Focus	cGMP Prospective		Hidden Lean management principles	
	No: of respondents	Percentage (%)	Link with cGMP (Yes / No)	Aspects
Ensure product effectiveness	All	100%	Yes	Reduce waste Create Value
Prevent Harm to patients	All	100%	Yes	
Product				

Development	77	77%	Yes	Value Stream, Quality Balanced with productivity
Process Robustness				
Regulated / Prudent				
Manufacturing capability	67	67%		
Quality Assurance	48	48%	Yes	Reduce cost, Improve Quality, Reduce cycle time, Reduce delivery time
Reduce complaints				
Prevention of deviations				
Reduce failures				
Validated process				
Quality Control	55	55%	Yes	Improve Quality
Quality First				
Minimize inventory or stocks	24	24%	Yes	Reduce cycle time
Minimize Errors	35	35%	Indirect Impact	Simple flow, Error Proofing, Quality function deployment
Documentation and Personal Training				
Validation and qualification				
Product stability	64	64%	Indirect Impact	Create value

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

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 8 out of selected 17 largest pharmaceutical firms. (Name of the surveyed organization names not to be disclosed, but supporting questionnaire data is available).

V. RESULTS / DISCUSSION FROM THE OUTCOME OF SURVEY

From the above data represented in the table 2, it shows that many of the Pharmaceutical industries follow the cGMP prospective which are in line with the LEAN management principles. Till today, the Pharma firms were mainly concentrating in the core aspect of ensuring the product effectiveness through innovative product development. The most of the hidden lean management principles are indirectly linked with the cGMP aspects.

It was decided to study the depth of implementation process of the cGMP / LEAN aspects reflected in the table 2. Based on the initial survey / discussion, it was observed that lot the lean management principles exist in the various pharmaceutical industries.

Most of the Pharma industries are concerned about the product quality with respect to cost and productivity.

RESEARCH STUDY / SURVEY – THROUGH QUESTIONNAIRE / DIRECT INTERVIEW

About 8 pharmaceutical Industries were surveyed through Questionnaire / Direct interview with the senior / middle level peoples in Hyderabad city, Andhra Pradesh to understand the Existing / Hidden lean management principles and cGMP practices in the Pharma manufacturing environment.

The following management aspects are identified which in turn improves the product quality. The major aspects which are identified in cGMP environment as well as LEAN management principles are

Reducing Waste, Create Value, Value Stream, Quality balances with productivity, Reduce cost, Process design, Reducing the process variations, Error Proofing, Risk analysis, Implementation of quality tools etc.

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

5.1 METHOD OF SURVEY:

To understand current scenario in the Pharma industry, the survey questionnaire are prepared as per the research study requirement. Then, the selected Pharma firms were identified and visited. The prepared questionnaire was distributed to the respective department 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 research study provides a framework for assessing the use of lean production (LP) practices in cGMP manufacturing. This study includes many stages: (a) defining Lean Practices applicable to cGMP, based on criteria such as the inclusion of practices that workers could observe, interact with and use on a daily basis; (b) defining attributes for each practice, emphasising the dimensions which were typical of their implementation in LP in cGMP environments; (c) 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; (d) drawing up a model of the relationships among the Lean Practices, based on a survey. This study supports the identification of improvement opportunities in cGMP 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 / informations / suggestions received from the Pharma companies were found to be adequate for the research study and tabulated in Table 3.

Table 3 Focus of LEAN aspects in cGMP environment:

cGMP Prospective / Hidden Lean management principles	Name of Companies surveyed (% given based on implementation)							
	A	B	C	D	E	F	G	H
Ensure product effectiveness	75%	75%	75%	75%	75%	75%	75%	50%
Product Design & Development	75%	50%	50%	50%	75%	50%	75%	25%
Manufacturing capability	50%	50%	50%	50%	75%	25%	50%	75%
Reduce complaints / Deviations	75%	50%	75%	50%	75%	50%	75%	50%
Reduce Waste	50%	25%	25%	50%	25%	50%	50%	25%
Validated processes	50%	50%	75%	75%	75%	50%	75%	25%
Minimize inventory or stocks	50%	50%	50%	25%	75%	25%	50%	50%
Create Value / Value stream	50%	25%	25%	25%	25%	50%	25%	25%
Reduce cost	25%	50%	50%	25%	50%	75%	50%	50%
Quality balanced with productivity	50%	25%	50%	25%	50%	25%	25%	50%
Effective Implementation of LEAN principles in cGMP environment	25%	25%	25%	25%	50%	25%	50%	25%

Source: Primary data, % calculated from survey.

