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.*

Key Terms *— Change Control, Continuous Improvement, DMAIC, Lead Time.*

PROBLEM STATEMENT

In the medical device and pharmaceutical industry, the Quality Management System (QMS) is used to coordinate and direct activities to meet customer and regulatory requirements, also improve its effectiveness and efficiency on a continuous basis [1]. The goal of QMS is to ensure compliance with regulations and distribution of products in a cost and resource efficient manner. The QMS consists of a series of standards and elements that help achieve the customers' and organization goals and requirements. One of the elements of the QMS is the Change Control process used to ensure that changes to a product or system are implemented in a controlled and coordinated manner per Regulatory and internal requirements. The Change Control process is measured to determine the approval lead time of manufacturing changes and the areas of opportunities the system can have. Lead time is defined as the amount of time that passes from the start of a process until its completion. 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.

The change control system is dedicated to the impact evaluation and approval of manufacturing changes to the devices. 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.

Research Description

The research project is about improvements to manufacturing change control system which is important to ensure changes are made with the control requirements establish per standards, internal policies and procedures and at the same time meet customer and operational requirements. Stakeholders, manufacturing floor, and management agree the Change Control system

needs improvement to the process to ensure projects and unexpected configurations and improvements to procedures are met in the require time.

Measuring the Change Control System of the company is very important to ensure changes are being routed per procedure and with the time required to make a proper impact evaluation and at the same time making sure the company implements changes and projects in the dates specified to management and stakeholders.

Research Objectives

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

Research Contributions

A reduction in approval Lead Time for Change Controls will provide the following benefits:

- Reduce lead time approval for manufacturing changes.
- Reduce the probability of a nonconformance to the process that can trigger a finding or observation by Regulatory Bodies.
- Reduce probability of a Corrective and Preventative Action (CAPA) and its financial impact.
- Meet customer's and operational demand on time.

BACKGROUND INFORMATION

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].

Six Sigma

Six Sigma is a method that provides tools to improve the capability of processes. It is used to increase performance and reduce process variation which at the same time will reduce defects and improvements in profits and quality of products or services [2]. The DMAIC approach is the most used Six Sigma methodology in the manufacturing industry. The DMAIC approach consist in identifying a problem and its scope (Define phase), measuring the actual process (Measuring phase), analyzing the data and identifying tools that will eliminate and reduce variation of the problem (Analyze phase), improve the process by implementing those tools identified in the analyze phase (Improve phase), and finally implement controls that will maintain the tools implemented to improve the process and alert if the process is out of control.

DMAIC Methodology

The DMAIC methodology consists of five (5) phases: define, measure, analyze, improve, and control. The Figure 1 demonstrates the DMAIC methodology consists of a series of sequential steps used to identify a problem, measure the current process, and identify the root cause of the problem, and implement improvement opportunities.

Figure 1
DMAIC Methodology [3]

The goal of each phase of the DMAIC approach is explained below.

- **Define:** During the Define phase the problem statement and goal is identified resulting in a project charter and the first phase of the A3 tool the Define phase. The DMAIC approach is data-driven therefore, the first phase involves data collection in the form of collecting the customer feedback or Voice of the Customer. Other useful tools use to understand the process is a high-level Value Stream Map (VSM) to understand how this problem is affecting the organization and the end customer and the SIPOC diagram (Supplier, Input, Process, Output, and Customer) [3]. The SIPOC diagram includes all the process from start, inputs from suppliers or from the team involve in the process, to finish which includes output of the customers.
- **Measure:** The measure phase consists in conducting a mapping of the process/problem out of control and collecting the baseline data. During these phase visual representations are used to interpret the data obtained like for example graphs.
- **Analyze:** This phase uses the data collected in the measure phase to identify the root cause or causes of the problem that was defined [3]. Some tools used include the Failure Mode and Effectiveness Analysis (pFMEA), Design of Experiments and other graphical and statistical tools [3].
- **Improve:** When the most probable causes of the problem (X or X's) are identified the next step is to address and eliminate the root causes [3]. Some of the tools that can be used to identify and eliminate the root cause(s) include Kaizen events, among others.
- **Control:** During the control phase data is collected to validate the expected benefits of the improvements implemented during the improve phase. Additional tools for process control include Quality Control Plans, Statistical Process Control (SPC), 5S, and Mistake-Proofing or Poka-Yoke [3]. The Quality Control Plan is the documentation of quality specifications, standards, and practices for maintaining quality for a product or service and be able to identify when process is out of control.

