

Cycle Time Reduction using Lean Manufacturing Techniques for a Solid Pharmaceutical Product

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Abstract — *The purpose of this project was to demonstrate that the Lean Manufacturing techniques could be applied to a Solid Pharmaceutical Product in order to reduce the cycle time. During the year 2007, the Solid Pharmaceutical Product studied had 52 days of cycle time. The goal is to reduce the cycle time 25% or to 39 days. Lean Manufacturing tools used in this project was the process map to develop the required knowledge of the manufacturing process and the Value Stream Mapping where the values added and non-values added activities were identified. A Multidisciplinary team, essential for creation and implementation of new ideas, a list of improvements was generated and weighted for prioritization. This prioritization matrix is the foundation to start the implementation of improvements. After the Multidisciplinary team implemented the short term improvements in the Manufacturing Area, it was observed that the Product Cycle time decreased to 37 days in the third quarter of the 2008. After completion of the study, it was proved that the Lean Manufacturing techniques can be applied to a Solid Pharmaceutical Product and can radically reduce the cycle time.*

Key Terms — *Kaizen, Value add (VA), Value Stream Map and Waste (muda).*

INTRODUCTION

In this age of economic uncertainty organizations are constantly searching for ways to reduce costs without compromising production rates or quality standards [7]. Cycle time reduction is one of the most important elements of successful manufacturing today. Customers are demanding that manufacturers quickly respond to their wants and needs, as well as deliver perfect quality

products on time. There are many challenges involved in reducing cycle-time and the first one is the fact that it is affected by nearly every function of the organization such as purchasing, planning, production, engineering, maintenance, facilities, quality, shipping and distribution. There are many improvements that can be made by focusing on changes in the individual parts of the process. Specifically, between the functional areas but in order to do so, the organization must be willing to breakdown the obstacles that commonly exist between functional areas.

Among the other challenges may be found are the maturity of the industry itself, the priorities of the organization, the complexity of the environment, the culture change required to complete the desired reduction, and accountability. Once these challenges have been overcome the process of reducing cycle-time can really begin. But as with any organizational initiative, in order to assure a smooth implementation, a systematic approach must be undertaken by those involved [4]. Accelerating cycle-time is important because pharmaceutical companies must recover all their research and development costs (typically between \$500-\$800 million), plus most of the drug's lifetime profit, in a limited time. From the time a new compound is first registered the US patent law provides 17 years of exclusive patent protection, and 7 to 10 of these are typically needed to bring the compound to market as an approved prescription drug. Once the patent protection expires, multiple generic drug manufacturers typically flood the market with competitive products sold for a fraction of the original branded price. Consequently, reducing the cycle-time results directly in incremental revenues, by getting the drug to market sooner and gaining a longer

period during which premium income can be obtained [6].

Since prescription drugs are so profitable, the industry for years has not been motivated to improve efficiency. Now, however, the payoff from investing in drug discovery is diminishing due to fewer new products coming out of their research laboratories. Therefore, savings from improving manufacturing processes are now looked upon as key sources to help establish profits. Furthermore, drug prices are continuously driven down by competition from generic drug sales, increase in smaller third party vendors, insurance provider subsidies, as well as the creation of government-subsidized prescription drug benefits. Companies are trying to drive costs out of their products, while they ensure stability, encourage compliance, promote safety, and meet regulations [5].

Value of Cycle Time Reduction

Reduced cycle time can translate into increased customer satisfaction. Quick response companies can launch new products earlier, penetrate new markets faster, meet changing demand, and can deliver rapidly and on time. They can also offer their customers lower costs because quick response companies have streamlined processes with low inventory and less obsolete stock. According to empirical studies, halving the cycle time and doubling the work-in-process inventory turns can increase productivity 20% to 70%. Moreover, quartering the time for one step typically reduces costs by 20% [7].

With reduced cycle times, quality improves too. Faster processes allow lower inventories which, in turn, expose weaknesses and increase the rate of improvement. After eliminating non-value added activities, there are fewer opportunities for defects. Fast cycle time organizations experience more rapid feedback throughout the supply chain as downstream customers receive goods closer and closer to the time they were manufactured [7].