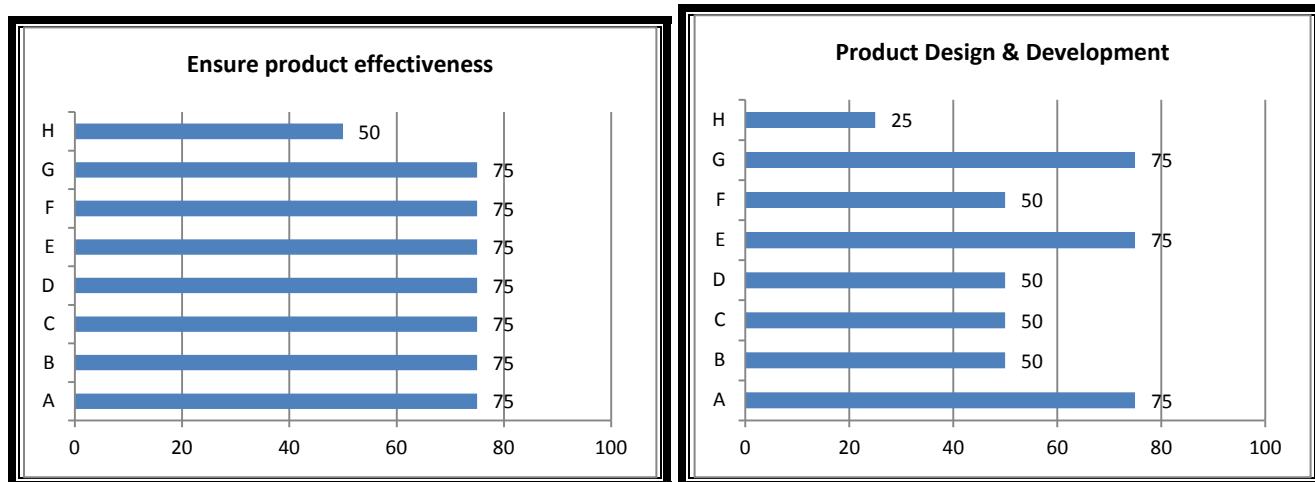
Information about the surveyed companies in Hyderabad:

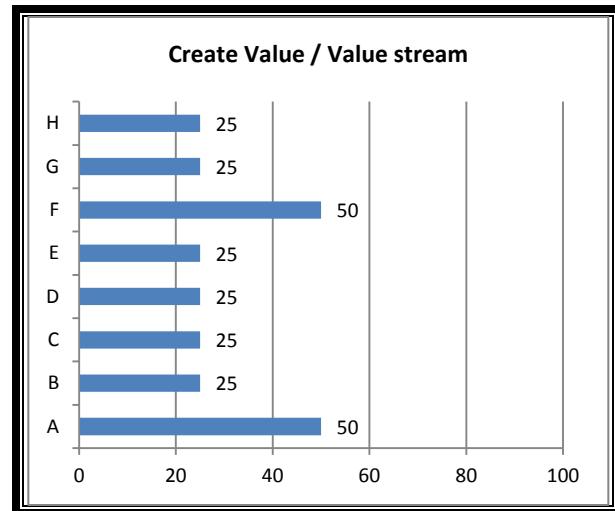
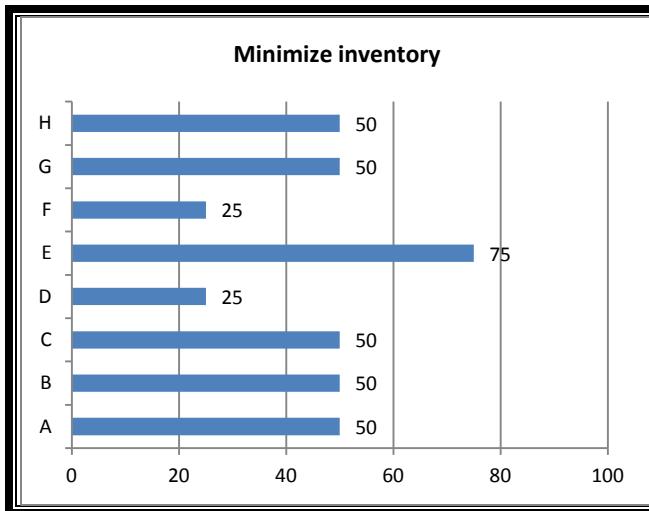
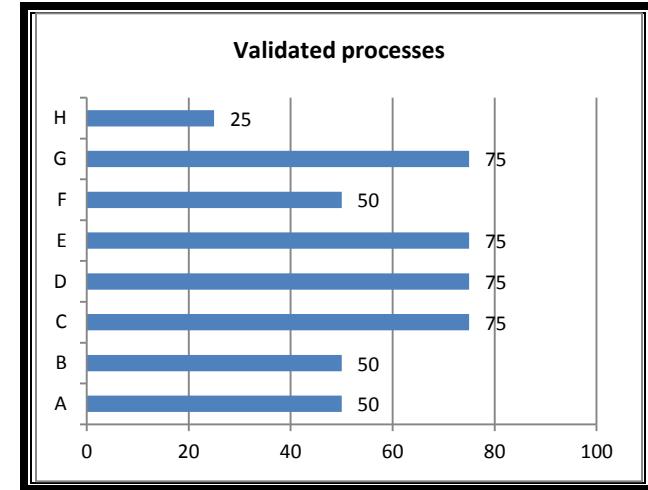
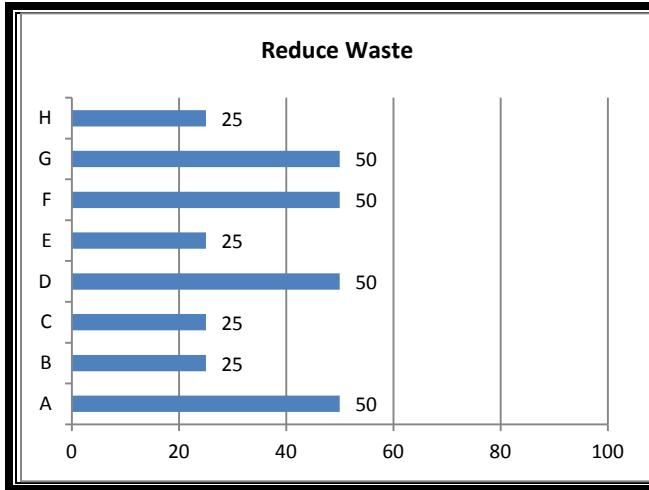
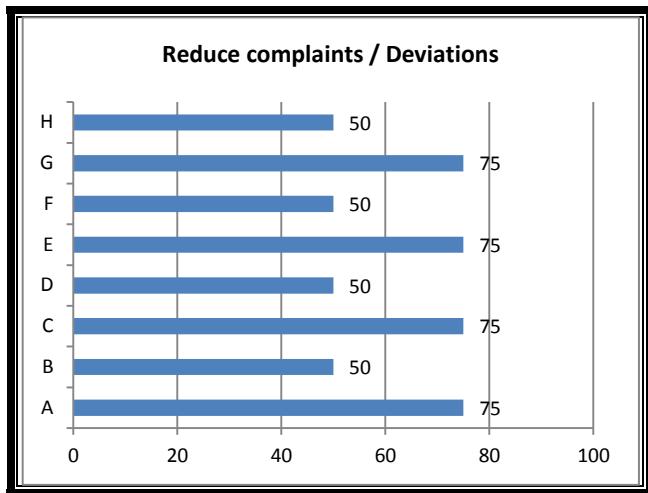
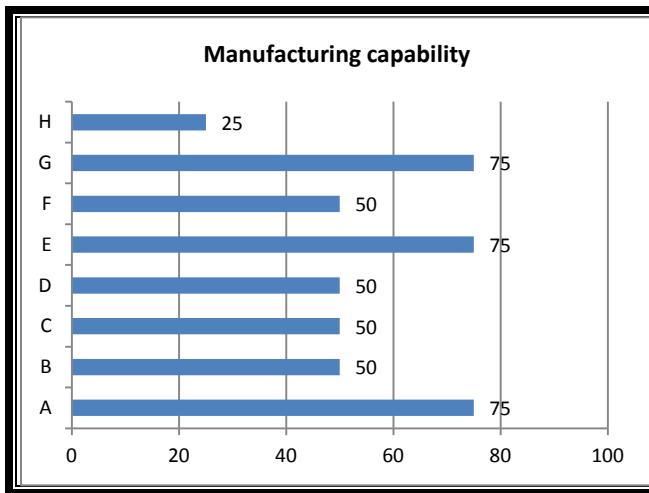
- A) XXXX Pharma limited:
 - * Formulation Unit
 - * Manufacture of the solid oral dosage forms e.g. Tablets

