Application of Lean Manufacturing And Lean Six Sigma Tools To Improve Back To Back Activities In The Compression Process

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Abstract

A recent opportunity regarding a product ramp up in the production schedule due to a potential product transfer requires the manufacturing area to look for creative ways to improve in order to comply with expected demand. By applying Lean Six Sigma concepts, the current process was defined, a baseline was established, and improvements were identified and executed.

The results achieved due to these improvements were: average back to back cycle time in the compression area was reduced from an average of 3.7 hours to 2.87 hours for a 22% reduction and a standard deviation reduction of 91% (1.44 to 0.131 hours). These results were achieved by implementing parallel activities as well as eliminating constraints (redundant documentation and availability of tools) throughout the process.

The improvements were also instrumental in achieving a potential capacity increase of an additional 1.33 lots for a work week due to additional time available.

Introduction

In the pharmaceutical industry, dealing with sudden change is one of the most difficult aspects of production. Is there a significant change in the market? Did a competitor suffer an unexpected setback? Is product X demand seasonal? These are some of the many situations that force companies to be prepared to handle product ramp up.

Using Lean Manufacturing and Six Sigma tools can help any company estimate their current situation and achieve solutions that make dealing with this change easier. The data provided by these tools is very valuable and place companies in a better position to make important business decisions that ultimately impact company bottom line as well as a substantial number of employees.

Background

As the pharmaceutical industry becomes more competitive, the never-ending quest for better results is alive now more than ever. Numerous factors such as globalization, market/currency fluctuations, patent losses and even politics can play a significant role. However, most of these factors cannot be controlled by most of the companies in the pharmaceutical sector. Therefore, the need for continuous improvement has become vital.

As more research becomes available, the number of tools and their applications to achieve this continuous improvement is abundant. This "abundancy" of tools brings a good problem to have and this is: Which is the best tool to use in order to get the desired results? Since there is not a "one size fits all" approach, company management is responsible to make the necessary decisions and follow through on deployment. [1].

It has been a consensus across the pharmaceutical industry that Lean Manufacturing and Six Sigma are improvement tools that have demonstrated to achieve remarkable results. [2] The potential benefits for can be estimated as high as $90 billion in worldwide cost savings and a reduction of more than 70% in cycle reduction time. [3].

Problem

The tablet compression area has been identified as the bottleneck of the manufacturing process since its process times are significantly greater than its previous process (blending) and later process (coating). Time variability encountered when going from one lot to another lot of the same product has been singled out as an area of opportunity by upper management.

There is no clear expectation of what the process is capable of and therefore presents a challenge to maximize available time and resources in the compression area. A recent surge in the production schedule requires an increase in efficiency in order to comply with the demand. Minimizing this variance can help achieve improved results and potentially increase productivity. The expectations are to use Six Sigma and Lean Manufacturing tools from the DMAIC methodology to address this problem in order to establish baseline and improve thereafter.

Objectives

The research objectives are the following:

- To establish a variation and average time initial baseline value for the compression back to back activities of the same product.
- To reduce variation and average time from initial baseline value for the compression back to back activities by 20% in 4 months.
- To achieve increase of 2 lots in potential weekly capacity output in the compression area after implementation of activities.

Methodology

The methodology for this design project has observational as well as experimental elements. Lean Six Sigma is a system that sets a baseline based on current practices, finds areas of opportunities, executes improvements and re-measures the process to see if indeed these enhancements were effective. It also focuses on how to maintain them. The research consists on applying DMAIC techniques to reduce compression back to back time and its variation in the compression stage of the process.

For the **DEFINE** phase, created in order to clearly communicate the problem statement, the goal, business case, scope, and timeline and team members responsible for executing the proposed project. Also, a Kaizen event with the key stakeholders from the process were present and contributed to set the tone of the project. Figure 1 and 2 show the format used for both activities.