Definition of Terms

Kaizen: Continuous, incremental improvement of an activity to create more value with less waste [1].

Value Stream Map: Value Stream Mapping is a lean technique used to analyze the flow of materials and information currently required to bring a product or service to a consumer [1].

Value add (VA): Activities that transform or shape products or services that are sold to customers, such as assembly, painting, machining, forming, welding, and heat treating [3].

Waste (muda): Anything that does not add value to the product is waste and must be reduced or eliminated [3].

Description

This Solid Pharmaceutical Product Cycle-time had an average of 52 days during the year 2007. These 52 days were calculated from the moment the raw materials were weighted until the release of the packaged product. These 52 days Solid Pharmaceutical Product cycle time included the weighing of the raw materials, the manufacturing process of the product, the packaging process, the Quality Control Laboratory Analytical testing and Quality approval for release of the product to the distribution center. During this study the scope was limited to the Manufacturing process. Refer to Figure 1.

The Solid Pharmaceutical Product Tablets manufacturing process consists of four granulation stages.

- Part I - Compounding I: Raw materials (including the active ingredient) are added in a vertical manufacturing line. Materials are added through a dumping station located in the second floor into a 20 Cu. Ft PK V-Blender located in the first floor.
- Part II - Wet Granulation Solution Preparation: Solution is prepared for the fluidization process.
- Part III - Wet Granulation: Executed in a Fluid Bed Dryer to bring the necessary properties and size to the granules for a better

compression. The Fluid Bed Dryer is charged with the granulation obtained from Part I-Compounding I process. This granulation is then infused with the wet granulation solution previously prepared in Part II. No additional raw materials are added into the Fluid Bed Dryer.

- Part IV - Compounding II: Granulation from the wet granulation stage is discharged in a vertical manufacturing line located in the third floor to a milling machine located in the second floor. In the milling process, a desired particle size is obtained with a mesh screen. Granulation flows from the milling machine into a 20 Cu. Ft PK V-Blender located in the first floor. Then, additional raw materials are added and the whole granulation is blended in the 20 Cu. Ft PK V-Blender to complete the granulation mixture for compression.
- Part V – Compression: Tablet cores are formed from the granulation obtained in Part IV-Compounding II. Tablet cores are formed with the specified dimensions, attributes and shape characteristics.
- After the compression stage, two coating processes are performed, the Seal Coating and Enteric Coating processes. The last manufacturing stage for the Solid Pharmaceutical Product is the Branding process, on which the brand name is printed on one side of the tablets.
- After all the manufacturing stages are completed a sample of each batch is sent to Quality Control Laboratory for testing as per Testing Method. That includes the manufacture, packaging the Quality Assurance release of the product. This cycle time reduction project will reduced the non value added activities in the Solid Pharmaceutical product manufacturing process using Lean Manufacturing Techniques.

The goal of this lean manufacturing implementation was to reduce the Solid Pharmaceutical Product cycle-time from 52 days to

39 days using lean manufacturing techniques, eliminating/reducing the non value add activities in the manufacturing process.

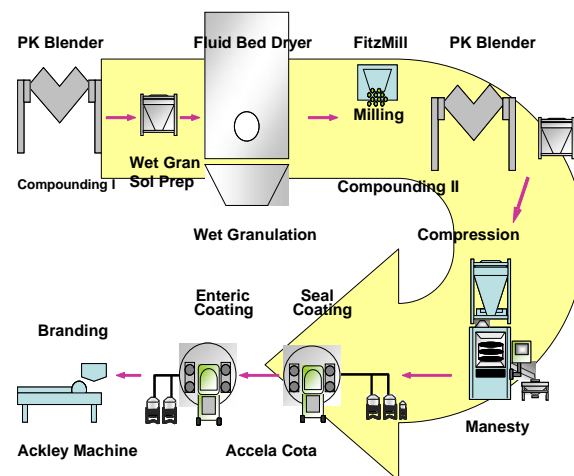


Figure 1
Solid Pharmaceutical Product Manufacturing Process

Objectives

With this lean manufacturing implementation, the organization:

- Reduce Product Inventory
- Reduce Work in Process

These two objectives saved money for the organization since eliminated the waiting waste of the product in the manufacturing area and provided a faster return of investment to the organization. The product is delivered faster to the customer. Reducing cycle times reduced costs, increased revenues, and made the plant more agile. Increasing throughput allowed the company to add more products to its mix as well as reduce costs. This implementation is standardized in order to be applied for other products in the industry.

