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.*

Key Terms *— Baseline Establishment, Cycle Time, Improvements, Lean Manufacturing.*

PROBLEM STATEMENT

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.

RESEARCH DESCRIPTION

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.

RESEARCH 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.

RESEARCH CONTRIBUTIONS

The research contributions include the following:

- Foresee and schedule products in short notice.
- These tools will contribute to increase area capacity and reduce cycle time between stages since there will be more product available to process.
- By increasing output and maintaining other operational aspects constant, the cost of the product can also be reduced.

LITERATURE REVIEW

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. 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]. However, to maximize the use of these tools, companies need to make sure what they want, and how they want to get there. In the pharmaceutical industry, looking at the production of batches is always a good place to start since this practice has been widely adopted by many companies. Batch production is tailor made for pharmaceutical processes since the output of the last unit should be as similar to the first unit produced. This scenario bodes well for improvement tools like standardization, SMED, VOC and statistical analysis among others. It also permits companies to interpret and evaluate a great amount of data due to the amount it generates and make significant business decisions based on this. Setup/Changeover time reduction is one of the aspects that is consistently mentioned when talking about areas of opportunities regarding improvement tasks in batch production. These activities are always considered non-value added and thus, are always a focus when brainstorming [4]. Lean Manufacturing is a method that pursues continuous improvement and the elimination of waste in any process. It is centered in removing anything that does not add value to the product. This philosophy was born in Japan as a way to redirect reactive thinking into proactive thinking in order to meet the production requirements of post-World War II. Japan was in dire need of revamping their manufacturing industry with the aim of jump starting their depleted economy. A Toyota employee named Taiichi Ohno is credited largely on grouping these main ideas of what would later become the Toyota Production System (TPS). The industry had to move away from mass producing based on targets and produce what was needed to avoid large costs. This way of thinking gave birth to Just in Time (JIT) which is at the core of Lean Manufacturing culture. Taiichi Ohno summarized this philosophy by identifying the 7 wastes. These wastes are:

- Waiting – Waiting for materials, waiting for approvals, waiting for machine reparations etc.
- Inventory – Materials occupying space for long periods of time.
- Defects – Having to correct something for not doing it right the first time.
- Overproduction – producing more than customer needs.
- Transport – Unnecessary movement of parts in a process.
- Motion - Unnecessary movement of people in a process.

- Extra Processing – Going beyond the consumer standard.

With its beginnings rooted in Motorola, Six Sigma was created as a statistical analysis tool that can help to define problems systematically, provides tools to measure and analyze influential factors, identify possible solutions as well as aid in maintaining/sustaining the results. The goal is to attain 3.4 defects per million parts, and it uses the DMAIC methodology. Define, Measure, Analyze, Improve and Control are the stages to follow when performing a Six Sigma project. Although Six Sigma has been proven to achieve results as a stand-alone option, integrating with Lean Manufacturing expands the toolbox from which companies can refer to and maximize results. Consequently, gains resulted from implementing projects meshing both concepts have the potential to yield better results and help companies make more informed decisions. Each step from the DMAIC methodology has tools that are appropriate for their scope of intent. An interesting twist that is found with Six Sigma tools is the fact that several of the tools that are used in Lean Manufacturing are also used for Six Sigma projects. It is at these steps of the process where several statistical tools are used [5].

As mentioned above, both philosophies have intertwined concepts. General agreement is that in order to maximize benefits, Lean Manufacturing and Six Sigma have to be implemented together and employee engagement is crucial in order to deliver the results [6].

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. Likewise, prospective and retrospective features are considered since the data used for determining initial baseline performance, comes from processes (cleanings/setups) already executed. On the other hand, as discussed above, the final results were the culmination of collected data points gathered after our improvement measures were implemented. A longitudinal approach was applied since the results are based on specific metrics over time after having implemented corrective actions. The research consists on applying DMAIC techniques to reduce setup/changeover time and its variation in the compression stage of the process. The data gathered was descriptive/quantitative since Lean Six Sigma requires the use of statistical analysis to evaluate data. However, verbal information from group exercises as well as interview/brainstorming sessions such as Kaizen was used. The sample to be analyzed for this research focused on the Korsch compression machine. Although there are more compression machines available, the complications of adding more than one compression machine to the study due to possible planning issues was considered and determined to be out of scope.

