Change Control Routed With Missing Information Delaying Approval and Implementation Date

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Abstract

The approval of manufacturing change control for MedDevice Inc., is currently acting lower than target (15 business days). Based on a 12-months data review, the lead time of approval of a change is approximately 36 days. This means that 25.8% of changes were routed for evaluation without the necessary information. The DMAIC methodology was used to determine what is causing the delay. The following possible causes were identified as part of the evaluation: (1) missing information i.e., Manufacturing Plan, Validation documents, and Product affected is not included. (2) Volume of changes being routed. (3) Time for identification and number of required approvers by type of change. During control phase, lead time for four months (Quarter 2) was collected, and results demonstrate a reduction of less or equal to 33 business days. The project goal was to reduce approval lead time process from 36 to 33 days by end of Quarter 2.

Introduction

MedDevice Inc. is a global medical device manufacturer that distributes product around 80% of the countries around the world with the goal of restoring quality of life of its customers. In order to meet customer demand and requirements the change control system must work in an efficient way to ensure changes to the devices are implemented in a controlled environment and with the urgency customers and stakeholders require. Based on a 12-months change control data review, the lead time of approval of a change control is approximately 36 days, resulting in impact to implementation of continuous improvement and business changes also, urgent changes that are routed due to downs in the manufacturing lines. This means that 25.8% of closed Change Controls during 12-months were routed for impact evaluation and approval without the necessary information and evidence, therefore, delaying approval time and implementation dates.

Background

To meet customer demand and necessities and be competitive in the market, manufacturing companies must engage in continuous improvement methodologies that will take their process, products, or services to the next level. Continuous improvement is a way of thinking and acting; is the process of ongoing improvement of products, services, or processes through incremental and breakthrough improvements [2]. Different continuous improvement methods can be applied depending on the problem identified and the scope of it. Some methods used in the manufacturing practice include the plan-do-check-act (PDCA), Six Sigma, Lean Six Sigma, and total quality management (TQM). All these methods emphasize teamwork and participation, measurement of processes, and reduce variation, defects, wastes, and cycle times [2].

Problem

Reduce approval lead time of Change Control process from 36 to 33 days by end of Quarter 2.

Methodology

The DMAIC methodology was used to determine the possible causes for the manufacturing change control approval delay.

Figure 1. DMAIC Approach

Results and Discussion

Define

25.8% of manufacturing Change Control requests closed in a 12-month period of time were routed for approval without the necessary information for a proper assessment, therefore delaying approval and implementation time. This represents an average of 36 days for approval when the process should take 15 days to be completed. Consequently, these delays estimated implementation dates of projects and urgent changes. A SIPOC diagram of the process is illustrated in Figure 2.

Suppliers	Inputs	Process	Outputs	Customers
Manufacturing department including Manufacturing Engineer, Originator of CCR, Product Development engineer, Design Quality engineer, Sterilization representative and Packaging representative, External Suppliers,	Change Control Request (CCR), Model affected list, Validation documentation required, Plan/Report to be implemented	Process to approve CCR	CCR closed and implemented	Operations, Manufacturing sites

Figure 2. SIPOC Diagram

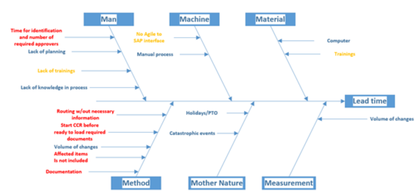
The scope of the project includes the process of approval of manufacturing change controls in MedDevice Inc., from the moment the change control is route to the primary phase until completion of second and final phase for implementation. The Is/ Is Not tool was used to define the problem.

	Is	Is Not
What	The lead time of approval of manufacturing change control requests is below the target date of 15 days.	Other changes documented under the Change Control System for MedDevice Inc.
Where	QMS - Change Control System	Other changes documented under the Change Control System for MedDevice Inc.
When	Jan 2021 - Dec 2021	Prior to Jan 2021 nor after Dec 2021
Extent	Manufacturing Change Control System	Other changes documented under the Change Control System for MedDevice Inc.

Table 1. Problem Statement - Is/Is Not

Measure

A fishbone diagram (Figure 3) and basic statistics were performed to demonstrate the necessity of the project. The inputs in red will be the primary focus.



The data from 12-months period was analyzed using Minitab to understand the process and its behavior. Figures 4 shows a process capability where it can be observed that the data does not follow a normal distribution since Process Performance Capability (Ppk) is less than 1.0, meaning the process is not centered.