Lead Time

The lead time is known as the amount of time that passes from the start of a process until its completion. The lead time is calculated as the sum of time of pre-processing, processing, and post processing or time of delivery. For the purpose of the manufacturing change control process described in this project, the lead time is defined as the sum of days (business days) from the first phase of the change control until the closing date (second phase of change control).

METHODOLOGY

The DMAIC methodology was used to determine the possible causes for the manufacturing change control approval delay. In the Define phase, the problem was stated with its scope and out of scope process and the goal of the project and business. The define phase also includes the stakeholders and the current and proposed states. The tools used to define the problem and its scope include Is/Is Not and SIPOC diagram.

The Measure phase is the collection of data to measure current process and understanding the behavior of the change control system. The data of the process will be obtained to determine the process capability with the following tools: fish bone diagram, C&E Matrix and basic statistics.

During the Analyze phase other basic statistics were used to identify the root cause or most probable cause for the delay in approval of the manufacturing change control. The data was interpreted to understand the performance of current process.

After the root cause(s) are determined during the abovementioned phases, the Improve phase will help to identify tools and actions that can be implemented to eliminate or reduce them. The tools

that will be used to identify to eliminate or reduce the root cause(s) include improvement plan, kaizen events, and basic statistics.

Finally, the last phase, Control, the improved process will be monitored for four (4) months after the implementation of process improvements to manufacturing change control procedure. Tools that will be used to monitor the process will be a control plan and basic statistics. To ensure the effectiveness of the changes implemented, the project must establish an approval lead time reduction from 36 days to 33 days or less.

RESULTS AND DISCUSSION

The results for the five (5) stages of the DMAIC methodology are described below.

Define

The 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.

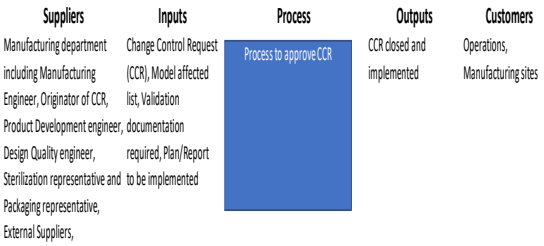

Figure 2
SIPOC Diagram

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 implementation. The Is/ Is Not tool was used to define the problem.

Table 1
Problem Statement – Is/ Is Not

	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.

Measure

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

The data of lead time of approval of a change control request was collected for the period January 2021 to December 2021 (12-month period).

The data from 12-months period was analyzed using Minitab to understand the process and its behavior. Figures 4 and 5 shows a process capability and individual and moving chart, respectively. The Process Capability chart, Figure 4, shows data does nor follow a normal distribution since Process Performance Index (Ppk) is less than 1.0, meaning the process is not centered. On the other hand, the Individual and Moving chart (I-MR), Figure 5, shows the average days it takes to complete a change control request which is 17.8 days. Another observation from the I-MR chart is the approximately at day 211 to 379 an agglomeration is visible meaning approval of change controls were equal or less than the average of 17.8 days.

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 diagram in the measure phase. Refer to Figure 6 to 14.

