MANUFACTURING IMPROVEMENTS USING LEAN MANUFACTURING TOOLS

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ABSTRACT

This project was executed in a Pharmaceutical Company in Guayama PR. The process selected is the manufacturing of a new product produced since July 2008. It is a solid dosage drug or tablets. The manufacturing consists of weighing, blending, compression, coating and visual inspection. It was selected since it was observed high product cycle times, high inventory levels, non uniform manufacturing procedures, poor equipment maintenance and activities that are non value added. The goal is to identify the wastes, which is any activity that does not add value. A value stream map was developed to look for opportunities to eliminate wastes and improve the manufacturing process. In the value stream map, the production flow was analyzed for understand the company's current cycle times, machine equipment capacity, and process communications. In addition, it was collected and analyzed information related to the product from start to finish for mapping purposes. The Takt time was calculated from the collected data. Cycle times, down times, work in process inventory, and material and information flow paths were documented. Based on all the information gathered, the Pharmaceutical Company may implement Lean manufacturing methodology to increase the productivity and the quality of this new product.

INTRODUCTION

Manufacturing operations are continually motivated to increase productivity and output of their operations. Their goal is to satisfy the customer with the exact product, quality, quantity, and price in the shortest amount of time.

Lean manufacturing is more than a cost reduction program or a problem solving approach [1]. The main idea is that an efficient production can be achieved by a comprehensive approach to minimize wastes. This means eliminating excess production and inventory, redundant movement of material, waiting and delays, over processing, excess worker motion, and the need for rework and corrections.

Part of lean manufacturing is reviewing operations for those components, processes or products that add cost rather than value [1]. Each step of the manufacturing process is monitored to determine if it adds value to the product. If it does not add value, the process could be delegated to a subcontractor or outsourcing company in order to focus the staff on value-added operations of its core business.

A value stream is the set of processes required to transform raw materials into finished goods that customers value [2]. In this project, a value stream map will be developed for a new product manufactured in a Pharmaceutical Company in Guayama, Puerto Rico since July 2008. Constructing a value stream map will allow the company to document current production lead time, inventory levels, and cycle times in order to determine the ratio of value-added to total lead time of the product being analyzed, creating a vision of an ideal value flow. The goal is to identify and eliminate the wastes in the production process. The company will use these results in order to map the future state and implement lean manufacturing.

STATEMENT OF THE PROBLEM

During the preliminary evaluation it was observed the followings problems:

- High product cycle times (40 days approx).
- Inventory levels between stages are higher than expected resulting in an enormous quantity of work in process and cost to the company (80 batches of work in process approximately).
- Non-value added activities such as an inspection process was observed adding time and cost to the production process.
- The speed of the process depends of the skills of each operator.

RESEARCH OBJECTIVES

The purpose of this project is to demonstrate the effectiveness of the value stream mapping tool in the process improvement of a recently installed manufacture drug product in a Pharmaceutical Manufacturing Company. The value stream mapping tool may help increase productivity, more competitiveness, better quality of goods produced, and reduce costs, total lead time, human effort, and inventory levels. The followings objectives were assessed:

- Determine the current state of the process activities by mapping the material and the information flow to calculate lean metrics.
- Analyzed the current state map for opportunities to eliminate wastes or non value added activities in the manufacturing process.
- Develop recommendations in order to improve the process flow and/or cycle time.
- Evaluate the current state map for opportunities to obtain a diminution on inventory and WIP.

IMPORTANCE OF THE PROJECT

To demonstrate the benefits of implement Lean tools for continuous process improvement, and the importance of constructing and analyzing a value stream map in a recently installed production line.

The value stream map that will result from this project will support the Pharmaceutical Company in order to reduce costs, improve lead time, increase productivity, and improve quality of the products produced. Also, these tools can be used in others products in the company to improve the manufacturing processes, the quality of the products produced and to be more competitive in the market distribution.

Since this is a new product produced from July 2008, it will be manufactured in the Pharmaceutical Company at least for 10 years more; therefore the project contribution is very important to the company in order to reach the process robustness.

