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Improvement of Manufacturing Operations through a Lean Management Approach: A Case Study in the Pharmaceutical Industry

Regular Paper

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Abstract This paper aims to demonstrate the positive effect of a Lean Management (LM) approach to increasing efficiency, even in a company which is subject to critical market issues. The pharmaceutical industry is a well-known example of a crisis-affected context and companies have directed attention to Lean Management for a long time, but they are stable in increasing effectiveness. This research uses a case study to move the attention to efficiency as an attractive LM goal.

The result of this study provides a reference for academia as well as the business field.

Keywords Lean Management, Pharmaceutical, Production Flow, Manufacturing

1. Introduction

The pharmaceutical industry has been greatly affected by the 2008-2010 global economic crisis. Moreover, recent specific trends may likely weaken companies more and more. Therefore, it may be necessary to push researchers and practitioners to establish improved approaches which are suitable for the industry [1, 2]. It is now widely accepted that Lean Management is of considerable benefit in manufacturing, so there is growing interest in it among companies in the pharmaceutical industry.

It can be said that most of the companies are still working on developing their effectiveness (TPM and TQM) rather than focusing on efficiency. This means that they are trying to build stable running machines and stable processes [3, 4] before targeting the objective of achieving a low inventory.

The aim of this paper is to present a case study of a pharmaceutical company that has focused on efficiency improvement. The goal is to determine strength as well to identify critical issues and to collect lessons learned about the correct approach that specific industries should adopt. In the case study, a Lean Management approach

was pursued through the re-engineering of the production flow and the implementation of a pull-based system. Results from the case study show that it was a successful choice: efficiency KPIs, Works in Process, Cycle Time, etc. were dramatically improved.

The paper is structured as follows: section 2 is devoted to presenting the context and the state of the art of Lean Management in the pharmaceutical industry. In section 3, a case study is presented and discussed. Section 4 provides some final remarks.

2. Lean Management in the pharmaceutical industry

According to IMS (Intercontinental Marketing Services) the global pharmaceutical industry will be worth US$1.160 billion in 2016 [5].A number of researchers and organizations [6] have identified the following key developments and issues in the industry:

- Shifts in the growth of *pharmerging* countries (Figure 1 and 2)
- The expiration of patents of products which were launched during the industry's 'golden era' in the 1990s and the progressive introduction of less expensive generic alternatives
- A common strategy of industrial concentration which has been adopted in order to deal with the growing costs of R&D

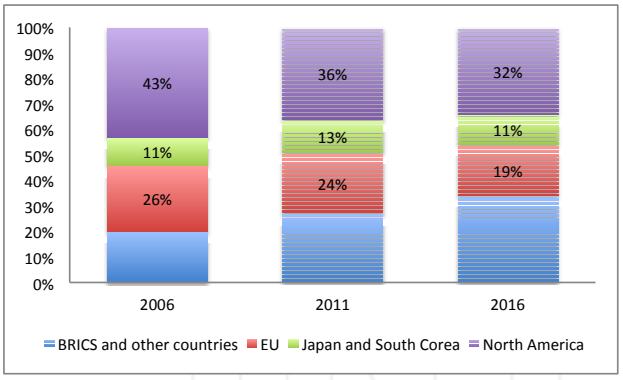

Figure 1. Global pharmaceutical market (% of total size)

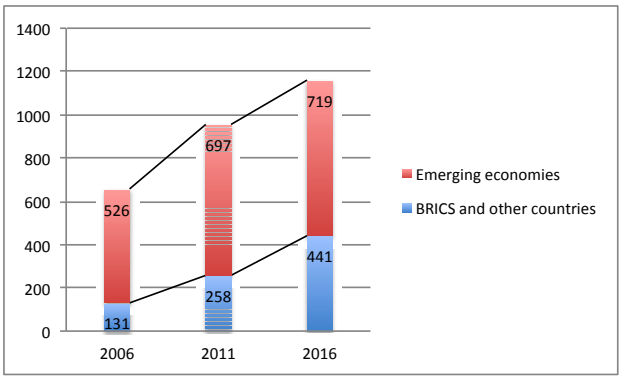

Figure 2. Global pharmaceutical market growth (billions of dollars and average annual growth rate)

All these issues have contributed to the present framework of the industry, in which revenues are decreasing because of competition from generic alternatives, while the costs of R&D are rising for [7] and competition is increasing. All these features push pharmaceutical companies to apply methodologies for performance improvement [8].

2.1 Literature review

'Lean Production', or rather 'Lean Management' is an intellectual approach consisting of a system of measures and methods which, when considered as a whole, have the potential to bring about a lean and, therefore, particularly competitive state in a company. The main fields of activity concerned are product development, the supply chain, shop floor management and, to a lesser extent, after-sales services [9]. There are multiple ways to combine the individual practices in order to represent the multi-dimensional nature of Lean Manufacturing [10], which is the reason for the considerable amount of literature on the topic.

