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# The Application of Lean Manufacturing for Operation Improvement: A Case Study of Black Cough Medicine Production in Indonesia

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***Abstract.****Nowadays, the pharmaceutical industry has a market tends to be unstable and volatile in meeting customer needs. This is due to the economic crisis that occurred in different parts of the world. The pharmaceutical industry currently uses good manufacturing practices (cGMP) to ensure that products are consistently produced and controlled according to the required standards. Pharmaceutical industry slowly started to move from cGMP to lean manufacturing that focused on reducing operating costs while ensuring compliance. The problem faced at the OBH (Black Cough Medicine) production line in this company is inconsistent production of the product to the market. Therefore, the purpose of this paper is to analyze the usage of lean manufacturing instead of the usage of cGMP to solve the problem. To conduct this study, literature review and company visit has been done. This analysis was applied by using value stream mapping (VSM) and 7-wastes methodology to analyze the problems in the OBH production line one of the pharmaceutical industry in Bandung, Indonesia. For the improvement, the lean manufacturing approach has been carried out and the future VSM has been developed. Finding reveals that the application of lean manufacturing in the cGMP environment helps the company to eliminate wastes in reducing lead time and cycle time in the manufacturing process.*

***Keywords:****Pharmaceutical Industry, cGMP, Lean Manufacturing, Value Stream Mapping, 7-Wastes.*

## 1. Introduction

Condition of business competition in today's global marketplace is rapidly increasing due to various changes in the needs and desires of consumer as well as the rapid development of technology (Danesh et al. 2013). Under these conditions, a company should have a right product and the right time to win the competition (Rosen et al. 1998). Along with the development of technology and information, the needs of pharmaceutical are also growing. Pharmacy as one of the basic human needs evolve along with the development of human civilization.In order to meet all the demands and requirements, and also to meet the challenges, pharmaceutical companies are struggling to find ways to reduce internal costs and cycle time by delivering high quality services to users, through innovative design and efficient response to an unexpected increase in demand for certain products (Chauhanand Singh 2011; Geller2007). Like automaking revolution carried out by the Toyota lean production system, the pharmaceutical company aims to secure the future of their industry by adopting lean philosophies and tools (Farber et al. 2009). In pharmaceutical manufacturing, the World Health Organization (WHO) defines cGMP as part of quality assurance which ensures that products are consistently produced and controlled in accordance with the standards for their intended use and as required by the customer (Pavlovic and Bozanic 2012). In the past, the pharmaceuticals industry, for which the principles of cGMP is mandatory, has slowly been embracing lean manufacturing, in contrast to other sectors that adopted relatively quickly and successfully (Greene and O'Rourke 2006).

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Today, manufacturers in the industry focused as never before to reduce operating costs while ensuring compliance. The goal of lean manufacturing is to excrete less human effort, less inventory, less time to develop products, and less space to become highly responsive to customer demand, while at the same time producing high quality products in the most efficient and economic (Chauhan and Singh 2011). Therefore, this paper discusses about the application of lean manufacturing in one of the pharmaceutical industry in Bandung, Indonesia, which has been certified by cGMP. The research was conducted at the OBH production line to find the wastes that occur in the production process of the OBH. The study was conducted over 3 months to improve operations in the pharmaceutical industry by applying lean manufacturing to identify areas of overlap, as well as the challenges faced by pharmaceutical companies when turning to lean manufacturing.

Based on the interview result and the data in Table 1, the problem faced by the company is the production of the products that are not consistent to the market. Table 1 is one of inconsistent production time examples. This data is the data OBH production in March 2013. It shows that production time should be done in one day but often occurs within 2-3 days of production.

Table 1.Inconsistent Production Time

| No | Process | Date |
|---|---|---|
| 1 | Bottle washing | 20 March 2013 |
| 2 | Mixing | 20 March 2013 |
| 3 | Filtration | 20 March 2013 |
| 4 | Filling and capping | 21 March 2013 |
| 5 | Visual test | 21 March 2013 |
| 6 | Labeling and packaging | 22 March 2013 |
| **Total Working Days** | | **3 Days** |

Owing to these problems, as has been discussed previously, this paper wants to discuss the application of lean manufacturing in this company to make the production of the product consistent to the market that can solve the problem faced by the company to meet the on-time delivery of products.

## 2. Method

For carrying out the lean manufacturing analysis, the selection of an appropriate production line in pharmaceutical industry was followed. It is an OBH (Black Cough Medicine) production line in one of pharmaceutical industry in Bandung. The methodology to analyze the lean manufacturing in pharmaceutical industry are interview and observation and be analyzed as presented in Subsection 2.1, literature review has been performed on lean manufacturing tools and the comparison between lean and cGMP.

