Validation Documents Process Optimization and Cost Reduction

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Abstract *— Every manufacturing and regulated site, performs multiple Validation Documents; being this area one of the most material cost and man hour consuming of the site. FMEA and Design Documents are constantly generated and revised during any Validation activity. The main scope of this study is to reduce the material cost, man hour and any possible quality issue during the generation of these documents increasing the efficiency of the area. Also, it will benefit the identified customers of these documents. To achieve the scope, and align the process to customer expectations Lean Six Sigma methodology was used with DMAIC (define, measure, analyze, improve, control) as core.*

Key Terms *— Design Documents, DMAIC, Failure Mode and Effect Analysis, Process Improvement.*

PROJECT STATEMENT

Validation Department is an area that manages multiple documents such as Validation Protocols, Design Documents (User Requirements (URS), Functional Specification (FS), Configuration Specification, Designs), Risks Assessments (Failure Mode and Effect Analysis (FMEA)) among others. The process, from the generation until its approval can generate multiple costs to the area such as man hours and material expenses (binders, folders, paper and printing). Also, the opportunity for document errors increase.

PROJECT OBJECTIVES

The main objective of this project is to:

- Reduce 100% of document errors (Quality Issues)
- Reduce by 100% material expenses (Costs)
- Reduce at least 50% of document approval time (Time Efficiency)

RESEARCH CONTRIBUTIONS

The main contribution of this study is to improve the actual process, making it efficient at low costs. The customers of the Validation Department, such as Manufacturing Plant and Quality Department, can obtain, approve and receive documents faster that comply with quality standards at low costs for the Validation Area, therefore, the company. This project will focus its efforts for the Failure Mode and Effect Analysis and User Requirement, Functional Specification Design Specification (DS) and Configuration Specification (CS) Documents.

LITERATURE REVIEW

FMEAs are a step by step Risk Assessment used to identify failures in a design, system, process, product or service. In this Risk Assessment, an evaluation and prioritization of the consequences (risks) of the failures and the actions to avoid (control) these risks, is documented. [1] This assessment is usually performed before a development of a product, during a validation process, during a Corrective Action/ Preventive Action (CAPA), process or system improvements, among others.

Currently, the procedure for the generation of FMEAs in the Validation Department is the following: 1. Gather a multidisciplinary team that can bring information about the design, process, quality, maintenance of the document scope, 2. Identify the steps of the scope and its function, 3. Identify the possible failures in each step (Potential Failure Modes), 4. Identify the consequences of the failures to the equipment, product, customer, etc.

Failure Mode and Effect Analysis (FMEA) Assessment Form

Title:										
FMEA Number/ Revision:							Project Coordinator:			
Manufacturing Area:							Author:			
Product/Process/System ID:							Reviewed by:			
Reference Document/Protocol/CC No/ CMT No:							Approved by:			
Description:										
Section I. FMEA Assessment										
Process Step or Item ID	Process Step or Item ID Function	Potential Failure Mode	Potential Effects	S	Potential Causes of Failure	O	Current Controls	D	RPN	Corrective Action? (Y/N)

Section II. Corrective Action							☐ N/A
Process Step or Item ID	Potential Failure Mode	Potential Causes of Failure	Corrective Action	S	O	D	RPN

Figure 1

FMEA Document Template Example [1]

(Potential Effect of Failure), 5. Determine the Severity of the Potential Failure Mode, 6. Determine the Occurrence (Probability of Failure), 7. Determine the detection rating (controls) based on how likely it is to prevent the failure before it happens, 8. Calculate the Risk Priority Number (RPN) (Occurrence x Severity x Detection), 9. Identify based on the RPN if a Corrective Action is needed, and 10. Address and document the Corrective Action. Figure 1 is an example of the documentation of this assessment.

Design Documents such as User Requirements, Functional Specification, Configuration Specification and Design Specification are used for the Computer System Validations (CSV).

User Requirements Specification (URS) is a document that must be generated on the early stages of any project. In this document, must be defined the intended use, function, GxP and Security requirements of the system that will be requested to the manufacturer.

Based on this document, a Functional Specification (FS) is generated. The FS must describe in detail the Computerized System functionality based on the approved URS.

Configuration Specification (CS) must cover the configuration of the Computerized System to meet the User and Functional Requirements including the description of settings and parameters used for the manufacturing/configuration of the system.

Design Specification (DS) must define the design of the custom software that will meet the Functional Specification. Design specifications shall document the design of the software including database, data mappings for interfaces with other system, etc.

These documents are managed individually and must be approved before the Qualification Phase of the systems.