Following its dramatic successes in manufacturing in the pharmaceutical industry, many companies have chosen to implement a Lean Management approach in order to accomplish such goals as decreasing waiting time to release products onto the market, to reduce production waste, improve communication with end users and raise quality levels, both in the course of production and in testing laboratories.

Most of the research work is aimed at supporting the implementation of Lean Management in the pharmaceutical industry: [11] states that Lean Management could transform the Pharma Industry. A more frequently covered topic is the current state of Lean Management implementation [12]. Some researchers have focused on typical contextual factors, such as plant size and company type, that have an influence on the degree of implementation of lean practices [13]. Others have identified some barriers to the success of Lean Management, as well as their potential mitigation [14]. Many others have worked on the financial returns on investments from Lean Management [15], as well as on the potential benefits of the operative parameters [16, 17, 18].

Many authors have benefited from the application of Lean Manufacturing concepts to different pharmaceutical areas, such as R&D [19, 20], clinical laboratories [21] or clinical supply chains [22]. Finally, even harmonization with legal regulations, as represented by the requirements for Good Manufacturing Practice (cGMP,) has been studied [23].

In most cases, Lean Management is analysed in combination with Six Sigma [24]. The idea for the research presented in the paper originated in the work of Goetzfried and Basu [25], who state that most of the companies are stable enough to work to achieve effectiveness goals using Lean Management. The literature is thus not lacking in references to Lean Management in the pharmaceutical industry, which can be consulted in order to increase efficiency.

3. Case study

In order to provide an example of how it is possible and convenient to shift attention from effectiveness to efficiency, we now present the case of a pharmaceutical company that is dealing with the challenges presented in section 2, and which has reaped large benefits by using targets for manufacturing operations. The case study concerns the plant of a primary multinational company of the pharmaceutical industry. This plant produces pharmaceutical products in a solid form (pills, tablets, capsules, etc.). The company has about 400 employees and its annual production adds up to about 100 million packages sold in the European market and to more than 100 markets globally.

Since early 2000, the company has been conducting a project of concentrating the production in a few specialized plants. The plant we have analysed has been chosen to produce 'growing' products. This means that in a few years it has increased its capacity in a dramatic way and its portfolio of products, as well as a reorganization and improvement of its production flows, have seen strong demand.

3.1 Objectives

The management has decided to implement a Lean Management approach, but the main focus has been on achieving efficiency through improvement activities which are aimed at:

- Reducing set-up time
- Deleting non-added value activities
- Minimizing inventories
- Decreasing balance delays

Within the general improvement programme, we have focused on a specific project that has been developed in two synergic ways in a pilot production flow:

1. Re-engineering of the production flow
2. Implementing a pull-based production system

Both methods have contributed to the following goals:

- Total Pipeline Lead Time reduction
- Throughput Time reduction
- WIP (Work In Process) reduction
- Layout re-design

Concerning the latter goal, the main problem was an excessive walkthrough product, which divided production flow into different production areas.

In the following sections we present the details of the activities the company has implemented on the pilot production line. These activities are characterized by a high level of technology and innovation, but which have never been reviewed under the Lean Management principles. This allows for an appreciation of the contribution of the methodology in terms of efficiency.

3.2 Re-engineering of the production flow

The process of drug manufacture (Figure 3) can be broken down into a series of steps:

A. Dispensing: This includes the operations which are designed to select a portion of pharmaceutical raw materials that are weighed and transferred to clean containers.
B. Blending: This is the amalgamation of all the ingredients. It can occur in a number of stages.
C. Screening: This is done in order to pulverize the materials more effectively.
D. Tableting: Here, each tablet is made by pressing the granules inside a die.
E. Coating: This is a process of evenly covering particles with a substance by applying a series of thin layers.
F. Packaging: This encloses products to protect them for distribution, storage, sale and use.

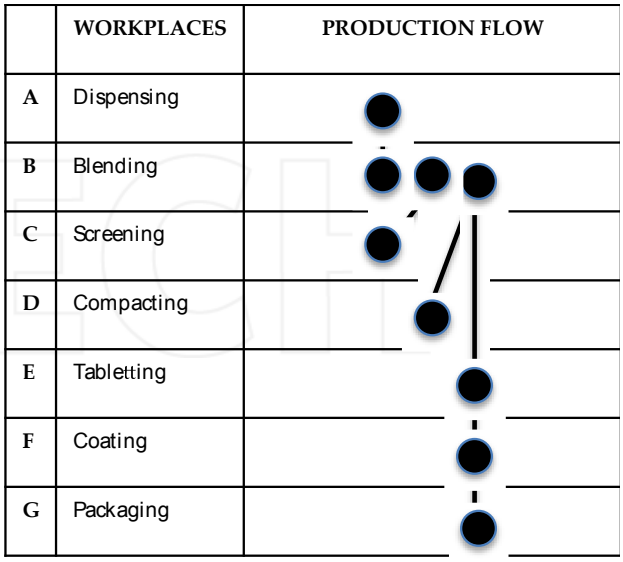

Figure 3. the production flow

The production flow is characterized as having a buffer just after the second blending for technical reasons. Moreover, cycle times up to the second blending were really similar and completely different from the second part of the flow. This creates the impression of a two stage production flow.

