Lean Manufacturing: Implementation and assessment in the Lebanese Pharmaceutical Industry

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Abstract

Lebanese industries are growing so fast and expanding their businesses while managing their time, inventory, labor, quality and other production factors in order to increase productivity and output while reducing waste. For that, lean manufacturing aims to reduce the inventory and gain more profits while getting a better quality of the goods delivered to the customers.

The aim of this Article is to assess and explain, through a survey, to which extent lean tools are implemented in a Lebanese pharmaceutical industry and to find out if there is any relationship between the application of these tools (Kaizen, JIT, TPM and standardization) and the effectiveness of lean on the productivity.

Keywords: Lean, Kaizen, Total Productivity Maintenance, Just In Time, Standardization, 5S, Effectiveness

I. Introduction

Industries around the world manufacture different types of products and deliver them to the customers in order to satisfy the market need. These products pass through a whole process since

the receipt of the raw materials from the supplier, going through all the manufacturing, packaging and testing stages until the delivery of the final good to the customer.

Many authors described "lean manufacturing" as a strategy aiming to decrease waste, costs and increase productivity of the firm. This concept evolved over the years and many companies across the globe tried to implement it while others preferred to adopt the traditional manufacturing process and resist change.

It generates a production cost reduction, manufacturing time cycle decrease, inventory reduction, higher quality, flexibility, higher profits and a cash flow improvement.

In this article, we will define the lean manufacturing strategy, starting from its origin and concept, then describing all the methods and tools followed in order to achieve the best productivity of the firm while reducing the wastes.

For this, we will take the case of a Lebanese industry that has its plant in Lebanon, manufactures locally then delivers the products and services to the customers in Lebanon and in several countries across the globe.

The wastes that are occurring in the Lebanese industries are reducing the productivity leading to higher cost and to lower quality of the finished goods delivered to the clients. These wastes have a negative effect on the performance of these firms, their profitability and their output.

The aim of this study is to identify, through a survey, to which level lean manufacturing is being implemented in the production department and this on the different employees' levels and to identify if a relation exists between the application of lean tools and the productivity of the firm.

II. Review of literature

Lean manufacturing is a strategy that aims to reduce the different types of wastes encountered in the production cycle thus generating higher profits, better quality and customer value.

The benefits of the production cycle are increased and this through a reduction of the work needed, of the wastes encountered, of the inventory in stock, of the capital needed and of the resources used. (Tinoco, Implementation of lean manufacturing, 2004)

It works on different levels from customer service, production, quality and this since the receipt of the raw materials from the suppliers to the final delivery of the products to the customer.

It aims at reducing the non-added value activities and redirecting the non-added value activities to added-value activities.

Lean can be applied to all types of industries and services. It is not a short-term strategy but a long-term vision of the overall corporate production process and strategy. (What is lean - History, 2009)

2.1. Origin

Henry Ford and his right-hand-man Charles E. Sorensen first integrated lean manufacturing in 1913 and they created the flow of production, also known as mass production.

Ford tried to group the manufacturing steps into a sequence of operations using special-purpose equipments. This made the work faster and the quality of the product better but Ford could not deliver a variety of products to customers.

Afterwards, many industries tried to elaborate and ameliorate Ford's strategy and expand their research in order to get a faster production cycle.

Then, Japanese engineers from Toyota, Taiichi Ohno and Shigeo Shingo, reviewed Ford's concept and invented the "Toyota Production System" in 1930. They tried to adjust the production capabilities to the batch size ordered by the customer while delivering a variety of products and a continuous workflow. They also introduced right-sizing machines to ensure the quantity needed, self-monitoring machines to ensure the best quality and they pioneered quick changeovers.

The "pull system" was then established whereby each step will notify the following step of the materials needed to keep the flow of materials smooth and the work performed faster and easier with less costs and inventory. (History of lean manufacturing, 2012) (Lee, 2003)

Nowadays, Toyota is succeeding in many countries of the world and this by applying lean manufacturing tools.

2.2. Lean wastes

Lean wastes have been developed by lots of authors who studied lean manufacturing and who tried to identify the reasons behind the high costs of production.

Tinoco (2004), Vu (2007) and Miller, Pawloski, & Standridge (2009) described seven types of waste as follows:

1. Waiting consists of the time needed between steps due to quality inspection and testing, space between stages, which can delay the process and add non-value added activities.
2. Overproduction is linked to non-required items leading to high cost and bigger inventory.
3. Excess inventory consumes a lot of time and needs a bigger storage thus increasing the cost.
4. Over Processing is when industries purchase more sophisticated equipment than needed.
5. Defects lead to a rework operation or a destruction of the units produced; consequently to a waste of products and time.
6. Transportation waste occurs when operators do not move the products with care and focus causing defects.
7. Motion includes movement of the employees in addition to health and safety issues.

