Designing a Standardized Process Flow for Regulatory R&D Service Center: A Design for Lean Six Sigma DMADV Case Study

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Abstract

Lean Six Sigma has great impacts in the removal of non-value adding activities and improving business performance. It does so by applying tools and techniques to eliminate waste, and focusing on implementing strategies to efficiently identify areas of opportunity and improve them. The research studies the effects of applying Lean and Six Sigma DMADV methodology for the improvement of an R&D service center's functional process flow and performance. The methodology is applied to identify variability in the process flow, measure and analyze this process flow with quality techniques and tools, and design remedies to improve project turnaround time. The results provide key inputs to focus on for future studies relating to Lean Six Sigma execution.

Introduction

Lean Six Sigma is the synthesizing agent of business performance improvement that, like an alloy, is the unification of proven tools, methodologies, and concepts, which forms a unique approach to deliver rapid and sustainable cost reduction [1].

- This research provides a clear foundation of the Design for Six Sigma (DFSS) DMADV methodology, and how it can be applied for continuous improvement efforts of an industry, as well as to identify what areas or tasks can be identified and deemed most important to measure and improve process workflow in a case study of an R&D service center.
- This project also serves to improve an R&D Service Center functional Process Flow by applying Lean Six Sigma Methodology to analyze the ongoing input and output of functional projects.
- The focus will be directed on the application of key techniques of the methodology that are useful to measure, and analyze the most important factors or key performance variables that affect the workflow, and on identifying and eliminating non-value adding activities, or waste, to improve the flow of work in the current functional process, and reduce a 10% in turnaround time (TAT).

Background

Many projects are initiated in the Research and Development (R&D) of new products, as well as in the process of updating the necessary information of old products and their components. To deliver quality projects, and continue improving the performance, as well as the efficiency of the workflow times, it is imperative to establish an efficient process flow of work, as well as appropriate timelines for completing the tasks that govern the whole process.

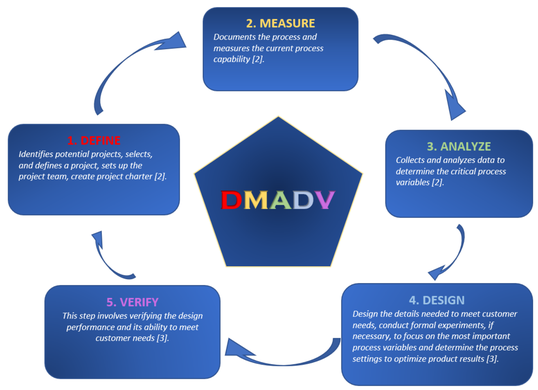
Problem

However, in the current functional role of the R&D area, an effective process flow, as well as workflow timelines are lacking standardization and have made the scheduling, monitoring, and completion of activities significantly inconsistent and has resulted in delayed project delivery, human resource overload, and errors that have led to re-work. The consequences for the overall business can lead to bad reputation of the service, which is something many industries work very hard to avoid.

Methodology

Lean and Six Sigma was defined and executed using the DMADV approach as in figure 1:

Figure 1: DMADV ROADMAP



Results and Discussion

1. ***Define***. The project charter, SIPOC table, and Gantt Chart was essential to structure the project tasks, completion timelines, as well as to identify the key stakeholders. Historical data of the events occurring, current outputs, and process flows were assessed to have a clear visualization of the key process input variables (KPIV's) and Key Process Output Variables (KPOV's).

Table 1: Project Charter

Project Name	*Design Project*	Start Date	*08-26-22*
Project Manager/Owner	*Jonathan M. Molina Cordero*	Scheduled Completion	*10-28-22*
Project Charter			
Purpose	To design a standardized process for initiating and completing customer request projects.		
Scope	This project will apply to all requests made by country/market, and all the specialists that are involved in the acquisition and delivery of regulatory information.		
Objectives	• Define and evaluate current state • Design future proposed state • Standardize process steps • Improve process efficiency, identify hidden waste in the process • Deliver a product that is consistently perceived as great to the customer		
Assumptions	• There are SOP's that are not easily accessible or incomplete creating waste. • Some processes are not standardized and creates waste. • Steps are improvised and not consistently done the same way. • There can be improved to ensure a consistent timely delivery. • Answer to the demand in one document set (all labels and artwork) per request		
Constraints	• Delivery Time is limited • Limited human resources • High wait times are endured during some steps		
Time/Decision Points	• On-time delivery • Identification of critical process steps and control parameters to avoid defects during the process. • Critical points are the "Initial Draft" preparation, delivery and wait times". • Project initiation FIFO and according to submission priority.		
Measurement Criteria/Quality	• Developing Current Flow of the process. • Measuring times during the process steps. • Measuring the wastes during the steps. • Adding controls to monitor differences in times vs quality of product. • What is misinterpreted information		
Major Risks	• Inconsistent or unknown process verification may cause setbacks or rework. • Uncertain delivery estimates may cause poor customer satisfaction.		
Key Stakeholders			
Stakeholder		Name	
Project Core Team		Jonathan and Team (x4 Specialists)	
Subject Matter Expert		SME (x1)	
Approvals			
Approvers		Virtual Signature	Date
Project Manager		Jonathan M. Molina	08-26-22
Sponsor		Sponsor	08-30-22

Table 2: SIPOC Table

S	I	P	O	C
*Country Manager *M&T Area *Label and Launch Science *Proofreading area	*Customer A Requested Information *Regulatory Information *Proofreading notes *M&T Request	*R&D Functional Process	*International Regulatory Doc Draft *Artwork *Regulatory Approval/ Rejection	*Customer A *Customer B