The **Define** stage is critical to effectively identify the problem which needs to be addressed. The more specific the definition of the problem, the easier it is to utilize other Lean Six Sigma tools during later stages. Also, project feasibility is key to determine and justify if a project is aligned with company strategy. A good tool to achieve this is to define project criteria and use an “Impact-Effort Matrix”. This matrix weighs the criteria selected and quantifies it in order to make a decision.

After confirming our project is adequate, a project charter was 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. The problem statement explains the fact that operations management is not sure what would be an accepted average time to perform for back to back activities in the compression area. At times, there have been many inconsistencies as far as the total time taken after completing a compression lot run and the beginning of the next one. One of the reasons for which management has expressed the need to investigate further is the fact that there was a potential for an increase in production demand due to a product ramp up. Management was looking for opportunities to improve across the supply chain and the compression area was identified as one that could benefit from an improvement initiative. A good way to provide further directions and clarify the required project scope is to perform a Team meeting/Kaizen event. In this meeting, key stakeholders from the process were present and contributed to setting the tone of the project. The documents created during the team Kaizen meeting were a SIPOC analysis, a data collection plan and an initial discussion of the types of waste encountered in the compression back to back activities. A SIPOC analysis was created to determine key players and processes involved. This analysis identifies the suppliers, its inputs and the processes they affect in order to get the outputs, and who are the customers of said processes.

The **Measure** stage started off with a data collection plan that was implemented to determine the type of data, the sample and the frequency. Data collection consisted of determining a changeover/setup time activity baseline off the chronological logbooks Chronological logbooks contain different activities which operators constantly document throughout the day. In this case, the information corresponding to the completion of a past lot as well as the beginning of the current one was chosen as the data to be collected.

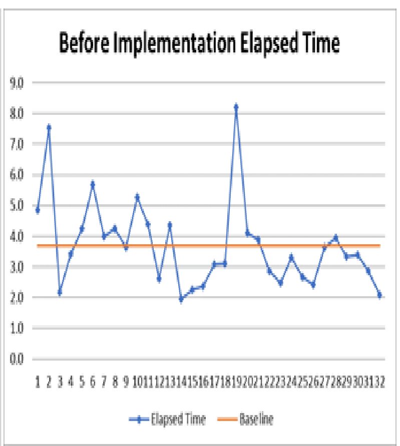
It is important to note that this book only reflects the time in which the compression lot is taken out of the room (reconciled) and the next lot is entered in the room (1st Approval). However, for this project, the activities considered were after completing a compression lot run up to the beginning of the next compression run. These activities were defined and considered in the Value-Added flow analysis (Analyze stage). In our study, the unit measured in order to create such a graph was time. Time is considered continuous/variable data since it requires to be measured and is often represented by fractions or decimals. The collected data used to determine an initial process baseline for the compression back to back time for 32 entries is contained in Table 1 below:

Table 1
Before Implementation Elapsed Time

Before Implementation Elapsed Time			
Sample	**BR Finish**	**BR Start**	**Elapsed Time**
1	6/14/2017 8:08	6/14/2017 13:00	4.87
2	6/15/2017 11:05	6/15/2017 18:37	7.53
3	6/20/2017 14:49	6/20/2017 17:00	2.18
4	6/21/2017 5:55	6/21/2017 9:20	3.42
5	6/23/2017 8:50	6/23/2017 13:05	4.25
6	6/23/2017 22:41	6/24/2017 4:22	5.68
7	6/28/2017 1:48	6/28/2017 5:48	4.00
8	7/20/2017 11:29	7/20/2017 15:44	4.25
9	7/21/2017 12:16	7/21/2017 15:55	3.65
10	7/26/2017 1:57	7/26/2017 7:13	5.27
11	7/27/2017 1:10	7/27/2017 5:33	4.38
12	8/2/2017 1:25	8/2/2017 4:02	2.62
13	8/2/2017 15:00	8/2/2017 19:21	4.35
14	8/10/2017 0:48	8/10/2017 2:45	1.95
15	8/15/2017 20:48	8/15/2017 23:04	2.27
16	8/18/2017 16:19	8/18/2017 18:41	2.37
17	8/29/2017 16:05	8/29/2017 19:10	3.08
18	8/30/2017 23:03	8/31/2017 2:10	3.12
19	9/14/2017 10:06	9/14/2017 18:18	8.20
20	9/18/2017 14:36	9/18/2017 18:43	4.12
21	9/25/2017 7:30	9/25/2017 11:23	3.88
22	10/3/2017 0:23	10/3/2017 3:15	2.87
23	12/8/2017 5:58	12/8/2017 8:26	2.47
24	12/11/2017 17:58	12/11/2017 21:16	3.30
25	1/12/2018 18:41	1/12/2018 21:21	2.67
26	1/13/2018 16:16	1/13/2018	2.42
27	2/16/2018 17:48	2/16/2018 21:26	3.63
28	2/19/2018 14:30	2/19/2018 18:27	3.95
29	3/22/2018 18:04	3/22/2018 21:24	3.33
30	4/18/2018 15:58	4/18/2018 19:22	3.40
31	5/2/2018 16:39	5/2/2018 19:31	2.87
32	7/12/2018 10:39	7/12/2018 12:45	2.10