This research carried out for 3 months, from February to April 2013. Waste identification process was carried out by discussions/interviews. Discussions were taken to bring about an understanding of the perceptions of the waste. Process of discussion involving employees who competent and know for sure the most influential waste that appear most frequently. Interview process carried out by some competent people, including the owner, general manager, PPIC manager, production manager, mechanical manager, QC manager, and some employees who perform the production process. After identifying the line, the current state VSM has been developed and analyzed through the 7-Wastes. Last, the future state VSM has been developed and various inferences that would improve the production line have been drawn.

### 2.1. Literature review

#### 2.1.1. Lean manufacturing

Lean was emerged from the Toyota production system with the key aspects including the never-ending quest for perfection, continuous search to eliminate waste and the recognition and importance of employee contributions. It founded by TaiichiOhno in the 1950s. Lean thinking has been utilized by manufacturing industries in order to decrease cost and improve quality and productivity by reducing variation and production defects (Shelly and Mortensen 2008). Lean provides a great set of tools to facilitate some of the key drivers that are imperative in today's economy and industry conditions.

The implementation of lean manufacturing are in order to achieve goals such as reduced waiting time to release product to the market, reduce production waste, improve communication with end users, and improvethe level of quality both in the production and in laboratory testing (Pavlovic and Bonanic 2012).

The advantages of the lean philosophy which is a performance-based process used in

manufacturing organizations to increase competitive advantage(Kovacs2012). The benefits of the implementation were tangible: the project was under budget and three weeks ahead of schedule, and subcontractors were more satisfied with their relationships with the GC (Salem et al. 2006). The improvement experiences due to application of lean principles combined with cGMP in a pharmaceutical company can reduce lead times, cycle times and WIP inventory in the manufacturing process (Chowdary and George2012).In a lean pharmaceutical manufacturing environment, cGMP and lean must be equal partners. The cGMP standards along with lean principles must be embedded into the culture of an organization and the business strategy must reflect this (Greene and O'Rourke 2006).A constant effort is essential to apply the principles of lean management in the cGMP environment for the manufacturing of the pharmaceutical products to ensure that the product quality and safety for the patients (Jaiganesh and Sudhahar 2013).

### 2.1.2. Lean Tools and Application

#### 2.1.2.1. The 7-Wastes

Seven wastes of lean are the root of all unprofitable activity. Other than those listed below, underutilizing people skills are considered a waste when talent is used for activities that do not add the value(Shelly and Mortensen 2008).

a. Inventory, means material sitting taking up the space, costing money, and potentially become damaged because stocks problems are not visible.
b. Over production, means final products produced more than needed or before it is needed for the customer is a necessary waste in lean manufacturing.
c. Waiting, means worker or machine is waiting for material or information.
d. Transportation, means material moving does not increase the products value to the customer.
e. Defects, means defective products blockthe material flow and lead to wasteful handling, time, and effort.
f. Excess motion, means any unnecessary movement that does not add the product value.
g. Processing, means additional process is not essential to add valuefrom the customer point of view.

#### 2.1.2.2. VSM

Value Stream Map (VSM) is tool of lean manufacturing in order to helps detail the flow of supplies and information as a product or service makes its way through a process (Shelly and Mortensen 2008).VSM is a simple tool to help operation managers understand how their flows currently operate and to help guide them through the process of analysis to improve those existing flows and design better ones in the future (Chowdary and George 2012).The main purposes of VSM are identifying, demonstrating and decreasing waste in a process. The VSM creation can take many forms, they are including the diagram of the process with real time measurements of the length of time an activity takes.

### 2.1.3. Lean Manufacturing vscGMP

There are two objectives of lean manufacturing, they are to reduce or eliminate waste and to create value On the other hand, cGMP's objective is to ensure that all levels of control are in place to deliver a safe and effective medicinal product (Greene and O'Rourke 2006). The comparison between lean manufacturing and cGMP is shown at table below. There are two big families in comparison betweencGMPand lean manufacturing, while cGMP focuses on manufacturing as a means to produce safe and effective products for the patient, lean manufacturing focuses on manufacturing as a location for improvement and value creation from a customer's perspective. Greene makes the comparison of the most important attributes of Lean concept and principles of cGMP as shown in Table 2.