2.3. Methods and tools

Wastes need to be eliminated/ reduced from the product life cycle in order to have a smooth production and an efficient process. For this, companies adopt one or several tools and methods to assure the reduction and the elimination of these wastes.

The lean tools are discussed as follows:

- Just in time by using the quantity needed, the time frame required and assuring the best quality of product for the customer and this to operate in a faster way.
- 5S Visual Workplace: this tool assures the continuous improvement by ameliorating the cleaning performance. 5S steps are sorting (to eliminate useless items), shining (to keep workplace clean), setting in order (to keep everything in place), standardizing and sustaining (to assure continuity).
- Standardized Work in order to eliminate unnecessary inventory by the first line supervisors.
- Total Productive Maintenance (TPM) ensures a better performance of the equipment by maintaining them in a good condition thus reducing the risk of troubleshoot and failure.
- Load Balancing aims to reduce the batch size to meet customers' demand on time.
- Pull & Kanban Systems: it states all the information of the current stage and which parts are needed for the next stage in order to respond quickly to the changes in the process for a better coordination.
- Work Cells: each step needs to be completed before the next one is initiated in order to better organize the work, to reduce the in-process inventory and to reduce the labor costs as different machines work simultaneously.
- Rapid Changeover (SMED): it aims to fasten the way the changeover is performed in order to reduce non-value added activities and the high costs generated from the waiting.
- Mistake-Proofing: it aims to reduce or prevent errors.
- Kaizen or "Continuous improvement" aims to involve all employees in the operation process and this training them and coaching them on their tasks.
- Value Stream Mapping (VSM) is a visual representation of the whole production process in order to eliminate all non-value added activities, emphasis on the value-added activities in the process and identify waste.

2.4. Lean and cGMP environment

Pharmaceutical industries, work in a cGMP environment in order to deliver the best quality of products for the customer and this through a whole production and testing process.

The current good manufacturing practices (cGMP) are regulations set by the US food and drugs administration. GMP tends to provide a consistency in the operations and a control of the quality in order to meet the standards. (Chowdary & Damian, 2012)

According to the US FDA, adhering to GMP requirements assures the quality, purity and the strength of the medication that is produced. In addition, it prevents risks of cross-contamination, deviations, mix-ups or any error that can occur in the production cycle. FDA mentions that these requirements are flexible and need to be updated on a regular basis, from which comes the name "current" before the GMP name.

One of the basics of cGMP is the existence of a big number of documentations, qualifications and audits. Each procedure and operation requires a certain documentation to follow and to report for better achievement of the control. It doesn't tend to reduce the product cycle time but focuses more on the quality rather than on balancing quality with productivity as lean does.

III. Procedures and Methodology

The methodology used is a survey that was distributed to employees from different levels of the organization going from the top managers to the employees passing through middle managers and supervisors.

3.1. Research problem

The wastes that are occurring inside the Lebanese industries are reducing the productivity leading to higher cost and to lower quality of the finished goods delivered to the clients as discussed previously.

The aim of this article is to identify how lean is implemented in a cGMP environment, especially in its production cycle and try to find out how it is evaluated on the diverse workers' levels.

Therefore, the problems that will be discussed will mainly cover the following issues:

- Wastes, that need to be eliminated, are occurring at different stages of the production cycle leading to less productivity.
- Employees who may resist change may not perceive lean tools application the right way.
- Many barriers that are preventing lean from being implemented the right way.

3.2. Research questions

The problems will be addressed by answering the following research questions:

- RQ1: Do managers and team members know about lean manufacturing principles?
- RQ2: Are lean tools applied inside the industry? How is this assessed from different levels of employees?
- RQ3: Do lean tools have a positive impact on the productivity?

The first two research questions will be answered after testing the first Hypothesis. As for the second hypothesis, it will answer the third research Question.

3.3. Hypotheses

- H1: Lean manufacturing tools are seen as an efficient management tool more and more adopted/implemented in the production cycle.

- H2: Lean manufacturing tools will increase the productivity by reducing waste.

3.4. Research design and methods

The research is based on a survey that was developed in order to assess the implementation of lean tools and this by taking the input of employees from different departments and levels.

The methodology used is qualitative. It will cover lean tools application and the main problems employees are facing in their daily tasks.

The survey will help identify the impact of factors such as changeover, operator involvement and skills (kaizen), equipment performance (total productive maintenance) and standardization of the work on the elimination of waste.

Cronbach's alpha will test the reliability of the survey in order to measure the internal consistency of the research that was performed. This will be calculated using "SPSS" Statistics for Statistical Analysis, Reliability testing and Analytical Process (Regression, Correlation,...).