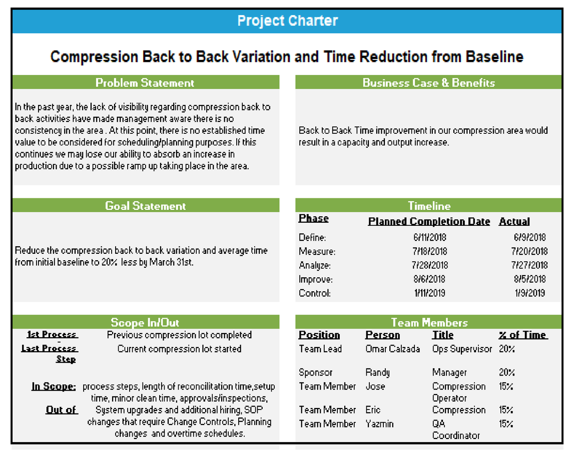


Figure 1: Project Charter

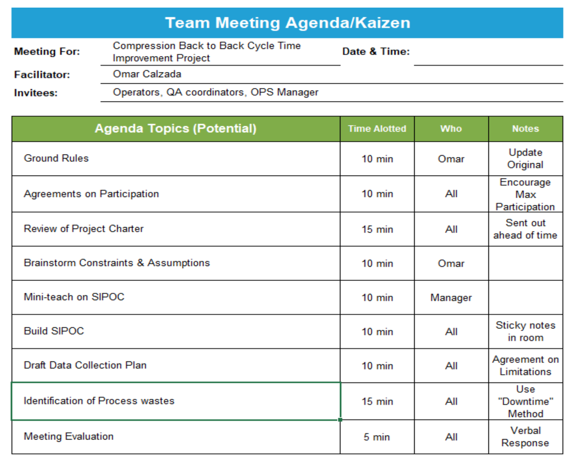


Figure 2: Team Agenda/Kaizen

The **MEASURE** stage required data collection from the chronological logbooks used in the compression area as described in Figure 3 and Table 1 below.

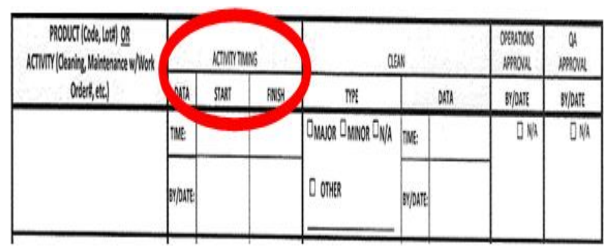


Figure 3: Chronological Logbook

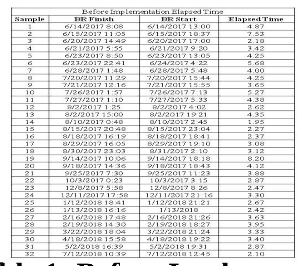


Table 1: Before Implementation Elapsed time

The initial data gathered before implementation was scrutinized using statistical packages. Figure 4 and 5 shows a visual representation of the behavior that was determined to be the initial baseline of 3.70 hours for back to back compression activities.

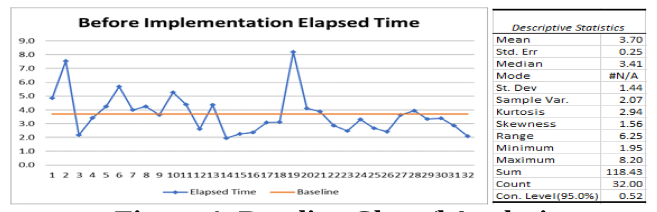


Figure 4: Baseline Chart/I Analysis

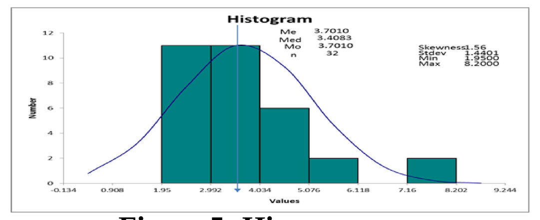


Figure 5: Histogram

The **ANALYZE** phase consisted of a 5 Why analysis, Fishbone Diagram along with a Value Added/SMED Analysis which helped determine waste activities along with their respective root causes. Figure 6 through 8 display the outcome of these activities.