Table 2.Comparison between Lean and cGMP

| Area | LEAN | cGMP |
|---|---|---|
| Objectives | Reduce waste<br>Create value | Ensure product effectiveness<br>Prevent harm |
| Focus | Value stream | Product development, manufacturing and quality assurance |
| Approach to manufacturing | Quality balanced with productivity | Quality first |
| Improvement | Continuous and simultaneous | Regulated and prudent |

Continue (Table 2. Comparison between Lean and cGMP)

| Area | LEAN | cGMP |
|---|---|---|
| Typical goals | Reduce cost<br>Improve quality<br>Reduce cycle time<br>Reduce inventory<br>Improve delivery | Follow validated process<br>Prevent deviation |
| Typical tools | Value stream mapping<br>Kaizen improvement<br>Error proofing<br>Moving to pull<br>Simple flow<br>Training<br>Quality function deployment | Documentation<br>Personal qualifications and training<br>Cleanliness<br>Validation and qualification<br>Complaint review<br>Audits |

(Greene and O'Rourke2006)

## 3. Result

### 3.1. Current VSM

The current VSM is to identify each significant action required to create the desired value (Womack2006).The current state VSM developed is shown in Figure 1.The information obtain from current VSM indicates that the process involve a total of six processes, they are bottle washing, mixing, filtration, filling & capping, visual test, and labeling & packaging. The bottleneck occurs at the mixing process in which the cycle time is 90 minutes. The calculations for the rest of the operations have been carried out. The total cycle time (TCT) for the process is 295 minutes whereas the total non-added value (NAV) is 263 minutes.The wastes that occurred in the OBH production line are shown in Table 3. And the detail of the current processing time is shown in Table 4.

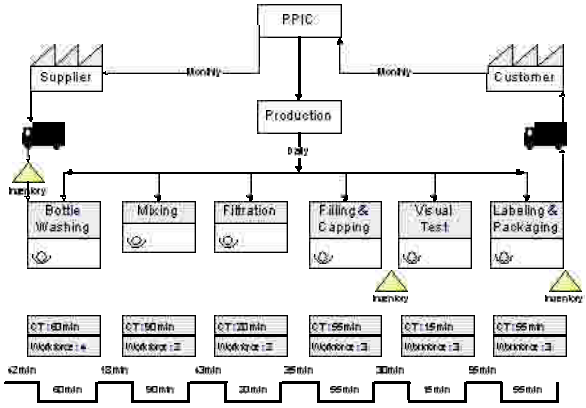


Figure 1.Current VSM

Table 3.Wastes Discussions Result

| 7-Wastes | | Washing | Mixing | Filtration | Filling & Capping | Visual Test | Labeling & Packaging |
|---|---|---|---|---|---|---|---|
| Inventory | Machine | - | - | - | Separated with labeling & packaging machine | - | - |
| | Material | - | - | - | - | - | Waiting for paper label |
| | Method | The bottles are kept during mixing and filtration | Need to test samples | - | Stored until baskets full of bottles | - | - |
| Over Production | Machine | The capacity is too large | - | - | - | - | - |
| Waiting | Material | - | - | Waiting for sample test | - | - | Waiting for paper label |
| | Method | Waiting for information (room and machine) | Waiting for information (room and machine) | Waiting for information (room and machine) | Waiting for information (room and machine) | Waiting for information (room and machine) | Waiting for information (room and machine) |
| Transportation | Method | The distance to mixing room is too far | - | - | The distance to labeling & packaging room is too far | - | - |
| Defects | Material | - | - | - | Risky for broken neck | - | - |

Continue (Table 3. Wastes Discussions Result)

| 7-Wastes | | Washing | Mixing | Filtration | Filling & Capping | Visual Test | Labeling & Packaging |
|---|---|---|---|---|---|---|---|
| Excess Motion | Man | - | Assure the tool is clean | - | - | - | Assure the labels attached to the bottles |
| | Machine | - | Less of tools | - | - | - | - |
| | Method | - | Doing the series activities | - | The bottles put back into the baskets | - | The bottles put back into the line process |
| Processing | Machine | Manual room condition recorder | Manual room condition recorder | Manual room condition recorder | Manual room condition recorder | Manual room condition recorder | Manual room condition recorder |
| | Method | - | Machine checking after one process before done | Machine checking after one process before done | Machine checking after one process before done | Machine checking after one process before done | Machine checking after one process before done |