In line with the Lean Management approach, the value stream map method was used in order to eliminate various kinds of waste, such as:

- Inappropriate processes-unnecessary processing or procedures
- Overproduction
- Rework
- Inventory and WIP
- Material transportation and handling reduction

On the other hand, the specific goal pursued by the re-engineering of the production flow was a layout design. The goal includes some sub-objectives strongly linked to the Lean Management:

- The creation of a continuous production flow
- A minimum distance from the beginning to the end of the flow
- Efficiency in the use of the space

With reference to the creation of a continuous production flow, pharmaceutical manufacturing has traditionally been a batch-wise process. However, several factors (reduction of cost, improved process efficiency, optimal use of equipment, flexibility in production capacity) encourage the pharmaceutical industry to investigate the opportunities offered by continuous processes [26]. Various technological advances (as mentioned above in tableting and granulation phases) have made this possible.

From an organizational point of view, the main obstacle to making the flow continuous was the presence of a bottleneck. According to Králová and Bielak [27], a production flow bottleneck can be individuated by calculating the average rate of utilization for each workplace with respect to the whole-system average of this rate. An operation with the minimal value of the rate of utilization is regarded as a bottleneck. In the case study the bottleneck was the tableting operation. The lower severity was for the packaging workplace. Both workplaces needed an expansion of capacity.

In order to remove both bottlenecks, the production machines were replaced with machines that were more advanced, from a technological point of view. This allowed for:

- Reducing cycle times, according to the goal of making the flow continuous
- Reducing space (the new machines are smaller), according to the goals of reducing the walkthrough of the product and to achieve efficiency in the use of the space

3.3 The pull-based production system implementation

The production flow performs a pull-based production system in order to define the inventory level. However, a specific goal for the company was to reduce WIP (see section 3.1). That is why the implementation of a hybrid Kanban-CONWIP system (Constant Work in Progress) was carried out.

The CONWIP system was introduced by Spearman, Woodruff and Hopp [28]. The basis of this system of operation is that, in order for parts to be admitted into the line, each part container should have a card attached to it. When a container is consumed at the end of the line, the card attached to it is returned to the beginning of the line, and is subsequently attached to a designated part container before being readmitted to the line. Thus, the consumed container is replenished upon completion of the designated part. CONWIP systems can achieve a lower WIP level than Kanban systems [20], because WIP is equal to the number of CONWIP cards in the system.

According to [29], there are some benefits of controlling WIP, such as:

- It limits the amount of material released into the system
- The amount of material that needs to be scrapped or reworked is reduced, and financial losses from sales of a now inferior product are diminished
- It reduces cycle time variability
- Production systems have a degree of flexibility that is lost when large volumes of WIP remain in the physical system

Sometimes it is possible to combine the benefits of a hybrid Kanban-CONWIP system. This is outlined in the case study in which the specific shape of the flow suggests that it could be split into two parts. One is controlled by a pure Kanban system (the focus being on the inventory level of each workplace), while the second is controlled by a mixed Kanban-CONWIP system (the focus here is also on WIP).

In Figure 4 we reported the final result of the implementation of the pull-based production system.

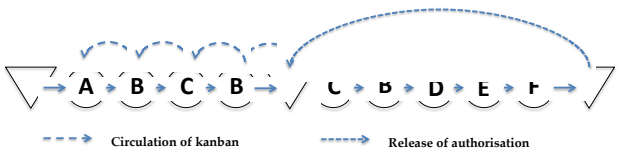

Figure 4. The production flow after the Kanban implementation

Since a CONWIP system behaves as a push system inside a black box, each workstation will continue to process work as long as there is work in the queue in front of it. WIP will tend to accumulate in front of the bottleneck workstation. However, a queue explosion does not occur as it does in a push system, since card control limits total WIP [29].

3.6 Analysis of results

The re-engineering of the production flow through Lean Management and the implementation of both Kanban and CONWIP led to the following results after 90 days (Table 1):

Goal	Target	Results
Total Pipeline Lead Time Reduction	6 days	5 days
Throughput Time reduction	3 days	2 days
WIP reduction	30%	37%
Lay-out redesign (walkthrough reduction)	300 mt	284 mt

Table 1. Results after 90 days

4. Conclusions

In this paper the authors have presented a successful case of Lean Management implementation in the pharmaceutical industry. The case has been chosen because the company has been using operational re-organization/re-engineering for several years due to the new context of the pharmaceutical industry. Moreover the company has chosen to focus on efficiency improvement. The results show that it is possible to create a competitive advantage in this way. Practical remarks about the case study provide the opportunity to perform a continuous production flow instead of a batch flow and in order to control the production flow.

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