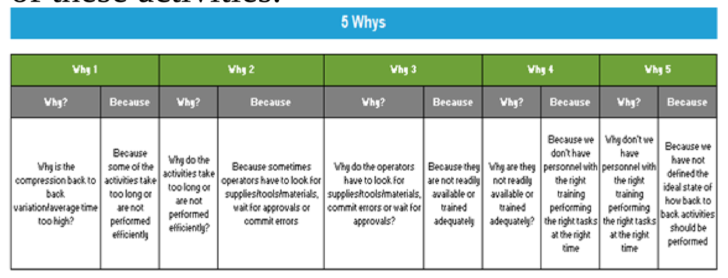


Figure 6: 5 Why Analysis

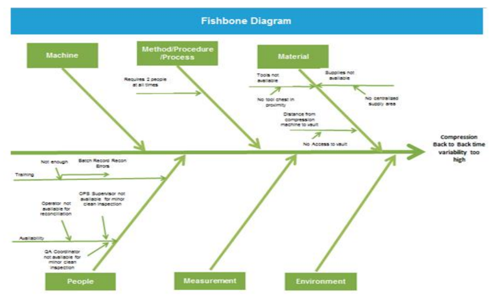


Figure 7: Fishbone Diagram

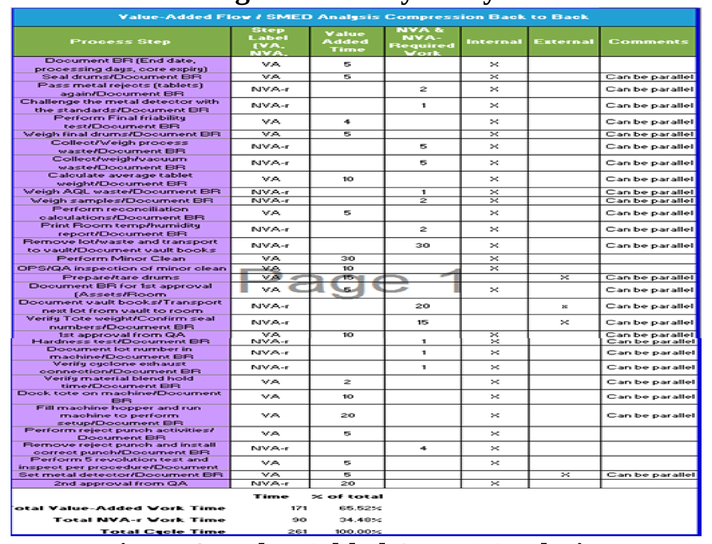


Figure 8: Value Added/SMED Analysis

The Fishbone Diagram unearthed several issues that were affecting the efficient execution of the compression back to back activities. The Value Added/SMED analysis determined that a total of 261 minutes were being accounted for as part of the compression back to back activities.

Methodology cont.

During the **IMPROVE** phase, a Compression Back to Back Standard Work/Parallel Activity was created to maximize the time spent in the different activities. Figure 9 shows a time reduction of these activities to 169 minutes.

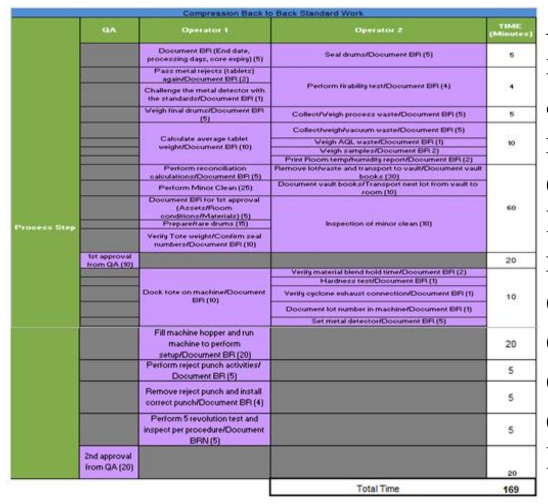
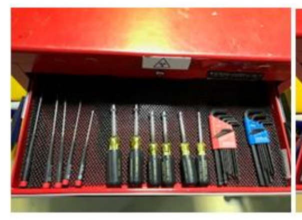


Figure 9: Compression Back to Back Standard Work/Parallel Activity

As additional measures, several improvements were performed in order to address the inefficiencies related to people, materials and process per the Fishbone diagram.
For example, A dedicated tool cart with the required tools needed for all the minor clean activities was included as well as a centralized supply cart with was set up close to the compression room to minimize downtime due to unnecessary motion.
Refer to Pictures 1 through Picture 3.