IMPLEMENTATION PROCESS

The lean manufacturing implementation process can be broken down into three phases. (I) Preparation, (II) Physical Transformation, (III) Living the System. Phase I is considered the preparation phase of the process and focuses mainly on the company's top management. Before implementing lean manufacturing physically,

certain steps have to be clarified beforehand in order to put prerequisites into place that assure a smooth process. Ultimately the responsibility for the success of implementing lean manufacturing lies here. The steps in Phase I include:

1. Carrying out a potential analysis.
2. Decision for the lean manufacturing implementation.
3. Develop a vision for the company's future.
4. Decision for external support.
5. Define objectives.
6. Carry out a strategic implementation planning.

Phase II involves the physical transformation of the company or the selected area, focuses on the analysis and implementation of tools and methods. Middle- and front-line-management levels are mainly involved in this phase of the project because they will be supporting and encouraging the people involved and the stabilize process.

Steps in Phases II include:

1. Project preparation and kick off.
2. Current state analysis.
3. Design of future state.
4. Implementation planning.
5. Implementation.
6. Review/Evaluation.

Phase III constitutes the never-ending team work phase of all hierarchical levels in order to drive the continuous improvement process jointly. It constitutes the adjustment of the company's culture concerning leadership and mindsets of the work force [3]. The steps in Phases III are:

1. Maintaining the standard.
2. Improvement of the standard due to Kaizen.
3. Develop new leaders.
4. Develop a problem solving culture.

Value Stream Mapping

The value stream mapping is an effective tool to build improvements and efficiencies for any organization. For completing this part of the lean journey, the payoffs can be immense for any organization. VSM requires a dedicated team ready

to ask difficult questions and think beyond the current state--and a team not afraid to admit error and use that eraser a few times along the way [2].

METHODOLOGY

The first step of the Cycle Time Reduction using Lean Manufacturing Techniques for a Solid Pharmaceutical Product Design Project is to defining the process flow for the Manufacturing Area.

The Manufacturing Area must have a Multidisciplinary team consisting of Subject Matter Experts of each discipline including Quality, Safety, Technology, Manufacturing personnel.

After the completion of the process flow, the next step was to divide the process flow in process steps.

Subsequently, it was defined the variables that were going to be measure in the project. Since the purpose of this project is to reduce the cycle time, the time and resources were the critical parameters to be measured.

The time per process step had to be calculated and tabulated in these categorizes:

- Time Required per batch (Hrs.)
- Cumulative time consumption (Hrs.)
- Required Man-hours
- Cumulative Man-hours

The instrument that was used to calculate this time variable was a stopwatch and had to start from the beginning of the process flow when the raw materials are weighted to process a batch and finishing with the branding area, the last manufacturing process step.

After the completion of collecting the data the Value Stream Map was used in order to construct a current state map of the Manufacturing area. The value added activities and the non value added activities were defined and classified. The total value added time was calculated.

The current state map was analyzed and brainstorm was performed for improvement opportunities. It is essential that all the Subject

Matter Experts participated during the construction, analysis and brainstorm of the Value Stream current state map. To achieve a great result of opportunities it was indispensable to think broadly and out of the box, therefore was a good strategy to invite persons that were not working the day to day manufacturing operations of the product. After the brainstorm sessions, the opportunities for improvement were determined and documented.

The ideas were documented in Process Improvement Table and then were evaluated for the impact stage that applied. After that, each improvement opportunity was weighted from 1 (low impact) to 10 (high impact) in the classification of time, cost and savings. Each result was multiplied to obtain a prioritization number. The higher result was the higher priority idea and the implementation was performed from the short term higher priority to low priority. Subsequently each improvement opportunity was classified by the waste reduction impact that had. In the Process Improvement Table, the different wastes were documented as a category in order to select the impact of each improvement opportunity into the waste. After that each improvement opportunity had to be categorized in the following categories: Improve cycle time, Improve Manufacturability, Improve Material Flow, Service Improvement, Quality Improvement, Cost Reduction and Improve Safety.