A powerful tool to quantify the level of variation in the baseline determination is to use graphs to visually display how the process is being executed. Additionally, statistical analysis from the graph was used to quantify the different characteristics that helped determine the initial baseline. Refer to Figures 1 and 2.

The statistical analysis results show the compression back to back process averaged a baseline of 3.70 hours. The upper and lower bound values at 95% Confidence Level are used to estimate operating intervals based on current practices at the time. Therefore, if no changes are performed to the current process, future activities would be between 3.18 and 4.22 hours. The elapsed time graph shows several outliers along with some trends (4 or 5 consecutive increasing/decreasing points). The histogram further confirms this lack of consistency by having a great concentration of the average times in the 2 – 4 average time bin and others as high as 8. Its positively skewed patter displays most of the data on the left side of the graph, which in itself is not considered bad since the process benefits from having values representing the short-elapsed times. However, the standard deviation of 1.44 hours supports a high variation of the sample along with its spread across a 6.5-hour range. This visually confirms there is no consistency or expected behavior across our process and correlates with a process that has high variation. As the waste analysis showed in the earlier stage, the higher outliers could have been caused by not having people assigned to the room to complete the minor clean or no personnel available to approve the clean. On the other hand, based on operator feedback, the low points could have been from assigning more resources to the room or prioritizing the room based on business needs during that day. Nevertheless, at this point, there were no established expectations on what an ideal average would be.



Descriptive Statistics	
Mean	3.70
Std. Err	0.25
Median	3.41
Mode	#N/A
St. Dev	1.44
Sample Var.	2.07
Kurtosis	2.94
Skewness	1.56
Range	6.25
Minimum	1.95
Maximum	8.20
Sum	118.43
Count	32.00
Con. Level(95.0%)	0.52

Figure 1
Initial Baseline Chart and Statistical Analysis

During the **Analyze** stage, a brainstorming session was conducted with the process stakeholders to communicate the findings of the activities done in the Measure stage. The tools used to gather the operator's input were a 5 Whys Analysis, Value Added Flow Analysis, SMED Analysis and an Ishikawa (Fishbone) diagram.