Picture no. 1

Picture no.2

Picture no. 3

An additional improvement made was the review of minor clean procedure (SOP-OPS-003) to permit a second operator to inspect the clean and eliminate the need for Ops and QA personnel.

The **CONTROL** stage culminated with improvements from the previous stage were completed and the next activities were monitored for a course of approximately 5 months. Table 2 represents a collection of data of the first 22 compression back to back samples performed after the improve stage. Figures 10 and 11 represent the statistical analysis performed after implementation of improvements.

After Implementation Elapsed Time			
SAMPLE	BR Finish	BR Start	Elapsed Time
1	8/7/2018 1:10	8/7/2018 3:59	2.82
2	8/7/2018 16:07	8/7/2018 19:01	2.90
3	8/21/2018 2:58	8/21/2018 6:00	3.03
4	8/22/2018 10:59	8/22/2018 14:01	3.03
5	9/18/2018 3:59	9/18/2018 6:45	2.77
6	9/24/2018 23:58	9/25/2018 2:54	2.93
7	9/26/2018 15:51	9/26/2018 18:41	2.83
8	10/10/2018 21:59	10/11/2018 1:03	3.07
9	10/14/2018 22:59	10/15/2018 2:01	3.03
10	10/15/2018 22:10	10/16/2018 0:58	2.80
11	10/16/2018 19:50	10/16/2018 22:48	2.97
12	10/24/2018 5:11	10/24/2018 8:05	2.90
13	10/25/2018 8:07	10/25/2018 11:05	2.97
14	10/28/2018 15:10	10/28/2018 17:51	2.68
15	10/29/2018 15:21	10/29/2018 18:12	2.85
16	10/30/2018 16:40	10/30/2018 19:17	2.62
17	11/6/2018 16:00	11/6/2018 18:59	2.98
18	11/7/2018 7:17	11/7/2018 9:59	2.70
19	11/20/2018 13:36	11/20/2018 16:32	2.93
20	11/21/2018 17:02	11/21/2018 19:51	2.82
21	11/22/2018 20:01	11/22/2018 22:40	2.65
22	12/12/2018 19:04	12/12/2018 21:58	2.90

Table 2: After Implementation

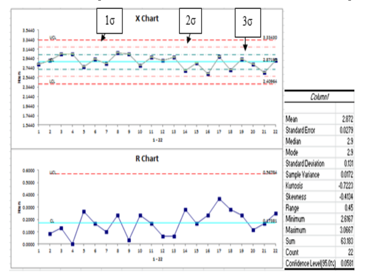


Figure 10: Ind. Chart

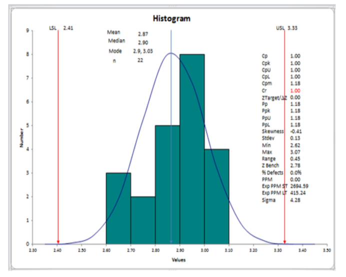


Figure 11: Histogram

The average time decreased to 2.87 hours and the standard deviation also decreased to 0.131 hours. This demonstrates an improvement on the overall average time and a significant variation reduction. A 22% reduction on the overall time was achieved as well as a standard deviation reduction of 1.31 hours (91%) after implementation.

Confidence levels used for upper and lower bounds conclude there is a 95% confidence that the future back to back activities will range between 2.93 and 2.81 hours when following the implementation activities of this project. This will provide management with an estimated time to be considered for schedule activities.
In this case, the recommended value to be used for planning the back to back activities was rounded up to 3 hours.

As a additional control strategy, operators will be responsible for properly executing the standard work and documenting the amount of time the compression back to back activities are taking. Also, the area supervisors will monitor and update the charts accordingly in order to assess if further corrections are needed. Figure 12 shows the Monitoring-Response Plan.