Furthermore, two other techniques were used in order to verify the results from a personal point of view:

- A focus group performed on 8 team members from the production department.
- An in depth-interview conducted with the production supervisor

3.5. Sample and data collection methods

A sample of 100 people involved in the operations were asked to fill the survey. Only 70 employees replied. It grouped employees from several departments involved in the production cycle from managers, to supervisors to team members and this to take into account all the factors that might affect production.

The survey was individually distributed to employees in hard copies and they were asked to fill out the survey "honestly" after explaining to them the purpose of such a questionnaire. Reminders were sent to team leaders each two days and this by phone in order to make sure surveys are being filled.

3.6. Variables and Conceptual framework

In order to test the implementation of lean manufacturing tools, and for hypotheses testing, questions were linked to different variables. The independent variables that will be tested are related to the different lean manufacturing tools (Kaizen, Total productive maintenance, Just-in-time and standardization). They will be correlated to one dependent variable, which is the effectiveness of such implementation on the company's productivity.

For that, the independent variables will be first tested separately in order to see to which extent managers and team members think that lean tools are being applied inside production in their daily tasks. This analysis will be used to test the first hypothesis H1.

Then, a framework will be developed in order to understand the effect of such tools on the productivity of the company. It will be a model to test the second hypothesis H2.

Figure 1: Conceptual framework

IV. Findings

In this section, we will analyze the results of the survey that was performed trying to test the hypotheses and to understand to which extent lean manufacturing tools are being applied and this from managers' and team members' opinion.

4.1. Analysis of results

In the statistical analysis of the first hypotheses, participants were divided into two groups (Managers/supervisors and Team members) in order to see how these tools and principles are perceived from the different points of view.

The following table represents the mean of the answers obtained from the questions.

Table 1: Statistical Analysis of Variables

	Managers	Team Members
Kaizen	3.23	3.00
Standardization	3.48	4.19
Just-in-time (JIT)	2.77	2.86
Total Productive Maintenance (TPM)	3.13	3.78
Effectiveness / productivity	3.20	3.52

Based on the table above, managers believe that employees are empowered and involved in decision making more than team members think.

Moreover, the company adopts the standardization tool, as mean variables are relatively high.

Both managers and team members think that work is not always performed in the time needed and that maintenance department is somehow performing the tasks but this needs further improvement.

Finally, employees in general think that lean contributed in a certain way to the effectiveness of the company. This effectiveness is not so high since many factors are contributing in lowering the productivity. This will be discussed at a later stage while analyzing the framework model. In conclusion, we can see that hypothesis H1 is partially verified taking into account the mean that were calculated from all lean tools determinations with values of 3.16 for managers and 3.46 for team members.

In order to test the reliability of our variables and before proceeding with the model testing, a scale analysis on all variables was performed using “SPSS”. It turned out that all variables are reliable as per the table below with a cronbach's alpha of 0.820 in the managers' group and 0.787 in the team members' group. So, our overall research is considered consistent and taking into consideration different statistical assumptions.

After introducing our variables and our framework, now it is time to demonstrate the relation existing between them and to see the significance in order to test the second hypothesis H2, using the multiple linear regression analysis from “SPSS”.

Kaizen, Just-in-time, total productive maintenance and standardization used as independent variables and trying to find the correlation between them and the dependent variable which is lean effectiveness on productivity.

This models show a consistency of 0.595 for the managers and 0.529 for the team members which is relatively low but shows some reliability as this is a social science.

The table below shows to which extent our hypothesis H2 is considered significant or not. We can see that all values of the variables in the managers group are higher than 0.05 so our hypothesis is not accepted in the managers' group, assuming a confidence level of 95%.

As for the team members' group, the significance is higher than 0.05 for the Kaizen and Just-in-time variables but lower than 0.05 for the TPM and standardization variables.

So, we can conclude that managers don't think that these lean manufacturing tools have a direct impact on the productivity of the company whereas team members think that TPM and standardized work have a direct impact on the productivity.

The second Hypothesis H2 is not accepted for managers and Partially Accepted for team members considering the difference in the tools impact.

Table 2 : Correlation and linear regression

Group	Variable	Result	Interpretation
Managers	Kaizen	.212	Non-significant
	Just-in-time (JIT)	.542	Non-significant
	Total Productive Maintenance (TPM)	.449	Non-significant
	Standardization (and 5S)	.653	Non-significant
Team Members	Kaizen	.309	Non-significant
	Just-in-time (JIT)	.210	Non-significant
	Total Productive Maintenance (TPM)	.006	Significant
	Standardization (and 5S)	.000	Significant

4.2. Discussions

Lean manufacturing strategy is implemented in some cases in the production cycle and the First hypothesis H1 is partially verified as previously mentioned and needs improvement.