Using the process flow and the Value Stream Map tools, a kanban was calculated in order to establish the quantity required of batches between stages. This reduce the work in process and synchronize the product flow in order to reduce or eliminate the non value add activities.

After the completion of analysis, the improvement opportunities had to be implemented. During the implementation phase, the coordination and communication was essential in order to obtain satisfactory results.

The cycle time has to be continued measure in monthly basis in order to determine the impact of the improvement implemented. After the implementation phase was completed, a Future

State Map with the improvement performed had to be created to continue observing new opportunities and create a kaizen culture in the organization.

IMPLEMENTATION

Following a product batch from beginning to end, the resources and standard times were taken in order to perform the Product process flow. Results obtained were documented in the Table 1.

Table 1
Batch Cycle Time per Process

Process Stage	Time Required per batch (Hrs.)	Cumulative time consumption (Hrs.)	Required operators	Required Man-hours	Cumulative Man-hours
Raw Materials Staging	12	12	N/A	0	0
Compounding I	3	15	3	9	9
Staging	60	75	N/A	0	9
Wet Gran. Solution Prep	4.6	79.6	2	9	18
Wet Granulation	7	82	2	14	23
Staging	18.9	100.9	N/A	0	23
Compounding II	3.9	85.9	4	15.6	38.6
Staging	68.7	154.6	N/A	0	38.6
Compression	6.6	161.2	2	13.2	51.8
Staging	58.7	219.9	N/A	0	51.8
Seal Coating	13.2	174.4	2	26.4	78.2
Staging	55.7	230.1	N/A	0	78.2
Enteric Coating	11.2	185.6	2	22.4	100.6
Staging	46.7	232.3	N/A	0	100.6
Branding	6.3	238.6	3	18.9	119.5
Staging	5	243.6	N/A	0	119.5
Totals	381.5	238.6	18	128.5	119.5
Total staging hours:		325.7	Total staging days:		13.6
Total process hours:		55.8	Total process days:		2.3
Total days to complete one batch:					15.9

From the data obtained of the standard times only, it was observed there existed a great opportunity of reducing the waiting waste since 325.7 hours of the 15.9 days total days to complete a batch, the batch was idle, waiting to be processed.

The batch that was studied was the first after a shutdown and a major cleaning campaign from the manufacturing equipments, therefore there was a minimum of material and batches between stages and still almost 86% of the time was idle (total staging hours-325.7 hours vs. total process hours-55.8 hours). This denotes a big unsteadiness in the process and a good opportunity to implement a kanban system in order to synchronize the production.

After the times were taken, a Multidisciplinary team participated in the creation of the

manufacturing current state map. Refer to Figure 2 Current State Value Stream Mapping.

From Current State Map, it is observed that the non-value activities time (13.6 days) is almost six times than the value-added activities (2.3 days). This rate of non-value-added activities vs. value-added activities denotes the process has excess of Work in process between the stages.

After the completion of it, the Multidisciplinary team observed the areas of opportunities in the Manufacturing area and the improvements ideas started flowing. These ideas were tabulated in the in Process Improvement Table and were weighted and classified accordingly by the categories mention previously. Refer to Table 2 Improvement Priority Rating Table.