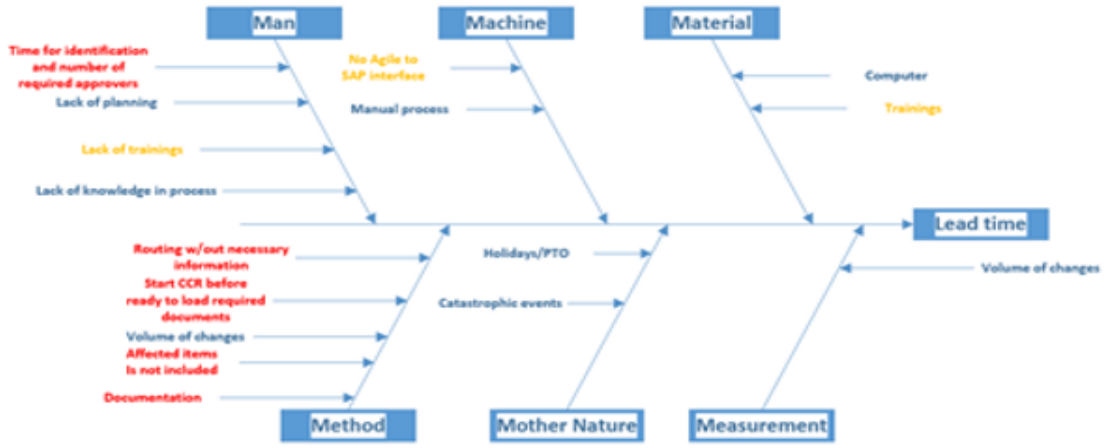

Figure 3
Fishbone Diagram

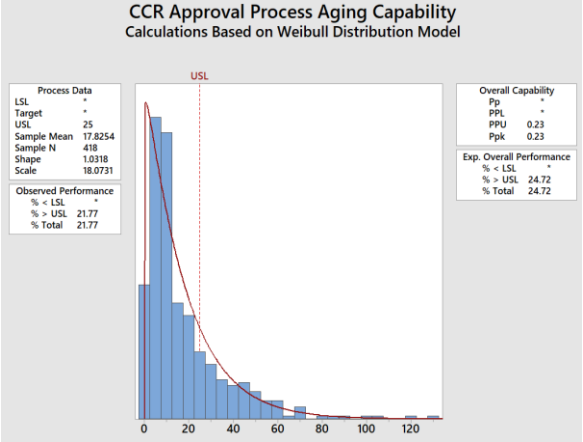

Figure 4
Process Capability Chart

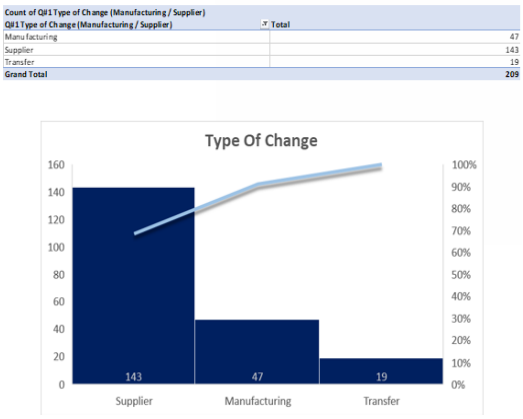

Figure 6
Type of Change (CCR) – Pareto Chart

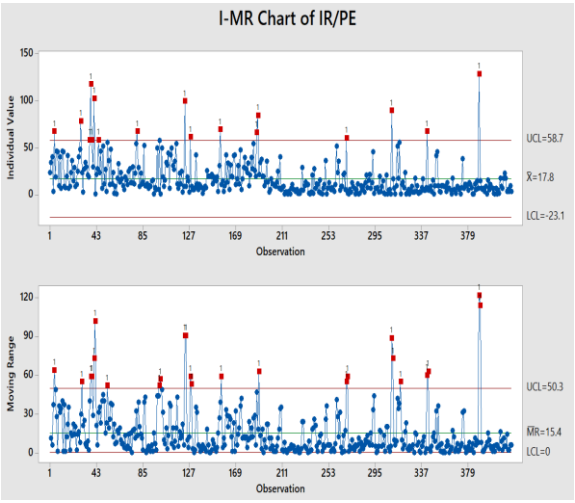

Figure 5
I-MR Chart of Impact Review and Plan Execution Phase

Analyze

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.