LIMITATIONS OF THE PROJECT

The limitations of the project were that:

- The results of this project are limited to the Pharmaceutical Company being analyzed, although can be applied to another companies.
- The results will be based on data collected from the production activities performed along the value stream selected.
- The project includes the development of the current state map for a value stream selected and recommends ways to improve the process, but the recommendations will not be implemented due to time limitations.

ASSUMPTIONS OF THE PROJECT

It is assumed that by designing a map of the present state with the necessary technical information, Pharmaceutical Company in Guayama, Puerto Rico will have the capacity to develop a future map in an effective way to implement lean manufacturing, in order to increase the productivity and quality, as well as to reduce costs, inventory, and cycle time. The following assumptions were taken:

- The data collected during the project is representative to the normal process on the production line.
- The manufacturing operators are trained in the operating procedures.
- During the data collection did not happen any unexpected situation that altered the behavior of the production line.

- That this new product is under a steady state of production.

LITERATURE REVIEW

Lean manufacturing is a comprehensive term referring to manufacturing methodologies based on maximizing value and minimizing waste in the manufacturing process. The manufacturing organizations are recognizing the importance of practicing lean techniques. Lean Manufacturing philosophy and techniques are rooted in the Toyota Production System. Toyota Production System uses many different tools to identify and eliminate waste including Value Stream Mapping.

A value stream includes all the operations and processes required to get a product or service into the hands of the customer. It includes both material and information flow. Value stream management is the elimination of waste as seen from the customer and business perspective. Waste is imbedded in the non-value added tasks that a customer would not pay for, and is the result of poorly performing processes.

DEFINITION OF LEAN MANUFACTURING

According to Tapping, the term "lean" represents a system that utilizes fewer inputs in order to create the same outputs than those created by a traditional mass production system, while increasing the range of different finished goods for the end customer. The term lean manufacturing is synonymous with different names, such as synchronous manufacturing, agile manufacturing just in time manufacturing, continuous flow manufacturing and world class manufacturing.

Lean manufacturing is an operational strategy oriented toward achieving the shortest possible cycle time by eliminating waste [5]. It is derived from the Toyota Production System and its objective is to increase the value-added work by eliminating wastes and reducing unnecessary work. The technique often decreases the time between a customer order and shipment, and it is designed to improve profitability, customer satisfaction, throughput time, and employee motivation.

The benefits of lean manufacturing generally are lower costs, higher quality, and shorter lead times [5]. The term lean manufacturing is created to represent less human effort in the company, less manufacturing space, less investment in tools, less inventory in progress, and less engineering hours to develop a new product in less time.

TYPES OF WASTES

According to Tapping "the ultimate lean target is the total elimination of waste. Waste, or muda, is anything that adds cost to the product without adding value". Wastes can be classified into seven categories [1]:

- Waste of overproduction: produces more than what is required by the customer.
- Waste from transportation: movements that are not required by the production process.
- Waste of motion: time that is wasted by workers, machines, and handling due to the fact that they are moving more than necessary.
- Waiting: Time is wasted whenever there is a period of waiting in between steps.
- Processing: Doing more to the product than necessary and the customer is willing to pay.
- Inventory: products that are still WIP that are not being immediately processed.
- Defects: the most obvious of all the forms of waste is the production of defective products.

STAGES OF LEAN APPLICATION

1. Demand Stage - This stage refers to understanding the customer demand and incorporating it into the lean process [1]. It involves knowing exactly the number of batches that the company needs each day.
2. Flow Stage - In order to meet customer demand the company needs to implement a flow manufacturing to ensure that the customer will receive the right products on time [1].
3. Leveling Stage - The leveling stage refers to leveling production; it means to spread the work required to achieve customer demand [1].

DEFINITION OF VALUE STREAM

A value stream is the set of processes, including value-added and non-value-added activities, required to transform raw materials into finished goods that the customers value [2]. Value streams brings an specific good or service through three critical management tasks: problem solving, information management, and physical alteration.