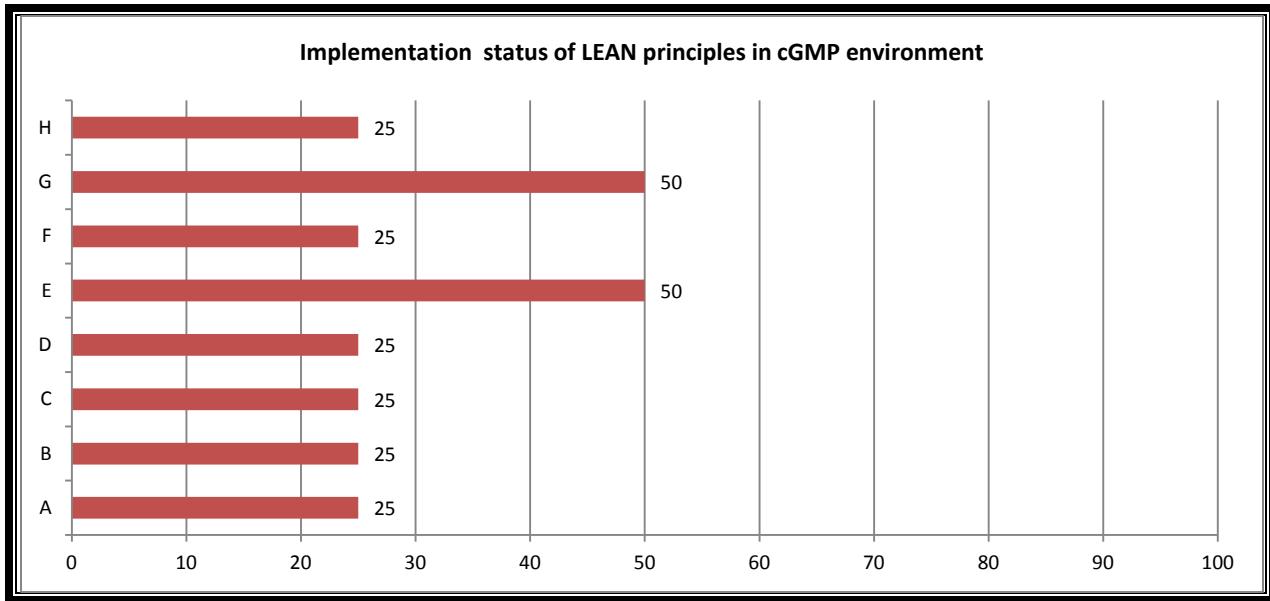
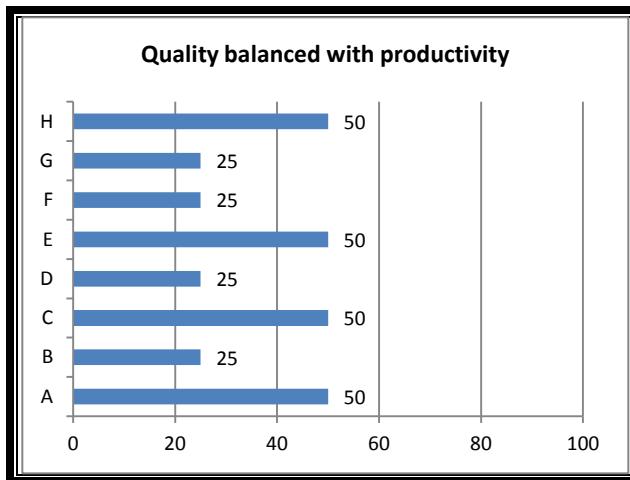
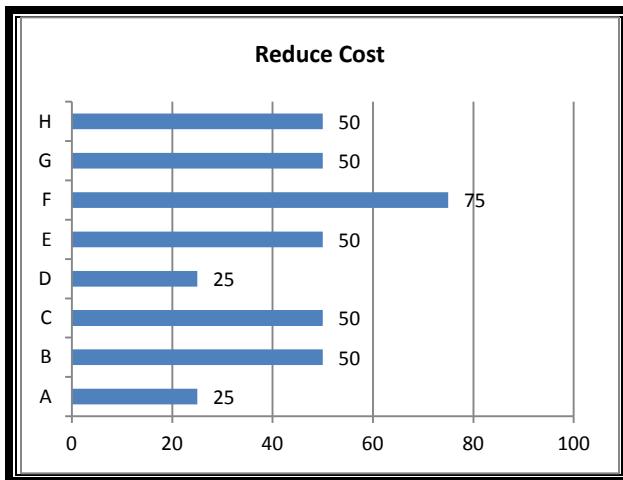
* Facility approved by USFDA, ISO 9001:2008 standards