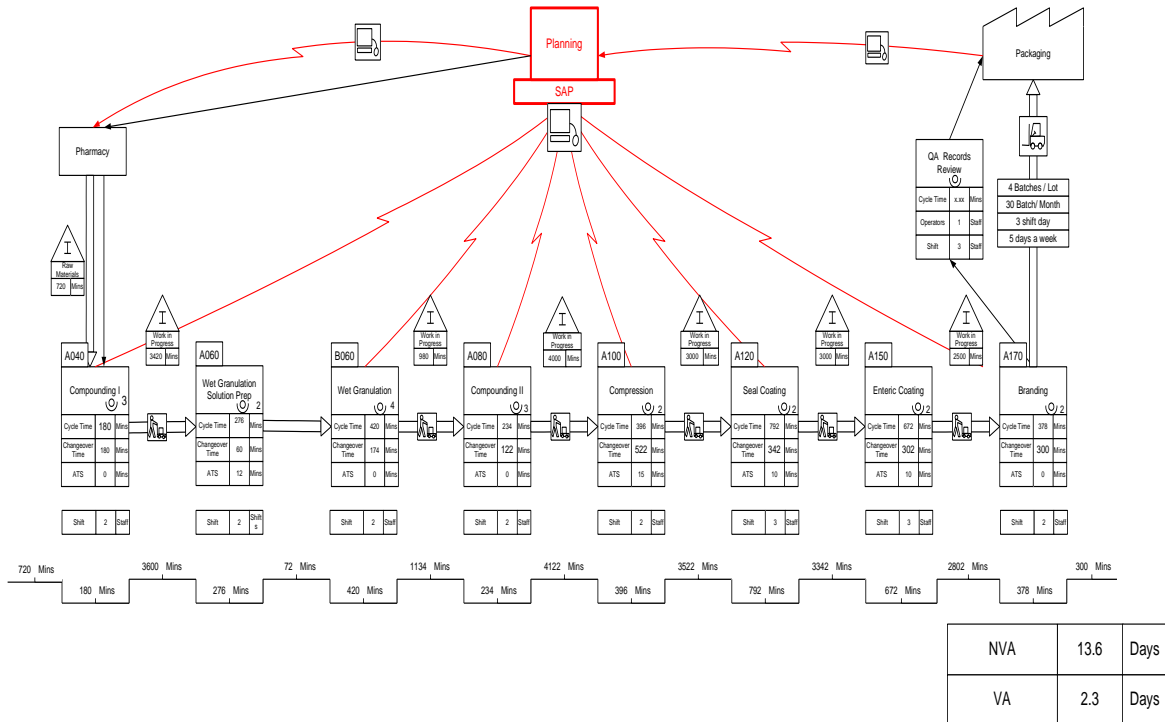


Figure 2
Current State Value Stream Mapping

The Improvement Opportunities were classified in Short Term (< 30 Days) highlighted in color green in the table, Mid Term (< 90 Days) highlighted in color yellow in the table and Long Term (180–360 Days) highlighted in color red in the table.

After that, the ideas were classified by the waste reduction impact and the operational improvement that was going to be observed. Refer to Table 3 Impact Analysis Table.

After the ideas classification completion, the Multidisciplinary team assigned the responsible person or team that was going to implement the ideas. The short-term ideas with the higher priorities were going to be implemented first,

following with mid terms and finishing with the long-term ideas.

During the implementation, it was critical to include the Manufacturing Operators in order to obtain a smooth transition of the improvements in the shop floor.

After the analysis of the current Value Stream Mapping, a kanban system was implemented prior of the compression process in order to maintain a synchronous flow and reduce the work in process. The staging area that was holding the batches up to twelve hours was eliminated since the Part-IV Compounding II is performed in less than four hours and the Compression process duration is almost seven hours. The Multidisciplinary team

decided to start the batch in the Part-IV Compounding II when the Compression process is in between process in order to avoid having a staging area prior the Compression area. This change replaced the cultural push system since the work in process in this area was the bigger in the manufacturing area for the Solid Pharmaceutical product.