Value stream mapping is a visual representation of all the specific activities, including the flow of material and information, which occurs along the value stream selected for a product or family [1]. The value stream mapping process will likely reveal that a significant amount of non-value-added activities are present in your current processes. These activities consume financial and human resources and make longer lead time without adding value. However, some of these activities are really necessary in the process; therefore the idea is to minimize their impact.

VALUE STREAM MANAGEMENT

Value stream management is a management tool for planning, managing, implementing, sustaining and linking lean-manufacturing improvements to daily work [1]. Value stream management consists of eight steps: committing to lean, choosing the value stream, learning about lean, mapping the current state, determining lean metrics, mapping the future state, creating Kaizen plans, and implementing Kaizen.

The goal for any manufacturer today is to reduce costs and lead times while maintaining the highest quality of its products [1]. In today's economies the market is very competitive and customers often set the prices or they demand price reductions. Under these scenarios the only way to stay making money is to eliminate waste from your value stream, increasing efficiency and reducing costs. Value stream management is a process that helps organizations systematically identify and eliminate the non-value-added elements from the value stream.

METHODOLOGY

The methodology for this project was chosen to meet each of the objectives. To gather data from the production flow and the activities being performed at the floor shop, it was required to go through the facility and identified each operation process involved from raw materials to finished goods. Also, identified all the places where inventory was stored between the processes, and observed how the material flows from one operation to another.

To observe and collect data related to the batch transformation and material flow, from raw material to finished goods. This required that the information was gathered with the help of the company's planner. This data was concerned with the communication between the company with customers and suppliers. Also, includes information on production control orders, product's forecasts, and frequency of released orders to the production supervisor. This value stream data was used in the construction of the value stream map.

In order to map the current state, it was decided to go to the floor to perform a three-day study in order to collect data. It began with the receiving area and worked toward the shipping area. The collected information was about material flow, inventory between processes, and process attributes. This data included: a) quantity of batches required per month, b) regular planned down time, c) available production time, d) number of operators per process, e) number of shifts per process. Also, was used a hand watch in order to collect the following individual metrics at each process involved: a) cycle time, b) cleaning /changeover time per shift, and c) available uptime.

Once the data was collected and sorted was calculated the daily requirements and the Takt time, and began to map the current state of the value stream selected. The next step was to construct the value stream map.

After the current state map was developed the appropriate metrics were selected, based on their ability to provide specific measures for a specific

operation, as well as a whole calculation for the value stream. Also, it was determined how to calculate each of the metrics selected. The following are the selected metrics:

1. Total value stream work-in-process inventory: The work in process inventory between each process were calculated and added up the amounts.
2. Number of days of work-in-process inventory: This metric was calculated dividing the total value stream WIP inventory by the daily amount of batches required by the customers.
3. Total production cycle time: In order to determine the total cycle time it was calculated the cycle time for each process and then added up the amounts.
4. Total lead time within the value stream selected: To calculate total lead time, it was required to got to the floor shop and tracked a batch from the time when the order was released to the time when the batch was delivered to the customer.

The last step was to look at the current value stream map for opportunities to eliminate wastes and improve the process flow. In this step were identified as many wastes as possible could be found in the value stream map. Finally, suggestions and recommendations were offered to the company.

RESULTS

In this project a value stream map was developed to identify improvement opportunities for a new product produce since July 2008 in a Pharmaceutical Company. This particular tool allows a company to document current lead time, inventory levels, and cycle times to determine the ratio of value added to total lead time of the product.

In order to map the current state, it was observed and collected information of materials and information flow paths, process attributes, and WIP inventory. This information helped determine the metrics for each process and for the entire process. Data was collected during three consecutives days, starting on Dec 22, 2008 to Dec 24, 2008. This information obtained was used to identify and eliminate wastes in the production process.

