Design Project Article Title

Author: Lisbeika Morales-Ramos
Advisor: Jose A. Morales, PhD
Master in Manufacturing Competitiveness

Abstract

This article provides a successful example of how the Sig Sigma methodology can improve the lead time associated to project/validation documents in the LMR company by 15%. In addition to the reduction in the lead time, a cost saving of one million was identify. This was achieved by the elimination of non-value-added activities, improving validation/project templates and development a system for the execution of minimum changes and First Articles Inspections avoiding the protocol generation. As consequence of this streamline process, the company have a capacity incrementation to absorb more projects that will contributed in the continuous improved in product quality and customer services.

Introduction

During the last two decades a recognized and valuated medical device company was highlighted as an example of high-quality standards and customer services. However, during the last six months, this company has been facing problems to achieve the validations/projects lead times established, especially during generation of documentation.

The name of this medical device was changed to LMR Company, in order to maintain the confidentiality of the process of this company. Company LMR started its operations in Puerto Rico in 1957 with the manufacture of thermometers. In 1987, LMR Company expands the manufacturing operations with the introduction of needles, cap, adapters, blood collection tubes and devices that enable the safe transfer of blood used in different medicals/surgical process.

Background

As a Six Sigma Green Belt partitioner, the best way to find opportunities for improvements is using the Lean Six Sigma (LSS) approach. LSS impacts positively on organizational profitability, efficiency, customer satisfaction, and quality [1]. For process improvement, Six Sigma is carried out using the DMAIC methodology [2] throughout the define, measure, analyze, improve, and control phases. This approach is regularly applied to manufacturing process, however, take in consideration that a systemic process like validations, projects, generation of documentation to perform the manufacturing process in compliance also will be improved using this methodology. The reason is that both process (manufacturing and systemic) presents the same type of waste in terms of waiting time between stages, duplicate processing, and non-value added activates.

In order to find the root cause associated to projects/validation delay, identify opportunities for improvements, waste, bottlenecks, and establish a sustainable process the five phases of DMAIC Methodology were used.

Problem

LMR Company has been facing problems to achieve the validations/projects due dates established during the last six months. The Total Lead Time (LTD) before DMAIC implementation was estimated in 46 days. The root cause was associated to documentation issues.

Methodology

To achieve the goal of reduce the lead time in the validation/projects during the document's generation of a company LMR, the five phases of the DMAIC Methodology were applied. The first was "Define", that is related to identify the objective, scope and goals. In this phase a generical project charter (gantt chart) was generated. Also was performed a survey (VOC) to know the complaints/concerns and identified opportunities for improvement during documents generation of documents.

In the second phase "Measure" was generated a data collection sheet from a period of 6 months to understand the reasons associated to the delay of projects/validations. Value Stream Map (current state) was development to fully understand the investigated process, identify opportunities for improvements and to estimate TLT.

In the third phase "Analyze", a pareto chart with the data obtained was developed to identify the possible root causes impacting the project time lines. According with the 80/20 rule, about seven (7) conditions had a mayor contribution in the project documentation delays. Additionally, in this phase was developed the fishbone analysis in which four categories (people, system, process, and management) were used for the creation of this.

In the next phase "Improve", the process was redesigned and improved to mitigate the causes found. A VSM (future state) was created reflecting the improvements. Additionally, an action plan was created to list the actions, assign the responsible for the execution of these and completion dates.

Finally, new metrics and process controls were implemented to monitoring the progress of the process and assure sustainability of the changes. This phase is named like "Control" phase.

Results and Discussion

The investigation related to the use of Six Sigma Methodoly to reduce the lead time related to the generation of validation/project document was successfully implemented. As consequence, the lead time associate to validation/project documents generation was improved more than 15%, meet with the target established. Additionally, was estimated a cost saving of 1M.

To identify the root causes associated to the delay in validations/projects, the first step was performed a survey (VOC) to the validation practitioner and project managers, in which 95% of the participants identified documentation issues and gaps during the process implementation.

Then of this a VSM (current state) was developed, and the lead time of the process was estimated in 46 days. Lead time is the amount of time that goes from the start to finish of any given process [4]. In projects/validations, this means the amount of time that passes between a project/validation is confirmed and the Purchase Order (PO) is approved, project/validation is closured/ implemented, and the project is released.

The Validations/Projects Total Lead Time (before and after DMAIC implementation) was calculated using the Value Stream Map (current and future state). These were development with the participation of a multidisciplinary team, composed for engineers, managers, supervisors, project managers, technicians, and clerks in which the time of each activity from project confirmed to project released was estimated based on their experiences (Figure 1).

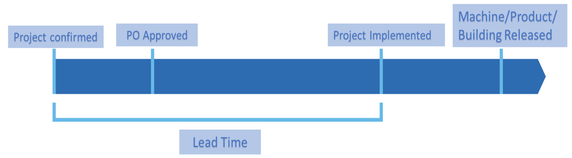

Figure 1
Lead Time Process

Figure 1
Total Lead Time

Type of Document	Lead Time Before DMAIC (days)	Lead Time After DMAIC (days)	Improvement
First Article	46	5	89%
Process Verification	46	5	89%
Protocol	46	36	15%

In the Table 1, time was identified as a significant source of waste in the validation/project process, especially during for the First Articles and Process Verification that obtained and improvement of 89% of the total lead time. These processes reflect a significant improvement in comparison with the "Protocols" that had an improvement of 15% of the total lead time, since for these were developed new forms/templates that allow the documentation in a more effective and simple way avoiding the generation of a protocol.

The next step of this investigation was analyzed the data collected from a period of 6 months (about 30 documents generated) to understand the reasons associated to the delay of projects/validations and for this a Pareto Principle & the 80/20 rule was used. This rule states that to maximize their efficiency businesses should focus on the vital 20% of activity. The 80/20 principle does not suggest that the remaining 80% can be simply ignored, it may just require less focus [5].

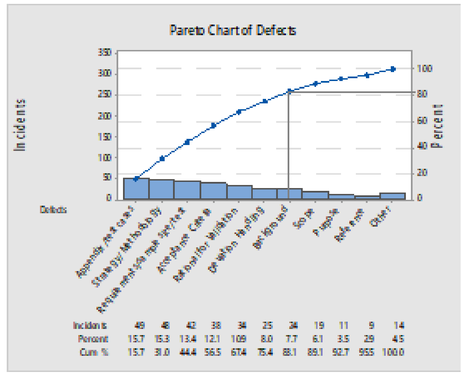

Figure 2
Pareto Chart

During the investigation, it was found that according with the principle 80/20 rule, there are seven categories (document sections) that have a mayor impact in the project delay, being the most common the "appendix/test cases follow by strategy/methodology. Refer to the Figure 2.

Conclusions

Based on the obtained results of this project, it can be concluded that the project was successfully and achieved the goal of 15% associated to improve the lead time for project/validation documents. Lead time reduction takes time, energy, and data, but can help your business improve its sales and fulfillment capability. Calculating, understanding, and acting on changes in lead time allows a business to prevent losses and fulfill orders quickly and efficiently. Additionally, was demonstrated that the five phase of DMAIC Methodology (Define, Measure, Analyze, Improve and Control) are an excellent tool to find root cause and improve systemic process.

Future Work

During the implementation of this project also were identified some opportunities for improvements that can be consider in a future. For example, establish a program for the periodical review of the validation/project process that include procedures, templates, and strategies. In addition, was identify the important of strengthening the training system for the validation/project area and assure that all the associates have the same knowledge and capacity to handle projects.

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