Table 2
Improvement Priority Rating Table

Product Process Improvement List						
Item	Ideas	Process	Cost	Time	Saving	Priority
1	Eliminate Approval to Start (Compression, Coating, Branding)	Compression, Coating, Branding	8	8	7	448
2	Branding Roll installation by Operators instead of Mechanics	Branding	9	9	5	405
3	Install a scale in the Branding Room	Branding	7	6	8	336
4	Prepare Sampling label in the Branding Room	Branding	10	10	3	300
6	Locate scale on Solution room of Accela Cota to weigh the solution	Coating	6	9	5	270
7	Align Manifold spray guns correctly to avoid un-necessary cleaning of pan load.	Coating	7	6	6	252
5	Evaluate extension campaign length	Granulation, Compression, Coating, Fluid Bed	6	5	8	240
8	Fats Implementation DOE to maximize optimal RPMs on Fette Tablet press with pre compression.	Compression	6	5	8	240
9	Pre- blend evaluation to reduce time in blending	Granulation	6	5	7	210
43	Revise Process Sequence in the Manufacturing Records	All	7	6	5	210
10	Operators performing the Manesty Plates calibration "Compression" instead of Mechanics	Compression	10	10	2	200
11	Operator cross training	All	7	4	7	196
44	Use the granulation line to compress. The compression machine must be located in the first floor and use the third floor as storage area simplifying the material transfer from line # 6	Granulation	7	7	4	196
12	Use two (2) Fitzmill instead of one (1). Add (1) Fitzmill to the Manufacturing Record	Granulation	8	6	4	192
14	Created Supermarkets between operations	All	9	7	3	189
17	Place all Cleaning agents on Washroom implementing a Kanban system	All	10	9	2	180
18	Evaluated cleaning Check List format to maximize process	All	6	5	6	180
19	Kanban Implementation	All	6	4	7	168
41	Fluid bed Optimization	Granulation	4	6	6	144
20	Operator should have the opportunity to print the Share Forms from the system without supervisor signature, Up grading the system to provide the date of impression and the operator electronic signature on the sheet format and locating stations with printer	All	6	7	3	126
21	Use transport bins instead of nosco palls thru Compression, Coating , Branding , Shipping	Coating, Branding	3	5	8	120
23	Locate the micronotions on Manufacturing Rooms	Coating	5	5	4	100
24	Perform set up of the next batch in the Second floor, as soon as the discharge of the fluid bed is completed.	Granulation	8	6	2	96
25	Raw material should arrive from pharmacy by stages.	Pharmacy	5	6	3	90
26	Train personnel so that they realize the works of cleanliness and set up of the machines. This would help to improve the process of production the following day. (These works must be realized during the second shift)	All	7	4	3	84
28	Drum Inverter installation	Granulation	5	7	2	70
29	Additional set of Tanks Valves and Manifold to be replace during cleaning	Coating	2	5	6	60
32	Use dumping system for Fitzmill and Swecco. (Same floor and room)	Granulation	3	3	5	45
42	Portable Coating Tanks instead of the dedicated Tanks	Coating	3	3	5	45
34	Incorporated Pharmacy process in to Manufacturing	Granulation, Coating	2	2	10	40
35	Third shift in all the areas to reduce the time that goes from operations	All	2	7	2	28
36	Re-allocated Coating Solution Room	Solution Prep	3	3	3	27
37	Implement Stock Room area inside of Manufacturing Tower	All	2	4	3	24
38	MES Implementation	Documentation	1	2	8	16
39	Transfer Packaging process to the Manufacturing Tower	Packaging	1	3	4	12
40	Material Filter Optimization	Granulation	4	7	3	84
45	Optimize pan load quantity	Coating	6	6	5	180

In effect, this change eliminated the routine idle time, and subsequent queuing, caused by waiting for the product to be utilized in the compression machine. This kanban increased the performance within the manufacturing area and delivered a smoother flow of material.

From May 2008 to July 2008, all the Short term ideas (highlighted green in Table 2) were implemented in the Manufacturing area.

During the Short term ideas implementation, I was met regularly with key production and planning personnel to discuss progress and problems. As improvement milestones were met, project updates were given at routine weekly meetings.

Table 3
Impact Analysis Table

Waste Reduction Impact						Operational Improvement						
Waiting	Motion	Over production	Inventories	Processing	Reject/Transport	Improve Cycle time	Improve Manufacturability	Improve Material Flow	Service Improvement	Improve Quality	Cost Reduction	Improve Safety
						X			X		X	
X							X					X
	X					X						X
		X				X						X
			X				X					X
	X					X						X
				X			X					X
X		X	X	X		X	X	X	X			X
		X				X						X
	X						X			X		X
												X
X	X											X
												X
	X											X
X	X	X	X	X				X	X			X
				X		X		X				X
	X						X					X
X	X	X		X	X	X	X	X	X	X		X
X	X	X	X	X	X	X	X	X	X	X		X

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problems. As improvement milestones were met, project updates were given at routine weekly meetings.

