

Coating Process Minor Changeover Reduction

Angel D. Negroni Pedroza
Master in Engineering Management
Dr. Hector J. Cruzado
Graduate School
Polytechnic University of Puerto Rico

Abstract — During the Covid-19 Pandemic, many challenges arose that force healthcare companies to execute in new ways. Product demand was increased due to its effectiveness against the pandemic impact in the patients. To provide a quick response to the demand increase, production sites were challenged to transform their operations using well proven practices and methodologies with a main goal: increase the site production. Working with the goal in mind, agility, flexibility, and improvement were concepts included in day-to-day activities. As a result, an improved process with a new performance level and a continuous improvement culture embracing the change was put in place.

Key Terms — Agility, Continuous Improvement, Demand Increase, Governance, Value-Added

INTRODUCTION

Johnson & Johnson (J&J) Consumer Healthcare Solid Dosage Manufacturing Site, located in the east area of Puerto Rico, produces pain fever relief products. Due to the current global situation, product demand increased, driving a volume increase at the site. An end-to-end analysis was performed to identify bottlenecks at the production streams.

The Coating Area was identified as a medium risk section due to the complexity added by the multiproduct plan. To mitigate the risk associated to the volume increase, the area productivity needs to be improved to accommodate more lots per week.

Process related activities (validated) were put out of scope due to the time and resources needed for re-validation. In scope are the tasks related to the Minor Changeover (beginning and end of the lot during a campaign – non validated activities)

of Coating process at the Accela Cota Machines for the A, B and C Product Codes will be analyzed to identified improvement opportunities that drives the minor changeover reduction. For the details regarding the manufacturing stages, correlation between product codes and similar scope of work, refer to Figure 1.

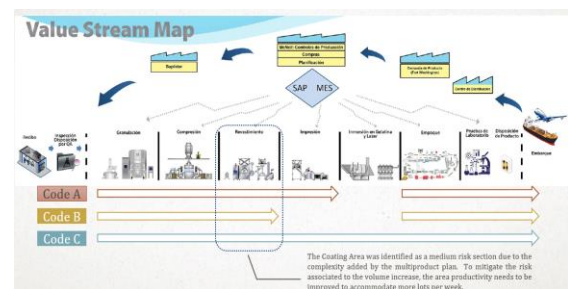


Figure 1
Value Stream Map with project focus area

LITERATURE REVIEW

When many professionals are talking about the continuous improvement approach, the toolbox under the phases Define, Measure, Analyze, Improve and Control (DMAIC); came with a lot of success stories. It is applied to many companies as Services and Finished Goods. DMAIC is in essence the multiphases used under the Lean Six Sigma Methodologies to solve problems analyzing people behavior, process or product trends and cultural thinking.

This is the beginning of the transformational process in which the end-to-end of a company is impacted. The main goal after the use of the Lean Six Sigma tools, is the total integration between the continuous improvement methodologies and the people grow and development strategies. Authors thinks that Lean Six Sigma needs to be part of the Company DNA [1]. If a company from the base implements tools that challenge the status quo, then it generates many changes in the day-to-day

business because it will change from a flavor of the month to the implemented culture.

DMAIC is not only a set of phases to structure a project or a process improvement strategy. It includes data behaviors, customers need, process changes, training, people development and company grow, among others. The Lean Six Sigma methodologies provides a standardize approach to challenge problems, identify root causes, simulate potential solutions, runs pilots and implement the solutions that is more aligned to the business need and expectations. In addition, this methodology has the capability to integer people at different levels, process and business strategies that responds to the market fluctuations. This is a key element that classified the Lean Six Sigma Methodologies as a complete approach with an extensive margin of impact [2].

Well known in the Pharmaceutical and Consumer Sectors, the Lean Six Sigma Methodologies provides a proven toolset that brings results impacting business, customers, and people. The proper used of these methodologies create an unique environment in the industry in which the people participate in the business decisions, in the process changes and impulse the innovation pillar which is a clear path to continuous improvement and business evolution [3].

ANALYSIS APPROACH

Entering to the improvement needs, the area in scope requires an analysis for the value-added and non-value-added activities. Also, within this approach, all activities that are regulated and requires qualification or validation exercises, are out of scope.

Process Related Activities

Processing a batch product in this manufacturing area includes three phases: initial tasks or set up, process and final tasks or closing documentation and minor clean up. From these three phases, the initial and final tasks, also known as changeover, will be improved. The Coating

stage includes the Weighing and Dispense, Solution preparation and Coating Application. In Figure 2, the focus stage for this project (Coating) is highlighted.