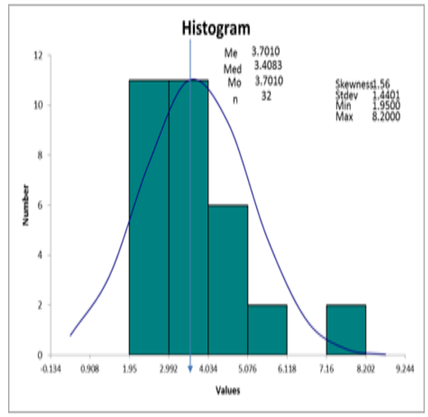


Figure 2
Before Histogram Analysis

This analysis concludes that the activities performed during the compression back to back have not been clearly defined and analyzed to determine the most efficient way to be performed. Therefore, a definition of the required tasks was completed by the key process stakeholders in order to execute a value-added flow analysis. This flow analysis defines the current steps performed, classifies the value based on Lean principles and details the time which the operators spent on each one. Classifications were Value Added, Non-Value Added and Non-Value Added-Required. Value added are activities that customers are "willing to pay for". Non-Value-Added activities are considered waste activities and Non-Value Added-Required can be activities that do not transform the product but are imbedded in your process and can't be eliminated. In our study, our customers were the packaging operators as this is the next stage of the process after compression. The list of the value/nonvalue activities defined by the operators was used to create a standard work document that determined which activities are classified as internal and external based on the Single Minute Exchange of Dies methodology (SMED). Per the Single Minute Exchange of Dies methodology (SMED), internal activities are the ones that require the process to be at a standstill before you can conduct them safely whereas external activities can be done while the process is still running. For this study, it was agreed to consider the activities between the last acceptable tablet and the next acceptable tablet of the next lot. The group identified any task that could be performed in parallel (whether internal or external) to another activity as a way to streamline the process. This exercise was recorded using video to determine the amount of time it was taking.

In addition to the analysis discussed above, a Cause and Effect Diagram (Ishikawa) was created with the help of the stakeholders. It was used to gather the different causes and effects of the variability that can affect the compression back to back activities. Refer to the Figure 3 below:

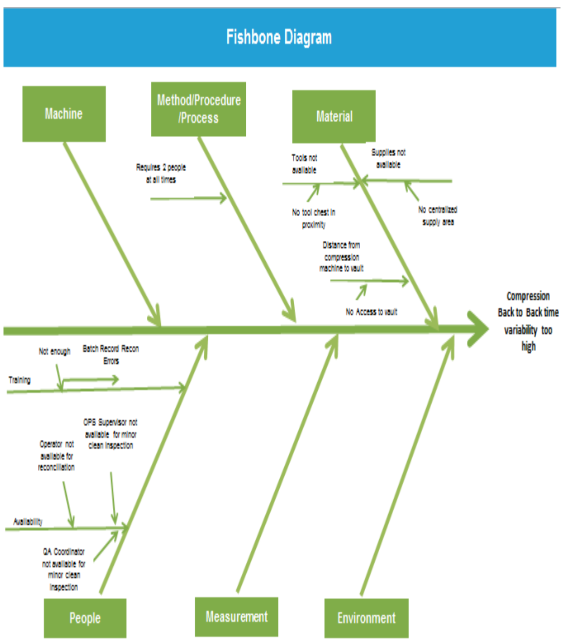


Figure 3
Cause and Effect Diagram (Ishikawa)

Among the different causes, the discussion centered on the following issues:

- Area Procedure
  - Requires two people at all times when processing controlled substances, increasing the burden on having specific resources at key moments of the activities. It also minimizes the chance of performing external activities to save time.
- Material
  - Tools not available when performing the recon/minor clean activities.
  - There was not a tool chest in the compression area for the operators to use.
  - Supplies for performing minor clean not available
  - There was not a centralized spot in the compression area for the operators to store supplies.
  - Distance from compression to the vault too far.
- People
  - Not all operators have access to vault.
  - Operators not trained enough to expedite the recon process.
  - Lead to recon errors that cost time.
  - Not performing the activities, the same way.
  - Personnel Availability during certain activities.
  - No QA personnel to inspect minor clean.
  - No Ops supervisor to inspect minor clean.
  - No second operator to perform the reviewed by in batch record.

A great tool for objectively deciding if a solution is appropriate for implementation is a Solution Selection Matrix. In this case, our results were very close to each other and implementation was agreed upon for all of them. The lowest criteria was the time to implement since several of the solutions proposed required extensive time to execute (standard work/parallel activity) or multiple layers of approvals or review (SOP changes). During the analyze phase, a hypothesis test was formulated to further sustain if the improvements that were executed in the improvement stage were statistically significant. The hypothesis testing was determined to be:

- Null - The average compression back to back time for the new process is equal or greater than the determined average baseline time.
- Alternative - the average compression back ot back time for the new process is less than the determined average baseline time.