Table 4. Processing Time

| No | Process | Time (min) | |
|---|---|---|---|
| | | Current | Future |
| 1 | Condition room recording | 2* | 0 |
| 2 | Washing machine checking | 10 | 10 |
| 3 | Oven machine checking | 15* | 0 |
| 4 | Lead time | 15* | 0 |
| 5 | Bottle washing | 60 | 60 |
| 6 | Condition room recording | 3* | 0 |
| 7 | Mixing machine checking | 10 | 10 |
| 8 | Lead time | 5* | 0 |
| 9 | 1st initial mixing | 10* | 10 |
| 10 | 2nd initial mixing | 10* | |
| 11 | 3rd initial mixing | 10* | |
| 12 | 4th initial mixing | 5* | |
| 13 | 5th initial mixing | 5* | |
| 14 | Lead time | 5* | 0 |
| 15 | 1st final mixing | 20 | 20 |
| 16 | Lead time | 5* | 0 |
| 17 | 2nd final mixing | 20 | 20 |
| 18 | Sample taking | 3 | 3 |
| 19 | Sample test | 35 | 35 |
| 20 | Lead time | 5 | 5 |
| 21 | Filtration | 20 | 20 |
| 22 | Lead time | 10 | 10 |
| 23 | Condition room recording | 3* | 0 |
| 24 | Lead time | 7* | 0 |
| 25 | Filling machine checking | 15* | 0 |
| 26 | Filling | 55 | 55 |
| 27 | Lead time | 20 | 10 |
| 28 | Condition room recording | 3* | 0 |
| 29 | Visual test tool checking | 7* | 0 |
| 30 | Visual test | 15 | 15 |
| 31 | Lead time | 90* | 60 |
| 32 | Condition room recording | 5* | 0 |
| 33 | Labeling and packaging | 55 | 55 |
| | **Total Cycle Time** | **295** | **195** |
| | **Total Lead Time** | **263** | **133** |

### 3.1.1.The Information Flow

The PPIC department will manage all the orders from the customers and translate them into a monthly master production schedule (MPS) by checking the existing products in the finish goods warehouse. The PPIC departments will also make a monthly material recruitment planning (MRP) by checking the existing raw materials in the raw materials warehouse. The MRP will be given to the purchasing division for the raw material purchasing and the MPS will be given to the production department for doing the production. The production department will execute the MPS and give the instructions to production personnel on a daily basis. The information flow is shown in Figure 2.

### 3.1.2.The Physical Flow

Bottles that will be used in the process of filling and capping washed beforehand to a washing process for 60 minutes. Any prior conducting processes, beforehand checked the condition of the room and machine that will be used. A washing machine has a capacity of 3,500 bottles. After the washing process bottles, bottles that have been washed stored for use during the process of filling and capping.

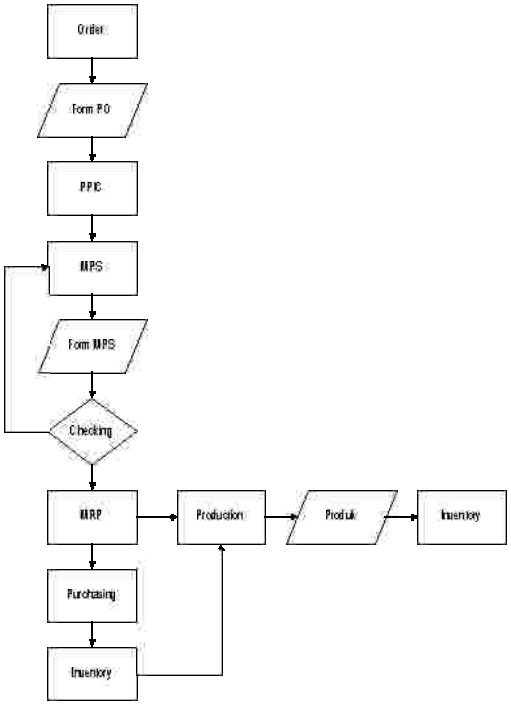


Figure 2. The Information Flow

The raw materials were mixed through two stages of the process, the initial mixing and final mixing. Initial mixing process consists of 5 stages, a length process respectively 10, 10, 10, 5, 5 minutes. While the final mixing process consists of two stages, a length process respectively 20 and 20 minutes.

After the process of mixing finished, raw materials that has been mixed evenly filtered in the process of filtration and having an average time process of 20 minutes. A solution has been filtered then included into machine filling and capping. The process of filling and capping spent 55 minutes to 2,000 bottles of OBH.

Prior to labeling and packaging process for 55 minutes, a visual check process will be done. Visual checking is done to ensure that there are no raw materials have been mixed to perfection. This visual checking length is 15 minutes.