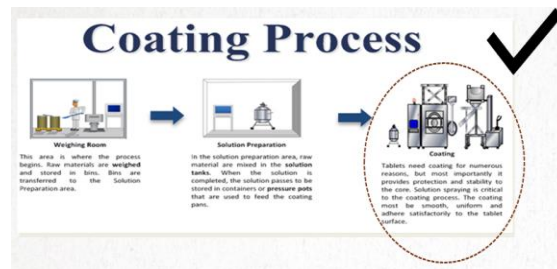


Figure 2
Process Stage in scope – Coating

Lean Six Sigma Methodology

The methodology selected for this project is the described and used for the Lean/Six Sigma Continuous Improvement projects and which phases are: Define, Measure, Analyze, Improve and Control (DMAIC).

The following paragraphs describes the proposed content in each phase as part of the project process completion. See Figure 3 for the Methodology and associated tasks tracker.

At the Define phase, it is defined the project impact to the business and your customers. Tools that will be included as part of the Define Phase are Project Charter, Voice of the Customer (VOC) and “As Is” Process Map.

At the Measure phase, visualize the process current state. Tools that will be included as part of the Measure Phase are Data Collection, Prioritization Matrix and Pareto Diagrams.

At the Analyze phase, it is determined the problem root cause. Tools that will be included as part of the Analyze Phase are: Cause and Effect Diagrams; and Plus and Delta Analysis.

At the Improve phase, looking for was that eliminate the problem or improve the process. Tools that will be included as part of the Improve Phase are Implementation Plan, “To Be” Process Map and Piloting Solutions.

At the Control phase, establishes methods that will remain the improvement. Tools that will be

included as part of the Control phase are Process Monitoring, Financial Benefits Analysis and Project Closure.



Figure 3
Methodology and Activities tracker

RESULTS

Following the DMAIC Methodology, looking into the project stages, an evaluation was performed to the baseline's indicators for Code A – 2.4, Code B- 0.95 and Code C – 1.7 (lots per shift), to establish the current state scenario. Confirmation of the completion of the required activities was demonstrated in the Table 1.

Table 1
Project Activities Weight % Completion

Task	Description	Status	Project Weight
1	Process steps were identified	Done	5%
2	Project Syndication	Done	15%
3	Equipment pre-adjustments	Done	15%
4	Training Strategy Alignment	Done	5%
5	Documentation Approval	Done	20%
6	Training Material Readiness	Done	5%
7	Hypercare Strategy	Done	5%
8	Training Sessions	Done	20%
9	Training Certification	Done	5%
10	Documentation Effectiveness	Done	5%

Results showed in Figure 4 demonstrate the following output increase per Product Codes vs the expected result: Code A – 2.55 vs 2.64, Code B – 1.01 vs 1.05 and Code C – 1.8 vs 1.87. These results were obtained from the Week 5 operations and provide a positive direction to meet the expected output increase aligned to a process stabilization. Process monitoring under the

hypercare strategy will be continued to address any issue or needs during the following weeks.

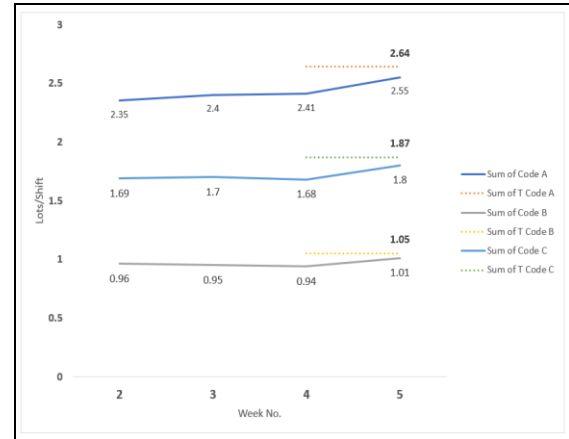


Figure 4
Product Codes Output Weekly Metric 2021

CONCLUSION

Looking into the results for the Product Codes A, B and C; it was observed the following percent increases with just one week of implementation: Code A + 6.25%, Code B + 6.32% and Code C + 5.88%. These numbers demonstrate an increasing path and results close to the desired state. Initial week of implementation includes the impact of the learning curve since people are executing the changeover with more precautions following the news steps than when they are executing with confidence.

Some remarks to highlight, and as a recognition for a great effort during the project execution, are directed to the are experts that were key during the design of the solution and in the implementation helping the team with the training and hypercare strategy. Also, the Technical team was committed to the project from the beginning to the end ensuring the proper implementation and within the time goal defined.

Since the principal goal is not meet yet, collaboration from the project team and process monitoring are required to be closely to the process stage during the ramp up to stabilize the output and make the adjustment as needed. Area Performance Metrics Governance will be the tier to monitor and

ensure that the output per shift reach the 10% increase.

REFERENCES

- [1] Eckes, G., *Six sigma execution : how the world's greatest companies live and breathe six sigma*", McGraw-Hill, 2005
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