MATERIAL FLOW

The material flow begins at the receiving area as raw materials and travels through the plant until it reaches the shipping area as finished goods. The operations involved in the production process are, in sequential order: a) receiving, b) weighing, c) blending, d) compression, e) coating, f) visual inspection/packaging, and g) shipping. As soon as the raw materials arrive are sampled, and moved from the receiving area to the warehouse stock area where they are stored until needed. When it is required, the weighing process is performed. After the weighing is completed, the raw materials are moved to the blending area to be mixed in a PK V-Blender. Then the batch is transported in a Transport Bin to the press charge room where the granulation is introduced through a dump tub in a compression machine to form the tablets. The compressed batch of tablets is then moved to the coating area. Once the batch is received in the coating area, it is inventoried and placed on a stockpile waiting to be processed. Once painted, the batch is moved to the inspection room where the tablets are visually inspected and placed in shipping containers. The batch is then moved to the shipping area where it is inventoried and prepared for transit.

The material flow was monitored in order to (a) identify the product flow, (b) determine how the raw materials are used to produce each batch, (c) identify the operations involved, (d) identify the areas where the batches are manufactured, and (e) identify the stock areas in which the product is stored through the entire process.

To produce each batch eight different raw materials are weighed following a manufacturing recipe and mixed in the blending area. Then the mix is transported in a Transport Bin to the compression machine to form the tablets. The compressed batch of tablets is placed in plastics containers and moved to coating. In the coating area a solution composed of five different raw materials is prepared to give color to the tablets.

Once painted, the batch is moved in plastics containers to inspection where the tablets are inspected and placed in shipping containers.

Information Flow

The flow of information between suppliers and customers was monitored with the Material Scheduler. The process begins when Material Scheduler receives a 12 month forecast and weekly orders through MRP system from customers. Then Material Scheduler transmits the forecast and daily orders to suppliers. After that, the Material Scheduler transmits weekly orders to production supervisor. The last step in the flow of information is when the supervisor releases daily orders to each operation. This planning is effective to complete the customer requirement of two batches per day.

Process Attributes

The following process attributes were collected, which are important because they are used to calculate metrics for the entire process: daily customer requirements, Takt time, and available production time at each process.

- 40 batches/per month
- Regular planned down time are two 30 minutes breakfast/lunch breaks per shift.
- One eight hours shift for weighing process, two eight hours shifts for blending and compression processes, and three eight hours shifts for coating and inspection process.
- 20 shipping days per month

Daily Customer Requirements

The daily requirements were determined dividing the quantity of batches produced per month (40) by the number of shipping days per month (20), resulting in 2 batches per day. Actually the customer requirement is accomplished; therefore two batches are shipped every day.

Takt Time

The Takt time was determined by dividing the available production time per day (840 minutes) by the total daily quantity of batches produced (2), resulting in 420 minutes for blending and compression, 630 minutes for coating and inspection and 210 minutes for weighing process.

Availability

The available production time per shift was determined by taking the total available production time per shift, which is equal to eight hours (480 minutes), and subtracting regular planned downtimes events per shift (two 30 minutes breaks); therefore the available production time is 420 minutes per shift.

The available production time at each work center is determined by multiplying 420 minutes by the number of shifts that the work center usually operates. The total available production time within a process was determined by adding together the available production time at each work center involved. The weighing process is comprised of one work center. This work center runs for one shift (420 minutes), which results in 420 minutes available for the entire weighing process. The blending process is comprised of one work center. This work center runs for two shifts (840 minutes), which results in 840 minutes available for the entire blending process. The compression process is comprised of one work center. This work center runs for two shifts (840 minutes), which results in 840 minutes available for the entire compression process. The coating process is comprised of two work centers. Both work centers run for three shifts (1,260 minutes), which results in 2,520 minutes available for the entire coating process. The inspection process is comprised of two work centers. Both work centers run for three shifts (1,260 minutes), which results in 2,520 minutes available for the entire inspection process.

The available production time was determined and based on the results it is concluded that each work center has the capacity to complete the daily goal of two batches per day.

Individual Metrics

The following processes were used to determine individual metrics at each work center.

1. Number of Operators: In order to determine the number of operators at each work center, the production supervisor was asked to obtain the information, and also it was checked visually. The operators were counted at each of the work centers and those numbers were added together for each process. (see Table 1).
2. Cycle Time: The cycle time was determined by measuring the time needed for each process involved in the manufacture of the batch. The instrument used to gather it was a manual timer. The total cycle time within a process was determined by adding together each of the individual cycle times involved (see Table 1).
3. Cleaning/Changeover Time: The total Cleaning/Changeover time for each process was calculated by adding together each of the individual Cleaning/Changeover times involved. The Cleaning/Changeover time was determined by manually timing how long it takes the operator to setup the work center in order to make a batch. (see Table 1).