For Figure 7, a total of 32% of supplier CCRs needed additional information in the cover page to understand the scope of change, 17% of manufacturing change controls needed additional information and 5% of supplier transfer changes also needed additional information to understand change.

Count of Q# 2 Change description Content Information Q#1 Type of Change (Manufacturing / Supplier)	Q# 2 Change description Content Information	Tot
Manufacturing	Clear Description of change /Stand alone document	3
	Need additional information to understand change	
Supplier	Clear Description of change /Stand alone document	5
	Need additional information to understand change	4
Transfer	Clear Description of change /Stand alone document	1
	Need additional information to understand change	
Grand Total		2

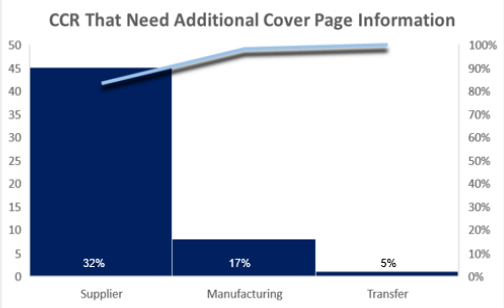

Figure 7
CCR That Need Additional Cover Page Information – Pareto Chart

Count of Q#3 Missing other information (Affected Item/validation data FAI Q#1 Type of Change (Manufacturing / Supplier)	Q#3 Missing other information (Affected Item/validation data FAI e	Total
Manufacturing	N/A	6
	No	36
	Yes	5
Supplier	N/A	36
	No	92
	Yes	15
Transfer	No	15
	Yes	4
Grand Total		209

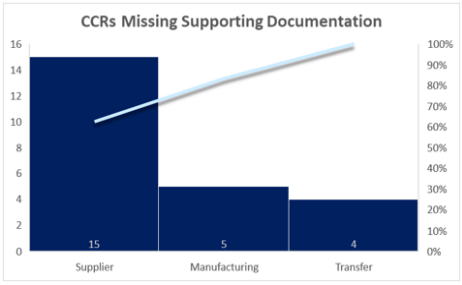

Figure 8
CCRs Missing Supporting Documentation – Pareto Chart

Count of Q#4 What Is Missing - Impact Review Q#1 Type of Change (Manufacturing / Supplier)	Q#4 What Is Missing - Impact Review	Total
Manufacturing	Additional information to understand the change	1
	Affected Items (Include components/Raw materials + finished devices)	1
	Country of Origin Information - for Transfers	1
	N/A	41
	Other	3

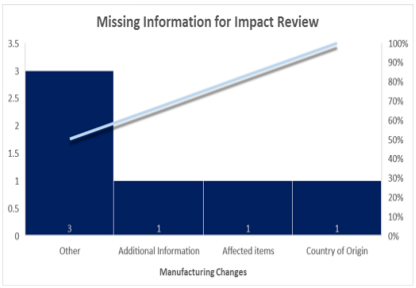

Figure 9
Impact Review Missing Information – Manufacturing Changes Pareto Chart

In Figure 8 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.

The pareto chart in Figure 9 for manufacturing related changes indicates that for Impact Review phase three (3) CCRs were routed missing three (3) documents/data required for proper evaluation. Also, one (1) CCR didn't include the affected product number, and other CCR was pending Country of Origin (COO) information which is required for evaluation and disposition of manufacturing transfers.

Count of Q#4 What Is Missing - Impact Review Q#1 Type of Change (Manufacturing / Supplier)	Q#4 What Is Missing - Impact Review	Total
Supplier	Additional information to understand the change	1
	Affected Items (Include components/Raw materials + finished devices)	5
	Country of Origin Information - for Transfers	3
	N/A	130
	Other	4

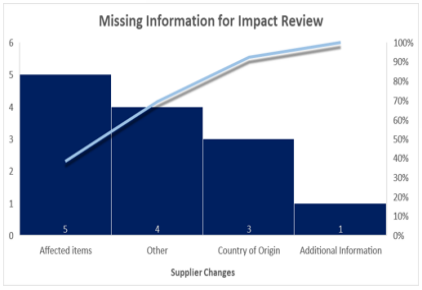

Figure 10
Impact Review Missing Information – Supplier Changes Pareto Chart

For Impact Review Supplier related CCRs shown in Figure 10, five (5) of them did not include affected product number list. Four (4) were under the category of other documents/data needed for evaluation and disposition of Impact review phase. Also, three (3) CCRs were missing COO assessment and one (1) additional information.

