Granulation Area Capacity Increase

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Abstract

Manufacturing pharmaceuticals are continuously looking for reduce waste to improve their processes and increase the manufacturing output. Granulation area capacity increase was evaluated for a solid dosage pharmaceutical industry in Las Piedras (LP), Puerto Rico. Volume increase for a pharmaceutical product is driving additional capacity requirement for granulation. Also, it was required to eliminate non-value added (NVA) tasks during the granulation activities. DMAIC process and its tools were used to increase the Granulation capacity. Kaizen principles, process mapping and cycle efficiency among others were used providing a high-level view of the value stream being targeted in the improvement. Equipment and Method were the most probable causes. Improvements such as new Ways of Working (WOW) to run two batches in parallel among others were actions implemented to granulation product capacity increase. As results of this project the business benefits were a cost benefit of time saving 27% cycle time representing 36 lots/month with a revenue of $1,947,886 per month.

Introduction

As business competition is growing and get tougher, there is much pressure on manufacturing and service organizations to become more productive and efficient. Manufacturing area is constantly pressured to improve quality, decrease manufacturing cost and increasing production volumes with less resources. Therefore, the organization must reduce the cycle time and improve customer satisfaction.

The granulation area volume increase for pharmaceutical product is driving additional capacity requirement for granulation. Granulation capacity will be exceeded in year 2019 even with twenty-four (24) hours operations. The current output for granulation area is 4-5 lots/day (130 lots/month) with a manufacturing cycle time of 4.4 hours/lot. The company requirements and forecast requested to increase the granulation output to produce at least 160 lots/months on a monthly basis, to meet the demand of 2019 and 2020. Each granulation lot is finally used to produce a solid dosage tablet.

Background

This project arises from the need to improve the granulation process of the pharmaceutical industry in Las Piedras, Puerto Rico and promote a culture of continuous improvement.

The objectives were defined based on a requirement of the LP Operation Site to improve the performance to meet the demand and to be more competitive. The improvements enhance value or excellence, and these characteristics are part of the pillars of the company, and these objectives obey the need to show the capacity of make a more efficient production and better cost, because the plant is being compared against the network. Project objectives were focused using Lean Manufacturing methodology. The following are the objectives of this research work:

- ❖ Implementation of parallel granulation activities.
- ❖ Decrease the manufacturing cycle time by 27% (1 hour/lot, at least1700hours/year).
- ❖ Increase Granulation lots Output: 7 – 8 lots/day, Aprox.157 lots/month.
- ❖ Meet demand requirement.
- ❖ Eliminated non- value-added tasks activities (No waiting time, simultaneously activities).
- ❖ Standardize Work, visual factory and improve area organization through 5S methodology implementation.

Problem

✓ Need additional Granulation Area Capacity during 2019 and subsequent years.

✓Eliminate tasks with no value added associated to manufacturing process.

✓Improvements in the procedures, implementation of a new Ways of Working (WOW) to run two batches in parallel.

✓Design new granulation room layout, implementation of 5S and standardize work .

✓Need a new downtime tracking system.

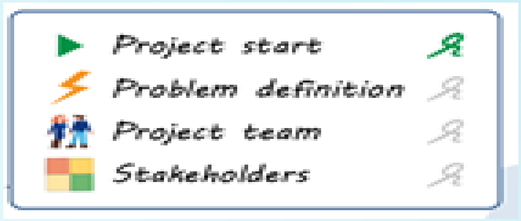
Methodology

This project will apply the DMAIC (Define, Measure, Analyze, Improve, Control) methodology to improve the maintenance cost, rationalization and eliminate the non-value tasks in Preventive Maintenance activities. The five phases that structure the process in which is based this project are:

Define → Measure → Analyze → Improve → Control

Results and Discussion

This project arises from the need to improve the granulation process of the pharmaceutical industry in Las Piedras, Puerto Rico and promote a culture of continuous improvement.