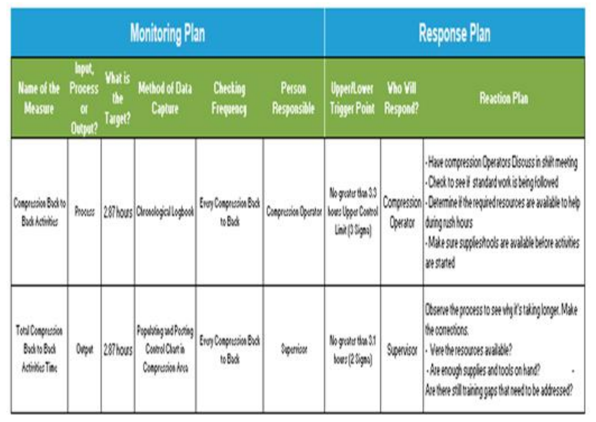


Figure 12: Monitor/Response Plan

Results and Discussion

The compression back to back process was defined and scrutinized by key stakeholders in order to determine solutions that were tailor made for their process. These tools were essential in creating a frame work of standardized work that was able to minimize process disruptions and maximize efficiency along with some procedure changes and agreements.

The data collection of the compression back to back time was displayed along with its descriptive statistics. Refer to Figure 13 below:

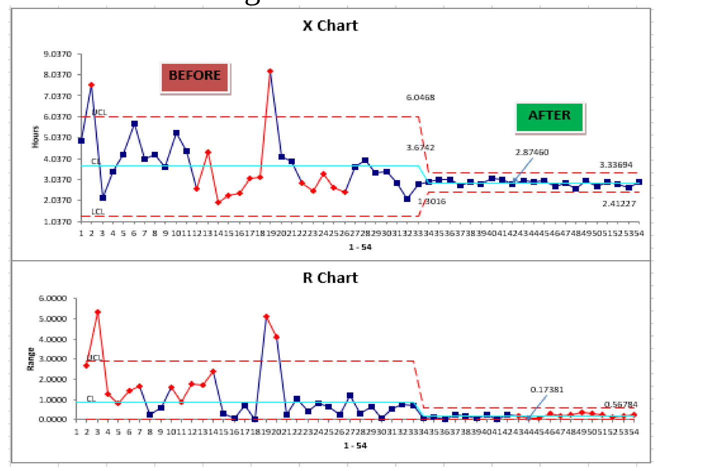


Figure 13: Before and After Implementation Chart

According to the samples collected, the average process time before the improvements was 3.7 hours. After successful implementation of Lean Six Sigma techniques, the average time for compression back to back was decreased to 2.87 hours. This represents approximately a 22% time decrease.

The process standard deviation went from approximately 1.44 to 0.131 hours. This result represents an improvement of 91% variability reduction as well as a potential output increase was approximately 11% or an additional capacity of 1.33 lot.

Conclusions

The implementation of Lean Six Sigma in the compression back to back process led to the creation of a standardized work tool and the elimination/modification of several activities, which helped achieve consistency and reduce unpredictability. These results translated into a reduction of 22% for average back to back time and 91% for variability.

This confirms that when followed correctly, the back to back process in the compression area is stable and predictable. Therefore, to provide clear expectations on the manufacturing floor when performing campaigns of the subject product, an estimate average of 3 hours was determined to be used for planning/schedule purposes.

In addition to the above time reduction benefits, there was also a potential capacity increase for the compression machine of approximately 1.33 lots.

Future Work

The research performed as part of this study contains several limitations such as limited access to data and time constraints.

However, although time and resource constraints limited our scope, future applications of this project can be investigated further by stratifying the data between products, personnel or shifts as well as other compression machines in order to determine if the established improvements are statistically significant. Likewise, implementing similar methodology in other areas (coating or granulation) can help confirm the effectiveness of Lean Six Sigma practices in different settings.

References

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[2] Bavuluri Seetha ram "Setup time reduction and Quality improvement on the shop floor using different lean and quality tools." *(2102) All theses. Paper 1306*

[3] Manzouri, M, Nizam Ab-Raham M, Rosmawati R, and Asrad Jamsari Ezad "Increasing production and eliminating waste through Lean tools and techniques for Halal Food Companies" Sustainability 2014, 6, 9179-9204