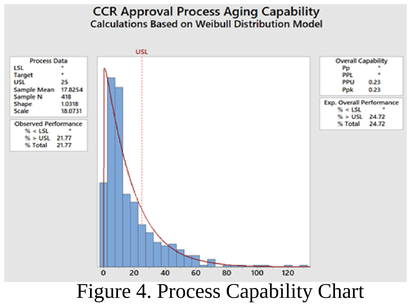


Figure 4. Process Capability Chart

Analyze

Pareto charts were performed for the change control process data including both phases, impact review and plan execution, and by phases to determine the cause or most probable cause for the delay in approval for the inputs identified in the Fishbone.

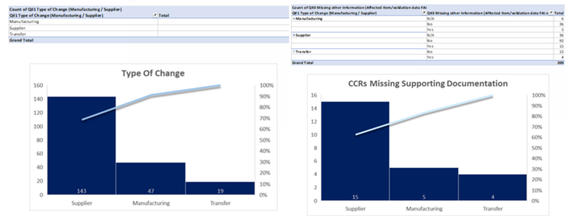


Figure 5 and 6. Type of Change (CCR) – Pareto Chart

From January 2021 to December 2021 a total of 209 Change Control Requests (CCR) were closed, 19/209 CCRs were related to supplier transfer change control, 47/209 were manufacturing CCRs, 143/209 were supplier manufacturing CCRs. Therefore, the majority of the CCRs routed and closed for the 12-month period were related to supplier changes. In Figure 6 a total of 15 supplier related CCRs were routed without supporting documentation required, for example, affected product and validation data. Only five (5) manufacturing related CCRs were missing supporting documentation required. For supplier transfer changes only four (4) CCRs were missing affected product and validation data.

Improve

After implementation of Change Control procedure updates to the Supplement B: Change Request Routing Requirements Table Verification which consisted in updates to Approval Requirements matrix including approval team by change code, trainings in how to document a change request were also given to the change owners, and finally weekly meetings for status of each change control a reduction in approval was observed. Refer to Table 4 for Improvement Plan implemented.

Task #	Task Description	Responsible	Due Date	Status
1	Change Control Procedure Supplement B: Change Request Routing Requirements Table verification	Bianca Álvarez & Change Control Team	Complete	Complete
2	Trainings in how to document a Change Control Request	Bianca Álvarez	Complete	Complete
3	Weekly Status Meetings	Bianca Álvarez	Complete	This is a weekly meeting to update and request information needed to complete each CCR routed weekly. Also, to identify urgent changes that must be implemented.

Table 2. Improvement Plan

Control

Approval lead time data for Change Control Requests was collected for four (4) months after the implementation of process improvements to manufacturing change control procedure. Based on the four-month (4) data review a Process Capability was conducted resulting in a Ppk of 0.46 meaning less variability from the data of CCRs closed during the 12-month period, January 2021 to December 2021 (refer to Figure 15). Higher Ppk means the process is more efficient and less variation between process output and specifications. In this time period the mean of approving a CCR is approximately 16.2 days.

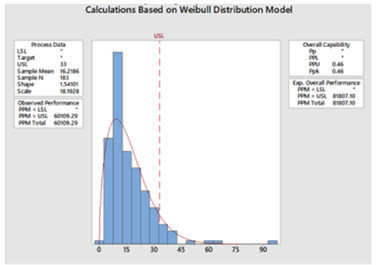


Figure 7. Process Capability Report for Closed CCRs after December 2021

Conclusions

The objective of the project was to reduce approval lead time of Change Control Requests (CCR) from 36 days to 33 or less by end of Quarter 2. Based on the improvements made to the Change Control procedure and process a reduction of 8.3% was achieved during a four (4)-month period. The Change Controls closed after the implementation of process and procedure improvements show a reduction in the approval lead time. Also, a reduction in process variability was observed and approval lead time for each phase, impact review and plan execution, was close to the target dates per phase.

Future Work

It is recommended to continue to monitor the process and identify other areas of opportunities of the process to harmonize and standardize it for the benefit of the Change Control and QMS system. The results obtained by this project and future ones will have a direct impact on process improvement project to the manufacturing floor and implementation of projects with a positive financial impact to the company and stakeholders.

Acknowledgements

Advisor: Jose A. Morales, Ph. D

References

[1] What is a Quality Management System (QMS)? American Society for Quality (ASQ).
[2] What is Six Sigma? American Society for Quality (ASQ).
[3] What is DMAIC? GO Productivity. 2020.