For supplier related transfer Impact Review changes in Figure 11, only three (3) CCRs were missing affected product list and one (1) the COO assessment.

Figure 12 shows for Manufacturing Changes Plan Execution four (4) of 47 CCRs missing validation documentation requested during Impact Review phase. Two (2) CCRs were under the category of Other and one (1) was missing GR&R validation related data.

Count of Q#4 What Is Missing - Impact Review		
Q#1 Type of Change (Manufacturing / Supplier)	Q#4 What Is Missing - Impact Review	Total
Transfer	Affected items (include components/Raw materials + finished devices)	3
	Country of Origin Information - for Transfers	1
	N/A	15

Figure 11
Impact Review Missing Information – Transfers Pareto Chart

Count of Q#5 What Is Missing - Plan Execution		
Q#1 Type of Change (Manufacturing / Supplier)	Q#5 What Is Missing - Plan Execution	Total
Manufacturing	GR&R validation doc - Attachments/Relationship tab	1
	N/A	40
	Other	2
	Validation Documentation - Attachments/Relationship tab	4
Manufacturing Total		47

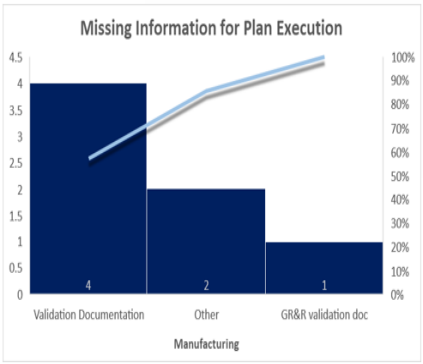

Figure 12
Plan Execution Missing Information – Manufacturing Changes Pareto Chart

Count of Q#5 What Is Missing - Plan Execution		
Q#1 Type of Change (Manufacturing / Supplier)	Q#5 What Is Missing - Plan Execution	Total
Supplier	Documented Rationale for no testing - Attachment - Relationship tab	2
	GR&R validation doc - Attachments/Relationship tab	7
	N/A	125
	Other	3
	Validation Documentation - Attachments/Relationship tab	6
Supplier Total		143

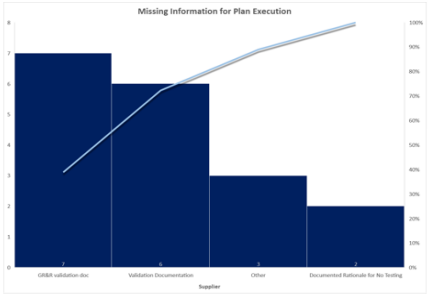

Figure 13
Plan Execution Missing Information – Supplier Changes Pareto Chart

Count of Q#5 What Is Missing - Plan Execution		
Q#1 Type of Change (Manufacturing / Supplier)	Q#5 What Is Missing - Plan Execution	Total
Transfer	GR&R validation doc - Attachments/Relationship tab	1
	N/A	15
	Validation Documentation - Attachments/Relationship tab	3
Transfer Total		19

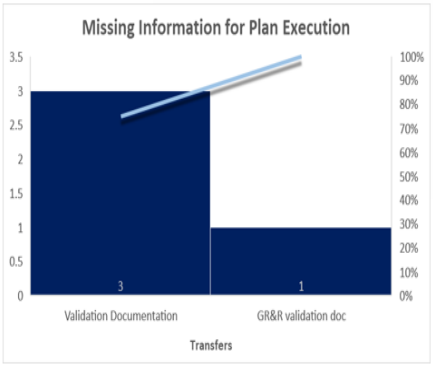

Figure 14
Plan Execution Missing Information – Transfer Pareto Chart

Finally for Supplier Transfer Plan Execution, Figure 14, a total of three (3) CCRs were missing validation documentation requested in Impact Review phase. Only one (1) CCR was missing GR&R validation documentation related data for Plan Execution.