Figure 2: Process Flow Diagram

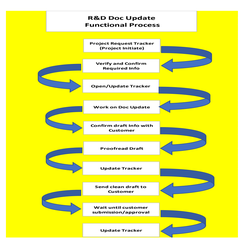
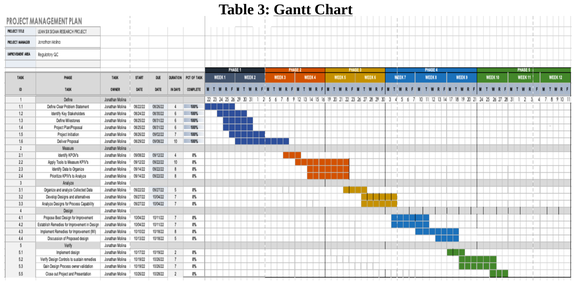


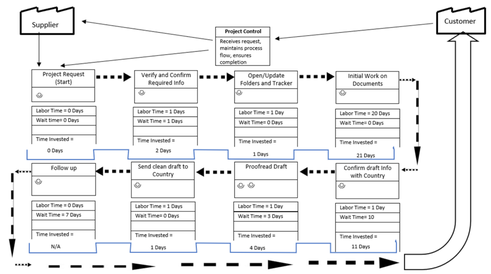
Table 3: Gantt Chart



Results and Discussion

2. ***Measure***. Potential KPIV's were identified using several basic analysis tools like brainstorming, voice of the customer, data collection, process flow charts. Value stream mapping (VSM) provided necessary information related to the KPOV's. The data from the VSM showed that many projects took at least 40 days to completion, although some took even more, and a few were requested with high urgencies which were delivered before the 40 days. The step that took the most time was the Initial Work on Documents with 21 days to completion.

Figure 3: Value Stream Map



3. ***Analyze***. The VSM was used to determine the events of the sequence of steps in the process and make assessments at intermediate steps to identify deficiencies. A fishbone diagram helped to find possible causes for delays in the Initial Work step. Further analysis of the VSM showed opportunities to eliminate a bottleneck and perform 5S.

Figure 4: Fishbone Diagram

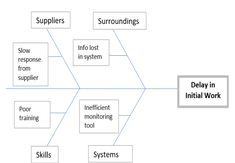
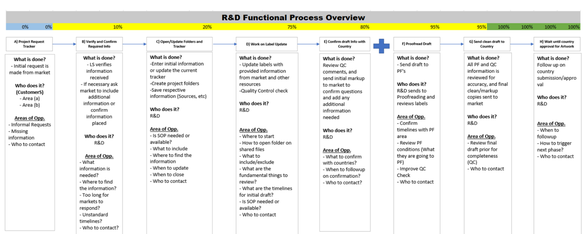


Table 4: 5S Definitions

Japanese	Translated	English	Definition
Seiri	organize	sort	Eliminate whatever is not needed by separating needed tools, parts, and instructions from unneeded materials.
Seiton	orderliness	set in order	Organize whatever remains by neatly arranging and identifying parts and tools for ease of use.
Seiso	cleanliness	shine	Clean the work area by conducting a cleanup campaign.
Seiketsu	standardize	standardize	Schedule regular cleaning and maintenance by conducting *seiri*, *seiton*, and *seiso* daily.
Shitsuke	discipline	sustain	Make 5S a way of life by forming the habit of always following the first four S's.

Table 5: Functional Process Overview



4. ***Design***. This work instruction details the Functional Process Overview, and includes visual aids to cover most, if not all, of the areas of opportunity that were mentioned in the analyze phase that directly affect the outputs of the process. New standard project folder was structured as a result of 5S, as well as a QC checklist for reviewing steps before delivery of projects.

Results and Discussion

5. ***Verify***. In the verification phase, the Standard Process Flow of the designed Work Instruction was introduced to the team for verification of feasibility. Training sessions were scheduled emphasizing the steps in the process, and to ensure understanding of the whole process, as well as the importance of following the standard steps and timelines. By reducing the standard time from 40 days to completion to 30 days to completion by following the established timelines, the process delivery or (TAT) will see a reduction of 25%. 5S in the general project folder resulted in reduction of folders from more than 30 folders to only 5 folders, as well as an overall cleanup of irrelevant files, folders, and a standardization of the practical project folder with specific sub-folders.

Conclusions

The Lean Six Methodology proved to be very resourceful for the improvement efforts of the process.

- The structured methodology, as well as the quality and lean tools and techniques that were used, had a great impact on the identification of the areas of opportunity, which led to the reduction of at least 25% TAT.
- It also gave a better understanding of the strengths of having a lean mentality, which focuses on reducing waste, and manifested itself in the reduction of waste, and making room for innovative ways of thinking and working.
- The analysis of data led to a design that improved the flow of the process by establishing a standard process that can be efficiently executed, monitored, and measured to continue improving the performance in the delivery of projects, and with high quality.

Future Work

In future work, more specific numerical data of the exact times it takes to complete the tasks, the times of delayed deliveries, and other defects, would improve the odds of evaluating the data with statistical tools in the measure and analyze phase and determine an accurate process capability. The use of Lean Six Sigma in the service sector should be greatly emphasized so more resources and knowledge can be gathered that would result in new innovative ways of thinking and making decisions.

References

[1] GEORGE, MARK O. The Lean Six Sigma Doing More with Less; Cut Costs, Reduce Waste, and Lower Your Overhead. John Wiley & Sons, Inc. 2010

[2] Gyrna, F. M., Chua, R. C. H., De, F. J. A., Juran, J. M., & Juran, J. M. (2007). Juran's quality planning and analysis: For enterprise quality. Boston: McGraw-Hill.

[3] Breyfogle III, Forest W. Implementing Six Sigma: Smarter Solutions Using Statistical Methods. Hoboken, New Jersey. John Wiley and Sons Inc. (2003)

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