Table 1: *Metrics for Each Process*

Process	*Operators/shift*	*Cycle time/batch*	*Cl/Change time*
Weighing	2	180 mins	120 mins
Blending	2	420 mins	240 mins
Compression	3	420 mins	0 mins
Coating	4	840 mins	480 mins
Inspection	4	1080 mins	180 mins

The Cleaning/Changeover time for compression was zero because the product has two compression machines. The Cleaning/ Changeover time for a compression machine is 48 hours. When a Cleaning/Changeover is required the process is not interrupted since they switch to the other machine.

4. Available Uptime: The available uptime within a process is calculated by subtracting the cleaning/changeover time from the total availability and then dividing by the total availability. The results were a) weighing-71%, b) blending-71%, c) compression-100%, d) coating-81% and e) inspection-93%.
5. Work in process inventory: It was observed that the numbers of batches varied daily due to the demand and the availability of the work centers. The variation in each work center consists in that during the day if the goal of two batches is not completed, due to an equipment malfunction or a lack of operator, the work center must produce more batches the next day. From weighing to inspection, was collected information at each of the work centers and between each of the processes involved for the production of a batch.

Table 2 compares the amounts of Work in process inventory throughout the entire value stream, and an average of the Work in process for each process for three days is also provided.

Table 2: *WIP Inventory between processes (batches in process/day)*

Processes	*Day 1*	*Day 2*	*Day 3*	*Average*
Receiving-Weighing	30	29	31	30
Weighing-Blending	12	8	10	10
Blend-Compression	12	10	14	12
Compression-Coating	10	8	12	10
Coating-Inspection	8	8	8	8
Inspection-Shipping	8	12	10	10

As observed in Table 2 the WIP inventory between processes is excessive and the space required to storage the inventory between the processes is enormous. This situation cause economics problems to the company since the costs of the WIP consist in one million per batch. Also, is more difficult to manage the productions schedules.

METRICS FOR THE ENTIRE VALUE STREAM

Once the data was collected, organized, and analyzed it was calculated the following metrics for

the entire value stream: total Work in process inventory, total product cycle time, and total lead time.

1. Total Value Stream Work in process Inventory: The total Work in process inventory was determined from table 2, by adding up Work in process inventory between each process resulting in a total of 80 batches within the entire value stream.
2. Total Value Stream Days of Work in process: The total days of Work in process within the value stream was determined by dividing the number total value stream work in process (80) by the daily amount of batches required by the customer (2 batches), resulting in 40 days.
3. Total Product Cycle Time: The total production cycle time was calculated by adding up the cycle time determined previously (Table 1) for each of the processes, resulting in 2,940 minutes.

LEAD TIME

To estimate the lead time (the transformation from raw material to a finished product) within the value stream, it was turned to the shop floor and tracked one batch from the moment it was released to the production floor until the end, when was shipped to the customer. The order was released to the supplier on November 14, 2008 and the end items were delivered to the customer on December 24, 2008. The result was 965 hours or 40 days, which means it takes at least this long to complete a customer order.

The preceding information all led to the result of this project, the value stream map for a new production in a Manufacturing Pharmaceutical Company, which follows. From the map, it was evaluated where wastes occurs in the process and were make observations and recommendations on how to make processes leaner (see Figure 1 – Value Stream Map).