During the **Improve** stage, the team decided to use the different elements from the 5 Whys

Analysis, Value Added Flow Analysis and the Ishikawa diagram and evaluated what type of improvements could be implemented. The solutions implemented were:

- People:
    - A standardized work/parallel activity initiative was completed as part of the activities to improve training/knowledge and minimize documentation errors among the operators, as well as to consolidate activities per the SMED methodology to minimize time. Only 2 operators are required to complete these activities making sure no added resources are needed. After grouping the activities, a time total of approximately 169 minutes or 2.82 hours was calculated for our target time.
    - An agreement was reached with the DEA compliance department in order to have more operators with access to the vault, therefore, increasing our chances of having any given operator assigned to move the controlled substance from and to the vault.
- Process/Method:
    - The procedure for managing controlled substances (SOP-DEA-001) was reviewed to eliminate the constraint of having more than one resource when dealing with the product. During the process or minor clean, one operator can remain in the room while the other can perform external activities of the compression back to back.
    - The minor clean procedure (SOP-OPS-003) was reviewed to permit a second operator to inspect the clean and eliminate the need for Ops and QA personnel.
- Material/Supplies:
    - A dedicated tool chest with the required tools needed for all the minor clean activities was included. See Picture Below:
    - A centralized supply cart with was set up close to the compression room to minimize downtime due to unnecessary motion.

The **Control** stage is set after the implementation of the improvements in which the data gathered was compared with our initial baselines. The 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.

Table 2
After Implementation Elapsed Time

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

Based on a similar approach used to determine our base line, a control chart (XmR Individual) was used to visually display the different points along with statistical analysis. Figure 4 and 5 below display the graphs after the implementation of activities took place. .

Visually, the chart demonstrates that all the values are well within the UCL and LCL limits. Furthermore, 8 samples are located within the 2σ limits and 14 values within 1σ limits. Additionally, the histogram displays an even distribution with respect to the mean, with almost all the values positioned within the normal distribution curve. This confirms at a glance that the process has less variation relative to the mean and has become more predictable. Likewise, our range values lie between our control limits further confirming the stability of our process.

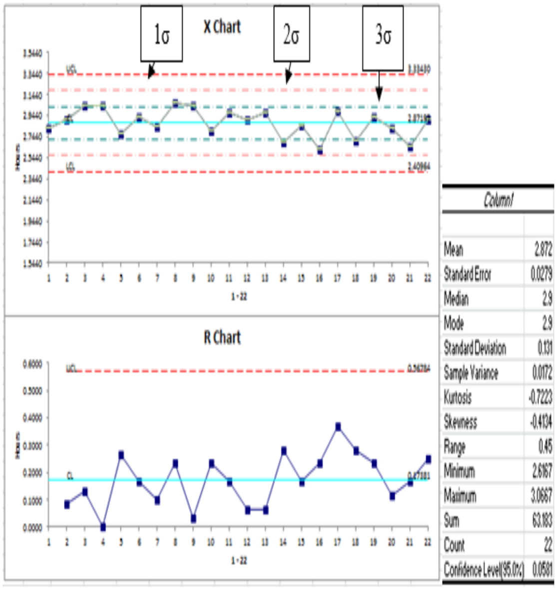


Figure 4
XmR Individual Chart and Statistical Analysis

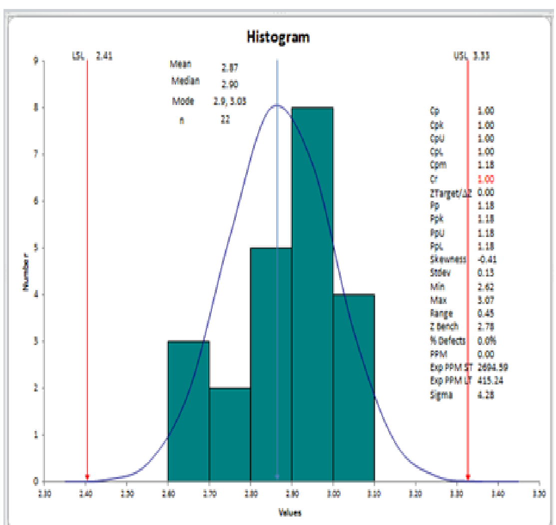


Figure 5
Histogram Analysis After Implementation

To determine the significance of our results, the hypothesis testing plan was updated to reflect our results by using the student's T Test formula:

$$t=\frac{\bar{X}-\mu}{\frac{S}{\sqrt{n}}} \qquad (1)$$

The resulting values for the formula were as follows: T crit = -1.717 and T exp = -29.75. Since the T crit value is greater that the T-exp value, the Null hypothesis is rejected, and we can conclude the new improvements for the compression back to back activities are more effective than the established baseline practices. Furthermore, the statistical analysis concludes the average 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 an 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. It is important to point out that including this project as part of a KPI or as a department goal is beneficial since it provides visibility across the company. Therefore, it can also serve as an example of how applying Lean Six Sigma methodology to simple problems can help to implement and sustain improvement in different ways.