- B) XXXX Pharma limited:
* Research & Development & Formulation Unit
* Manufacture of the General category & solid oral dosage forms e.g. Tablets, capsules
* GMP Facility
- C) XXXX India limited:
* Formulation Unit
* Manufacture of the solid oral dosage forms e.g. Tablets
* Facility approved by USFDA standards
- D) XXXX limited:
* Formulation Unit
* Manufacture of the solid oral dosage forms e.g. Tablets and Injections
* Facility approved by USFDA standards
- E) XXXX Pharma limited:
* Formulation Unit
* Manufacture of the solid oral dosage forms e.g. Tablets and Injections
* Facility approved by USFDA standards
- F) XXXX Labs limited:
* Formulation Unit
* Manufacture of the Eye Drops / Injectables
* Facility approved by USFDA standards
- G) Dr. XXXX Laboratories ltd:
* Formulation Unit
* Manufacture of the Injections & R&D
* Facility approved by USFDA, MHRA standards
- H) XXXX laboratories limited:
* Formulation Unit
* Manufacture of the solid oral dosage forms e.g. Tablets, Capsules
* Facility approved ISO 9001:2008 standards

IMPLEMENTATION STATUS OF LEAN PRINCIPLES IN cGMP ENVIRONMENT,







INFERENCE FROM THE ABOVE SURVEY: Lack of LEAN implementation (around 25% only)

IDENTIFICATION + IMPLEMENTATION OF LEAN in cGMP = PRODUCT QUALITY

Effective quality management systems for the companies are the integral part of the company because it enables them to provide products and services that are useful for the targeted consumers. Based on the survey data analysis, it was observed that most of the companies are focus in ensuring the product effectiveness and patient safety. Some of the companies are in lack of research and development activities but existing process validation data helps them in improving product quality. Core lean aspects like reducing the waste, create value principle are not much improved. The main cause for the same is due to the lack of training and business process was not clearly defined. Minimum inventory and quality balanced with productivity aspects are marginally applied to the quality systems in the existing cGMP environment.

The most important fact to be viewed in the survey was the lack of understanding and weak implementation of the lean methods around 25% of implementation in the cGMP environment. 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 effective product quality will be achieved only through the effective quality management system through the implementation of the lean methods. 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 in cGMP environment with proper guidance to improve operational excellence to ensure that system will yield the desired results.

VI. CONCLUSIONS

Change is the only constant in today's world and every industry has to implement the quality management systems 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 Hidden lean management principle in cGMP environment 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 area. Moreover, some % of people was not aware completely about the 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 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 cGMP environment. So, the Employees should need complete education and training about lean methods implementations in the cGMP area.

Based on this research study, primary data review & research survey of the Pharma we have derived that employee knowledge on the lean management to be improved and senior level people should implement the lean management principles in cGMP environment. A well-designed implementation of a cost of quality system not only reduces the costs but also enhances the reliability of product quality.

The following hidden lean management principles derived from this research study are represented below which are to be implemented effectively in the cGMP environment to enhance the operational excellence and product quality.

- 1) Identify the Product life cycle and Process variations – Create value
- 2) Implement Lean methods effectively in cGMP environment
- 3) Ensure effective product development
- 4) Implement quality systems to ensure product quality & safety
- 5) Reduce inventory / Error Proofing / Reducing Risks
- 6) Process design / Create value

Outcome of the study

A constant effort is essential to implement the LEAN management principles in the cGMP environment for the manufacturing of the pharmaceutical products to ensure that the product quality and safety for the patients.

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