After implementing the short term ideas in the Manufacturing Area, it was observed that the non values added activities were reduced from 13.6

days to 3.6 days. This implementation reduced the manufacturing process cycle time of the product from 15.9 days to 5.9 days. Refer to Figure 3 Current State Value Stream Mapping after implementation of short term ideas.

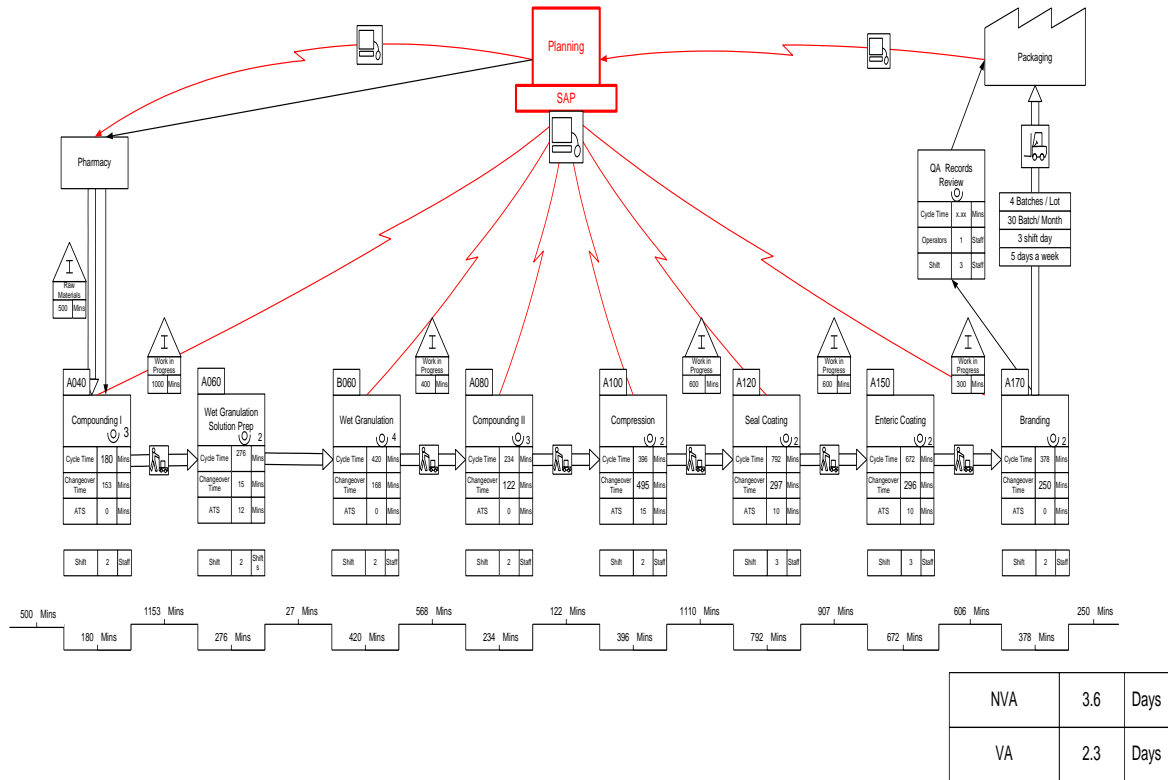


Figure 3
Current State Value Stream Mapping after implementation of short term ideas

This manufacturing process cycle time reduction impacted the Average Solid Pharmaceutical Product Cycle time that had observed a decrease from the 52 days of the last year to 37 days in the third quarter of the 2008. Refer to Figure 4 Solid Pharmaceutical Cycle Time.

Figure 4 shows the cumulative effect on the short terms ideas implemented since were implemented together. Until the third quarter of the 2008, the Solid Pharmaceutical Product cycle time has been decreased by 29%.

Also it was observed that after the implementation of the short-term ideas in the Manufacturing Area, that the Work in Process and

the Inventory cost had decrease. Refer to Figure 5 Product Inventory Trend.