- Kaizen (employee involvement) is on the average mean. Employees do not think managers allow them to take decisions by themselves and sometimes only managers have access to some information and to decisions.
- Standardization is implemented in a positive mean. If we link this variable to cGMP where much documentation is needed, we can demonstrate why this average is high in a cGMP pharmaceutical industry. This helps us prove our discussion of cGMP focus on standardized procedures.
- JIT's (Just-in-time) mean is low. Going back to the previous point and to cGMP requirements, we can explain why many procedures are needed, lots of standard documentation have to be prepared, lots of inspections, testing, audits and controls need to be performed. These are essential in a cGMP environment but they delay the work and the delivery of the product on time.
- TPM (total productive maintenance) is well assured. This is because plant equipment is not recent and troubleshoots can happen during operation. As per the employees' opinion, TPM is not enough and should be reinforced for a better performance of the equipment and a decrease of the delay in the work process.

If we want to prove the partial application of lean tools, we will talk about the barriers that prevent pharmaceutical industries from completely adhering to lean principles; they are linked to the application of cGMP requirements that consume a lot of time and this from documentations, standard operation procedures (SOP), deviations and other written procedures. If we compare the mean of each of the variable, we can see that the lowest is related to the just-in-time variable, which comes back to the same explication concerning the cGMP restrictions.

cGMP application doesn't go the same way as lean even though both tend to provide the customer with the best product; lean focuses on assuring a balance between productivity and quality while reducing waste, whereas cGMP focuses on quality based on documents, procedures and inspections.

Smart (2010) also mentioned that cGMP requirements made the pharmaceutical industries shy in adopting lean principles.

Chowardy and Damian (2012) mentioned that all the rules established by GMP and regulated by QA (Quality Assurance), namely the written documentations, are sometimes useless but their application is a must as any violation of the requirements can lead to penalties. (Chowdary & Damian, 2012)

Concerning the Second hypothesis H2, we saw that the hypothesis could be verified in the team members' group and not in the managers' group.

According to their answers, from the focus group, team members think that productivity is not increased because there are lots of documentation that consume a lot of time and prevent them from doing work in the time frame requested.

They think that they are not evaluated in a good way. Incentives are not frequently given.

Team members insisted on the fact that every operation they perform needs to be well described in a written document called SOP (Standard Operation Procedure) in order for them to better understand the process in each step of the production. They believe that a clear SOP facilitates the work and increases productivity and this by reducing the number of defects.

Furthermore, based on his answer, the production supervisor mentioned that documentations are certainly delaying the production but this doesn't affect the overall productivity of the company.

According to him, these steps are essential for the good functioning of the operations.

Production supervisor emphasizes on the fact that employees can't be empowered in all decisions. He surely believes that they can be involved in some issues but not in everything.

According to him, some information can only be handled by managers and supervisors.

He also stated that standard operation procedures are essential for the consistency of the work and the adequate communication of instructions but this should not be fixed. According to cGMP, these procedures, once standardized, need to be followed by letter and any deviation should go under a complete investigation which goes back to the point of JIT that we already discussed.

This leaves us with one conclusion; the second hypotheses H2 is validated in the team members' group and not in the managers' and supervisors' group.

Lean is partially implemented in the company. The research showed that it is somehow difficult to totally implement lean, as there are many barriers that prevent such a change like cGMP and the culture of the employees especially the managers who are insisting on adhering to cGMP principles as if it is the only way for quality guarantee.

V. Conclusions and Recommendations

The objective of this article was to study the implementation and assessment of lean manufacturing in a Lebanese industry.

The results showed that lean tools are somehow applicable in the production cycle; standardization is among the tools the most used and Just-in-time is the tool that employees are not adopting very well due to lots of documentations and delays in the process.

Furthermore, the results showed a relationship between the application of these lean tools and the effectiveness and productivity of the company in the opinion of the team members whereas managers do not believe that this relationship is so tight. This is linked to the fact that cGMP requirements regulate all the process and they consume a lot of time. According to the managers, the cGMP requirements are the basic tools of quality and they are fundamental even if the work is delayed in some cases. Doing the job in a faster way without adhering to cGMP is not a guarantee for effectiveness and efficiency.

The challenge of a pharmaceutical industry is to try implementing lean tools in its strategy while following all cGMP rules and regulations in order not to get penalties. In fact, there should be a balance between lean and GMP for a better performance of the work because lean is essential for cost reduction and waste elimination and GMP is also essential in order to keep the best quality of medication especially that we are delivering the products to ill patients who are seeking to get healed.

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