Currently, lack of capacity in the granulation area to meet demand requirement the expected was identified as a potential problem to be increased using Lean Methodology and DMAIC approach. A multidisciplinary team was selected to work with this project.
The problem was defined as volume increase for granulated API and it is driving additional capacity requirement for granulation area. The customer and their requirements were identified.

Measure Phase

In this stage, the data gathering was obtained from SAP reports. Data was plotted to established a baseline performance and quantify the problem. The data can be showed in graphical and statistical forms. The data and information of the current process is portrait in the figures 1-5.

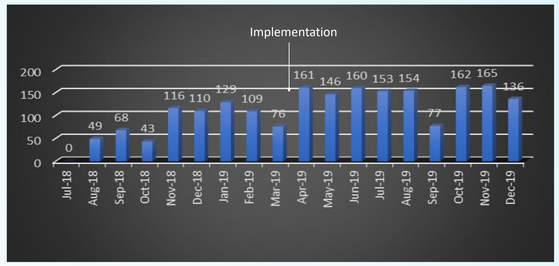


Figure 1: **Chart of Monthly Comparison of Granulation Lots Manufactured before and after Improvements Implementation**

n	Min.	Max.	Median	X̄	SD
50	43	129	93	88	33

Figure 2: **Descriptive Statistics for Granulation Lots Manufactured Before Improvement Implementation**

n	Min.	Max.	Median	X̄	SD
50	136	165	157	155	10

Figure 3: ***Descriptive Statistics for Granulation Lots Manufactured After Improvement Implementation***

Figure 4: **Chart of Process Cycle Time Before and After Improvements Implementation**

	n	Min.	Max.	X̄	SD	t(98)	p
Before	50	239	287	264	10	47.391	≤.05
After	50	182	200	192	4		

Figure 5: **Cycle Time (Min.) Before and After the Improvement Implementation**

Analyze Phase: In this phase the cause (s) of the problem are identified. Fishbone diagram was used to analyze the root causes. The top offenders of the current process that are identified as Equipment and Method are represented in Figure 6, "Fishbone Diagram".

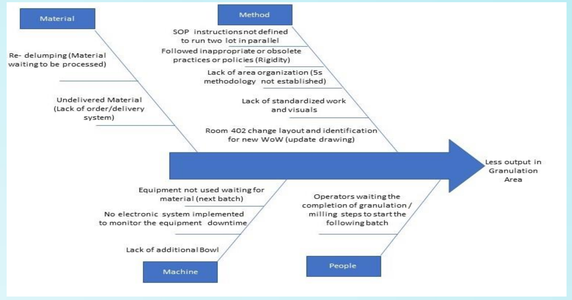


Figure 6: **Fishbone Diagram**

Improvement Phase: For this stage, Project Management Fundamentals & Kaizen DMAIC tools were used to develop and deploy an implementation plan. The following actions and their benefits were part of the implementation plan. These actions and benefits included:

- Cost benefit of time saving 27% cycle time decrease (1 hour /lot, at least 1700hours/year). This represents approximately a production increase in additional 36 lots/month (432 lots/year). Approximately $1,947,886 per month.

- Process standardization was implemented for accurate and consistent job tasks. Having a standardized system for process improvement can increase efficiency, reduce variation, cost reduction from eliminated NVA (waiting) and create a lean culture.