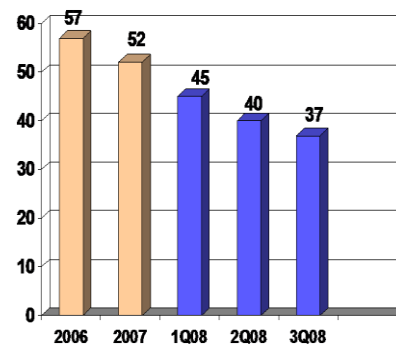


Figure 4
Solid Pharmaceutical Cycle Time (days)

Figure 5 shows the cumulative effect on the short terms ideas implemented in terms of the work

in process reduction, finished goods and raw materials. Until the third quarter of the 2008, the Solid Pharmaceutical Product work in process cost has been decreased from \$40,900 to \$21,800 for a 47% of reduction, the finished goods cost been decreased from \$166,600 to \$85,600 for a 49% of reduction and the raw materials cost been decreased from \$55,900 to \$37,700 for a 33% of reduction.

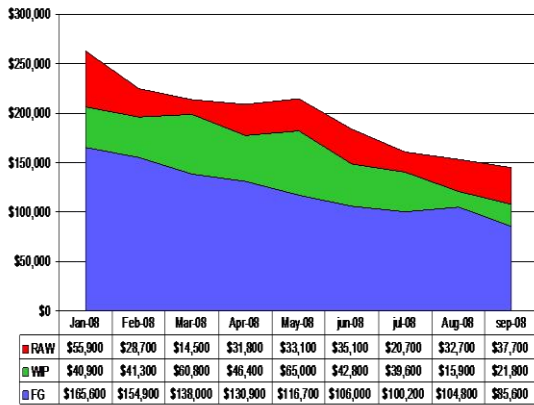


Figure 5
Product Inventory Trend

After the completion of the short term ideas, a future state map was performed in order to analyze the changes performed and the new opportunities that can be found. Refer to Diagram 2.

From Future State Map, it is observed that the non-value activities were reduced from 13.6 days to 3.6 days. This change was reflected in big part due to the reduction of Work in process in between the stages and the elimination of the staging prior of the compression area.

CONCLUSION

This project examined the application of Lean Manufacturing to a Solid Pharmaceutical Product, defining the cycle time as the reduction variable. The methodology used provides an effective and efficient process for specifying the value add activities in the Manufacturing area and gave the multidisciplinary team a snapshot of the non-values activities that were the focus areas.

Since this study began, the average cycle time for the Solid Pharmaceutical Product has decreased by 29% exceeding the target established of 25%.

Also, until the third quarter of the 2008, the Solid Pharmaceutical Product work in process cost has been decreased from \$40,900 to \$21,800 for a 47% of reduction, the finished goods cost been decreased from \$166,600 to \$85,600 for a 49% of reduction and the raw materials cost been decreased from \$55,900 to \$37,700 for a 33% of reduction.

The Product Process Improvement Table tool was developed during the study and optimized the implementation process since the ideas are implemented by prioritization. The table gave the opportunity to use it for a different operational area improvement since classified the ideas in cycle time improvement, Manufacturability improvement, Material Flow improvement, Service improvement, Quality improvement and Safety improvement. Also it can be use to eliminate the required waste that the industry is looking for since the improvement opportunities are classified by the waste reduction impact that will have. The key to successful lean manufacturing implementation is partnering with production.

This study shows the benefit of applying lean manufacturing to reduce cycle time to this product; however the improvements opportunities can be applied for another project scope using this Product Process Improvement Table tool due to the classification and data recollected with this tool. This tool facilitates the analysis and simplification for a satisfactory implementation.

The success of this project has led to a factory-wide acceptance of the benefits of lean manufacturing techniques in order to reduce the cycle time and will standardize the methodology to use it for the others Pharmaceutical Products in the industry.

LESSON LEARNED

Throughout this project several important points during the implementation have been highlighted in order to have smoother transition. A summary of these lessons learned are:

- Ensure full time facilitator or leader- work teams with a full time facilitator progressed more quickly
- Involve work teams directly with the manufacturing operators - gain operator input.
- Provide adequate time and resources to work teams to allow them to pursue improvement activities - improvements can stall if sufficient time to resolve is not allocated.
- Address peer pressure issues early on - initial pressure not to partake in improvement process.
- Prominently post shift results - some competition can be a good thing.

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