### 3.2. The 7-Wastes Analysis

7-wastes analyzed through the stages of the production process. The wastes will be seen in every stages of the production process ranging from washing to labeling & packaging based on man, machine, material, and method. The 7-wastes discussions result is shown in Table 2.

In every production process, there is a processing waste that impact to the waiting waste. Waiting wastes happened because unfavorable machine and method. Every process done by manual room condition recorder and always doing the machine checking after one process before done. The most common waste in the production process is the filling & capping process. Therefore, the detail of processing time is shown in Table 3.

Table 3 provides an explanation of the time of each production process. The tables that marked with (*) are current waiting time that might be reduced even eliminated. By applying new machine and method, the processing time can be reduced. The explanation of the new machines and methods will be given in subsection 3.3. After applying the new machine and method, the future processing time can be developed. Therefore, the future VSM is shown in Figure 3.

### 3.3. Future VSM

Once the current state VSM is complete, the realistic future VSM can be created (Manos 2006). By analyzing the existing wastes through the 7-wastes analysis and discussion with several managers that relates to the production process, the various modifications through the lean manufacturing approach have been developed for reducing the processing time.

The discussion with several managers at the company is useful to determine the readiness of a company's management to accept the proposal given to the application of lean manufacturing (Vinodh et al. 2010). The future state VSM developed is shown in Figure 3.

The various modifications that have been developed are the implementation of 5S in the cGMP environment, the formation of a new operation sequence, and the utilization of the new operation tools. The implementation of 5S incorporated is the lean manufacturing could improve both quality and productivity performance significantly (Bayo et al. 2010).

The new sequence of the operation has been developed, the bottle washing process parallel with the mixing process and perform 1st, 2nd, 3rd, 4th, 5th initial mixing parallel. By performing the parallel process, the processing time of bottle washing as if dispensed and the processing time of initial mixing can be reduced.

And the last modification is the utilization of the new operation tools. The usage of manual room condition recorder can increase the total NAV. By utilizing the automatic room recorder can eliminate the waiting time and make cycle time faster (Waurzyniak 2007).

Calculations have been carried out for the rest of the new operations, and the total cycle time (TCT) for the process is 195 minutes decrease from 295 minutes whereas the total non-added value (NAV) is 133 minutes decrease from 263 minutes. The detail of the future processing time is shown in Table 3.

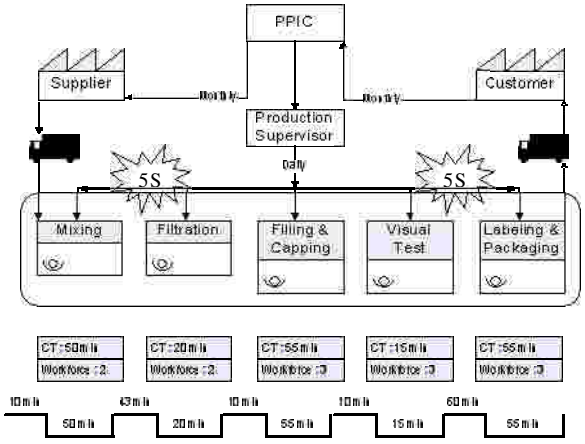


Figure 3.Future VSM

## 4. Conclusion

The application of lean manufacturing in cGMP environment can lead the pharmaceutical industry more cost effectively and avoid wasting time. Lean manufacturing is well applied to the pharmaceutical industry (Chowdary and George 2012; Greene and O' Rourke 2006; Pavlovic and Bozanic 2012).

This can lead the production time in OBH production line to be consistent. Therefore, the problems faced by the company, inconsistent production of the products to the market, can be solved. Knowing for sure the production time, the company can provide assurance to customers about the arrival time of products to the market.

The first step that needs to be done in implementing lean manufacturing is making current VSM. Current VSM is a tool to determine the value stream flow (Upadhye et al. 2010). By knowing the value stream flow, we can identify and categorize the wastes that occur in operation process through the 7-wastes analysis. The concept of lean manufacturing has been used to eliminate non-added value named wastes and enhance the operation performance (Manuele 2007; Rahman et al. 2010).

Reduction in cycle time is usually considered the best ones attacked by lean principles (Snee 2010).The last step is making the future VSM by doing various modifications. The various modifications made must be adjusted to readiness of a company's management to accept the proposal given to the application of lean manufacturingVinodh et al. 2010). One of the

tools used during this approach is 5S. Although the company uses the cGMP guidelines, there are great opportunities to better organize the work and this applies throughout the operation, ranging from warehouses, manufacturing, and to the Labs (Maslaton 2012).

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