RESULTS AND DISCUSSION

In this case, 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.

In chapter 4, the data collection of the compression back to back time was displayed along with its descriptive statistics. Refer to Figure 6:

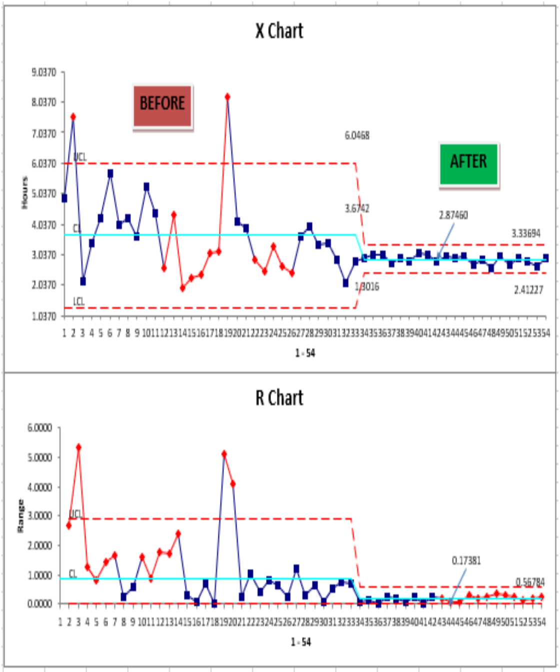


Figure 6
Before and After Control Chart

The chart shows the positive change in process behavior after implementation of the improvements since variation and average time was reduced. 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. The average time decrease can be used to confirm if the planning department is able to schedule an additional 3 lots during a 5-day 3 shift work week with 120 working hours and 15 break hours. There are 9 back to back activities performed in a 10-lot campaign. After the 10th lot, a major clean which is assumed to take 12 hours is completed. The expected run time for the product in the compression stage is 4 hours. Using the initial baseline, an approximate of 38 hours is spent per campaign executing back to back activities (9 *3.7 = 33.3 hours). Interestingly enough, by estimating a baseline and abiding by it, the company can still potentially increase its output since 120 (total working hours) -15 (total shift break hours) – 40 (total run time hours 10 lot campaign) -33 (total time back to back activities) = 32 available hours. Assuming a 12-hour elapsed time for a major clean after the 10th lot, 20 hours are available to schedule additional lots. Considering the 4 hours of run time and 3.7 hours of back to back, and additional lots could be scheduled 20 hours available/(4 hour run + 3.7 B/B) = 2.6 lots. Therefore, by using the baseline of 3.70 hours of back to back activities, the total amount of lots for a work week was determined to be 12.6 lots. After implementation, this time decreased to 26 hours (9*2.87= 25.83 hours). Considering a work week has 120 hours to work, 15 hours of break time across the different shifts and a total of 40 hours of run time for a 10-lot campaign, the remaining hours to account for back to back activities are (120-15-40-26 = 39 hours). Assuming a 12-hour elapsed time for a major clean after a 10th lot, 27 hours are available to schedule additional lots. Considering the 4 hours of run time and 2.87 hours of back to back, an additional 4 lots could be scheduled: 27 hours available/ (4 hour run +2.87 B/B) = 3.93 lots. Therefore, the new improvements yielded a potential of 13.93 lots for a work week. This potential output increase was approximately 11% or an additional capacity of 1.33 lot.

CONCLUSION

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. It is important to note that although the average time reduction does not seem very substantial, the standard deviation reduction was very significant. 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. The research performed as part of this study contains several limitations. Limited access to data and times constraints were concerns noted during the execution phase. The established agreement discussed with upper management for project implementation was one compression machine out of a total of five and avoid disruptions to base business operations (no additional resources would be provided, complete project in allotted time regardless of status etc.). This restricted our efforts to expand the collection of data and its evaluation, thus preventing the study of confirming if this data could have helped further influence/support our conclusions. For example, would there have been an average time difference using our methodology across other machines? Was there significant variability difference between first shift and second shift? Having recorded this data would have allowed us to statistically determine our method was effective considering other variables. As discussed previously, 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.

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