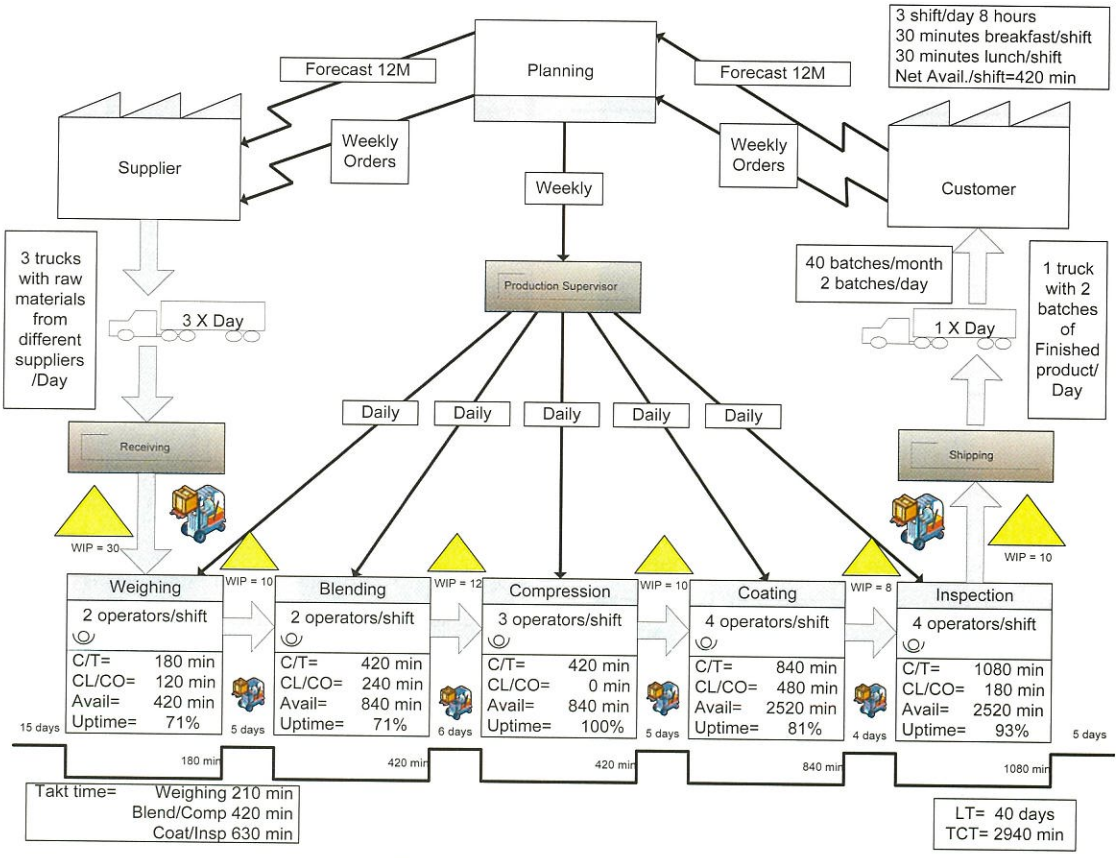

Figure 1: *Value Stream Map*

DISCUSSION AND RECOMMENDATIONS

The purpose of this study was to demonstrate the importance or the utility of a value stream map for a new product produced in a Manufacturing Pharmaceutical Company since July 2008. This particular tool allows a company to document current lead time, inventory levels, and cycle times to determine the ratio of value added to total lead time of the product. To identify wastes in the process and evaluate areas for improvement, it was examined the current state map that was produced as a result of the project. The following observations and recommendations were made to the Pharmaceutical Company:

1. It was found that the time it takes to make one batch, or the total product cycle time for the value stream, was 2,940 minutes. However, the total lead time, which is the time to make a raw material into a finished product, was 40 days. The lead time (40 days) minus the cycle time (?,940 minutes) is the non-value-added activities such as cleaning/ changeover machines, moving materials, and waiting for materials. This indicates that there is much opportunity for improvement.
2. The total number of days of work in process inventory is equal to the production lead time, which means that the company keeps on hand a safety inventory that is sufficient to satisfy customer demand during the lead time.
3. The result obtained from the cumulative available uptime reflects that the company is spending an enormous amount of time in cleaning/changeover the machines during the weighing (29%), blending (29%) and coating process (19%). It was observed that each operator runs the work center in different ways and that the operators change the tools in different ways, spending between two to four hours to cleaning/ changeover the work center. The speed of the process depends of the skills of each operator since they do not have visual aids to perform the processes.