STANDARDIZE WORK - GLATT 9: SIDE A & B

ITEM	STANDARD WORK ELEMENT	LOT #	TIME (MIN)	OPERATOR A	OPERATOR B	OPERATOR C	MACHINE
1	Verificar estatus del cuarto **LADO A** y entrada de lote a MES	LOT 1	15				
2	Entrada del lote al cuarto **LADO A** y los logbooks	LOT 1	15				
3	Realizar Set up, Prueba de spray y Computrac	LOT 1	15				
4	Llenar formas 3502	LOT 1	15				
5	Glatt (precalentamiento)	LOT 1	15				
6	Preparar y abrir drones para la carga	LOT 1	15				
7	Check integrity y carga de Metformin	LOT 1	15				
8	Completar la carga de Metformin	LOT 1	15				
9	Atomización de Povidone	LOT 1	90				
10	Monitorear el proceso de atomización	LOT 1	90				
11	Preparar kit de descarga y tarar drones	LOT 1	20				
12	Prueba de LOD	LOT 1	10				
13	Verificar prueba del LOD y finalizar receta	LOT 1	10				
14	Imprimir reportes, cerrar los logbooks, formas y abrir limpieza menor	LOT 1	15				
15	Mover el bowl de **LADO A** a **LADO B** con su documentación y logbooks pertinentes y proceder a grapar el Product Bowl al Mill Feeding System. Luego abrir el uso del cuarto **LADO B** y equipos correspondientes.	LOT 1	15				
16	**LIMPIEZA MENOR** - Al nozzle, cuarto **LADO A** y equipos correspondientes	LOT 1	20				

Figure 7: **Standardized Work Template**

- Granulation procedures were revised and implemented to include specific instructions to run two lot in parallel in the same manufacturing Room.
- New layout for granulation Room was established for a new WOW. Side A is dedicated to perform the granulation Milling and Packoff processes while Side B to the granulation process.

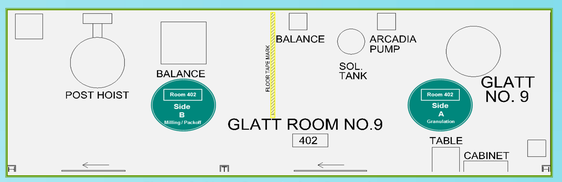


Figure 8: **New Granulation Room Layout**

- The visual board and production material replenishment system were implemented to monitor the daily/monthly production plan and provide a standardized system to assure a continuous delivery of material.
- New electronic downtime tracking system was designed to monitor the equipment downtime and be able to easily graph the lost time and its causes to minimize or eliminate it.

Control Phase: The main purpose of this phase is to control the improvements identified, and thus, keep the process on the new desired path. Some tasks or documents that will be periodically monitored are:

- ❖ Standardize Work
- ❖ 5S
- ❖ Downtime Tracking System
- ❖ Visual Factory and Material Replenish System
- ❖ Granulation Area Procedures
- ❖ Personnel Training
- ❖ Governance

Conclusions

Using DMAIC approach it was possible to increase the Granulation area capacity driving additional capacity requirement at the pharmaceutical industry in LP. After collect and classify the data, Lean Manufacturing tools were used to determine what the possible root cause of the granulation lot output limitation and tasks with no value added. As result was obtained the improvements in the procedures, implementation of a new Ways of Working (WOW) to run two batches in parallel, new granulation Room layout, improvement in the granulation procedures, additional product bowl to provide additional capacity, 5S implementation and certification as well as the creation of the standard work and a new electronic downtime tracking system were actions implemented to increase the granulation capacity.
Also, a cost benefit of time saving of cycle time from 4.4 hrs./lot to 3.2 hrs./lot (1 hour /lot, at least 1700hours/year) was achieved. This represents a 27% in cycle time decrease. This represents approximately a production increase in additional 36 lots/month (432 lots/year). Cost reduction from Non-Value Added in waiting (Material and People), added to approximately $1,947,886 per month in revenue. In addition, as results of this project the business benefits were a better work organization and standardization, improved area organization through 5S, granulation availability to meet the demand, flexibility to perform tasks in parallel and reduce respond time.

Future Work

Even though the improvements were successful, and the expectations and goals complied, there are lessons learned and additional opportunities to improve in the manufacturing area. Some opportunities are:

- ❖ To extend the granulation area improvements for Operations (Blending, Compression, Coating and Packaging Areas).
- ❖ Evaluate in deep the cycle times, implementation of standardized work and manufacturing area 5S certifications.

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