Table 3
Wastes Identified in the Process of CCR

Waste	Transactional
1. People Motion	The CCR process is dependent of a Change Analyst that can inform all that is missing in the CCR and what needs to be removed. This makes the process slower since not always the Change Analyst will be available, or the Change Originator does not follow up the change.
2. Waiting	Approvers must wait until Change Originators incorporate feedback for disposition of CCR.
3.Transportation/Moving	Emailing back and forth, forwarded emails/ communication.

Table 3 shows some of the wastes identified in the process of evaluation of Change Control Requests. Waste do not add any value to the process nor customer.

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.

Table 4

Improvement Plan

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.

Figure 15 shows the four (4) month data obtained after implementation and is observed a total average of 32 days approximately to be approved/closed. This data shows improvements based on the results of the 1-month period data obtained. However, this process will need continue improvements to accomplish the goal of the CCR process.

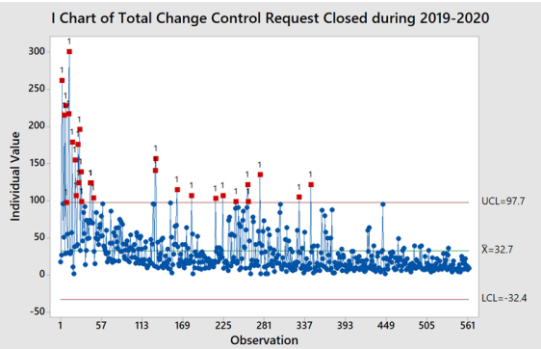

Figure 15

I-Chart of Total CCR Closed After Implementation

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 oh 0.46 meaning less variability from the data pf CCRs closed during the 12-month period, January 2021 to December 2021 (refer to Figure 16). 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.

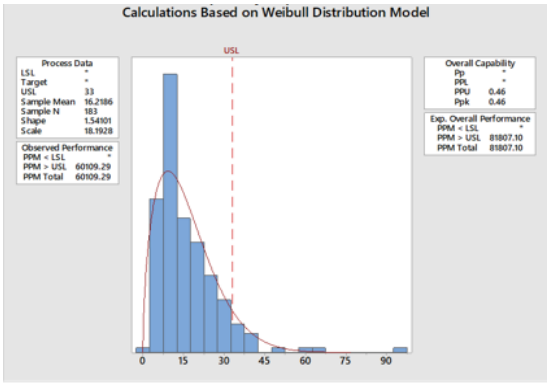

Figure 16

Process Capability Report for Closed CCRs after ecember 2021

The Individual Chart in Figure 17 shows a comparison between the process of approved CCRs for the 12-month and 4-month period time. After improvements to the Change Control process were implemented, less variability can be observed (after) and approval took approximately 16.2 days.

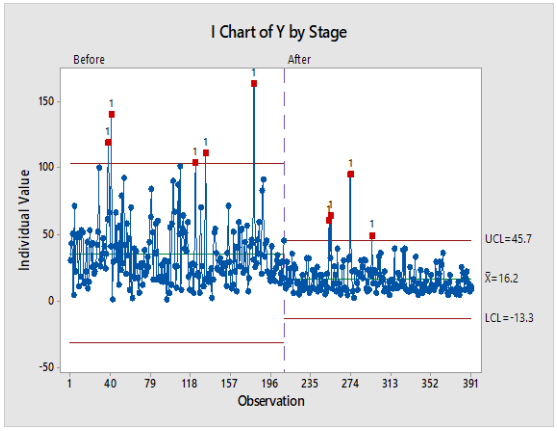

Figure 17

I-Chart by Stage

CONCLUSION

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. 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.

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