In order to reduce the cleaning/changeover time at the weighing, blending and coating process it was suggested the application of quick changeover /setup reduction techniques. This setup reduction technique is based on the principles of the single minute exchange dies (SMED) system to dramatically reduce or eliminate changeover time. The systematic process includes analyzing a changeover, then applying quick changeover techniques and strategies to reduce the machine downtime. Some examples that could be utilized in this situation include:

- Utilizing a multi-die function reducing the number of setups by equipment.
- Setting tools close to the work center, reducing the time that the operator spends looking for the tools.
- Standardization of the setup operations, so each operator must perform the setup in the same way and must run the work center similarly.
- Establishing a standard time to perform a setup. By this approach every operator must perform the setup of the work center in the same period of time.

4. Some of the batches that were initiated on December 13th were still incomplete and remained in process. This event occurred because the work center did not have an operator available to run the machine. Also, many of the work centers were not running for the reason that they had mechanical problems due to poor maintenance.

In order to increase the capacity of the plant without capital investments and also to avoid unplanned equipment downtime, it was suggested the implementation of total productive maintenance, which is a process to increase the efficiency as well the useful life of the equipment involved. One of the key elements of this technique is employee involvement, so each operator must take care

of the work center and/or equipment, maintain it, and report any damage occurred.

5. Once the batches were made, they spent too much waiting time before they were moved to the next operation. It was observed poor communication either between the machine operators and production supervisor or between the machine operators and the material handler.

   In order to reduce waiting time between each operation, it was suggested the utilization of Kanban systems. As mentioned, a Kanban is a tool to achieve just in time. It consists of a card containing all the information that is required to be done on a product at each stage along its path to completion and which materials are needed at subsequent processes. By the utilization of this tool the batches can be moved quickly from one work center to another, improving the material flow and reducing the work-in-process between processes.

   Also, in order to improve communications, it was suggested the utilization of a visual control system. Some of the techniques that could be applied include call lights and Andon board lights, standard operations sheets, digital display panels, and a monitor screen and clock at each work center. Call lights and Andon board lights could be used to call immediately for a supervisor or general workers for different types of assistance (e.g. move material, problem in the machine, etc). Standard operations sheets could be used for the first line supervisors to eliminate unnecessary inventory and workers and to eliminate accidents. These sheets measure all three elements (cycle time, a standard operation routine, and a standard amount of work-in-process) every certain period of time. Digital display panels are another recommendation which would normally be used to show the pace of production (Takt time), the day of production and the number of batches that has been produced during the day. This would inform every person at the plant about exactly at what rate they must be working in order to satisfy customer demand. Another recommendation is to implement a monitor screen at each work center showing drawings and steps to disassembly, cleaning and assembly the machines. Last, setting clocks at each work center in order to determine how much time an operator is spending in cleaning/changeover.

6. In the manufacturing areas it was observed disarranged work centers, tools in different places and equipment out of service.

   In order to improve the housekeeping it was suggested the implementation of 5S techniques for the workplace standardization and organization, during the manufacturing process. As mentioned, this technique includes the implementation of five steps: remove all unneeded equipments, create locations for the needed equipments, keep everything clean after utilization, set standards and procedures, and employee involvement.

7. During the monitoring of the visual inspection process it was observed that the company is investing an enormous quantity of time to remove cosmetically defects tablets and the quantity of those defects is very low. The company inspected all batches produced.

   In order to reduce the manufacturing lead time and low down inventory levels, it was suggested that the visual inspection process must be eliminated since is a non value added activity that is not necessary. The company must dedicate resources to eliminate the source of the defects instead of inspecting every batch produced.

The goal of this study was to collect necessary information and develop a value stream map for a Manufacturing Pharmaceutical Company in Guayama, Puerto Rico. The value stream map served as a tool in order to make observations and recommendations to improve processes at the company. If the company implements these recommendations the operations will be improved.

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Volumen 15

Num. 1 - Abril 2010

UNIVERSIDAD POLITÉCNICA PUERTO RICO