METHODOLOGY

Lean Six Sigma is a methodology that combines the benefits of Lean and Six Sigma Strategy. The Lean strategy main objective is to eliminate waste through the elimination of non-value added activities. It is focused on reduce costs and increase the speed of the process. On the other hand, Six Sigma objective is to reduce defects through the optimization of the processes and the reduction of variation. It is focused on the quality improvement and cost reduction.

The most common metrics used in the Lean Six Sigma are Quality, Time and Costs. Some of the tools used to identify, solve and monitor these metrics are: Value Stream Process Mapping, 5s, Kanban, Define, Measure, Analyze, Improve, Control, among others.

Define, Measure, Analyze, Improve, Control (DMAIC)

DMAIC model covers five (5) different stages where specific tools are applied to achieve them. These stages must be performed in sequential order.

The first one is called Define Phase. In this phase, the area to be improved and the customers (internal or external) are identified. Also, the potential resources, the project timeline and project charter is defined.

In the Measure Phase, the inputs and output variables of the process are established. The main objective is to collect data needed to analyze and sustain the improvements performing data comparison before and after the improvement implementation.

During the Analyze Phase, the data is used to identify the possible reason that affects the output. This phase is one of the most critical. The correct identification is crucial for the project success. If the possible cause is selected incorrectly, it is possible to need the verification of the Measurement methodology.

Once the Analyze Phase is concluded, the identification of the improvements to be applied to optimize the output and reduce defects or wastes is performed. This one is called Improve Phase. In this phase modifications of procedures, retraining, among others can be done.

Then in the Control Phase, the monitoring of the process is performed to guarantee the sustain of the process improvements performed in the Improve Phase [2].

RESULTS AND DISCUSSION

Following, the findings of this research using the DMAIC methodology.

Define Phase

In the Validation Department, the generation and revision of FMEAs and Design Documents are performed at least, on a weekly basis. During the generation of these documents, the author, must look in the Quality File Room if there is any already generated document. If not, an identification number must be assigned using a logbook. Then, after the generation of the document, the author must identify the approvers and bring the documentation personally. Then, the document is storage in a Quality File room. Refer to Figure 2 for the Process SIPOC.

After reviewing this process, it was identified that for the Failure Mode and Effect Analysis documents:

- Errors has been made assigning the next consecutive identification number to the document.

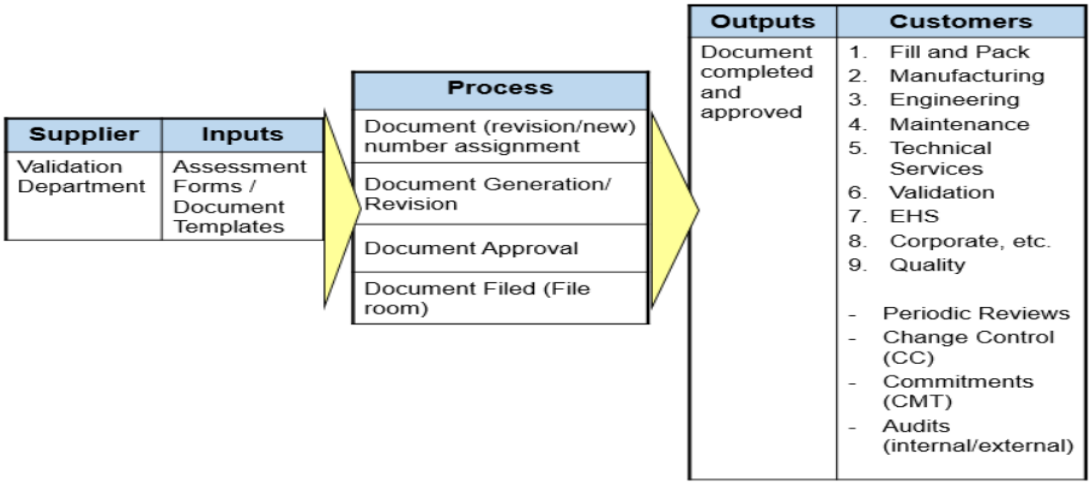

Figure 2
FMEA and Design Document SIPOC

- Errors has been made assigning the next consecutive revision number to the document.
- There is no system to know if a document is under revision by other person or department at the same time.
- The average document approval period is three (3) days.
- No tracking of the document approval status is available.
- No tracking of the approvers' comments is available.
- Material costs were not available.
- Documents were not delivered to file room after the approval.

Also, for the Design Documents, it was found that:

- No tracking of the document approval status is available.
- No tracking of the approvers comments is available.
- Material costs were not available.

The objectives for this project will be addressed to assure the reduce 100% of document errors, reduce by 100% material expenses and increase the Efficiency of the process by reducing the average document approval period.

Measure Phase

Approved FMEAs, filed in a file room, were verified for data collection. Through ten years, a total of 142 FMEAs were generated and 468 revisions were performed. From these documents, it was noticed quality issues that are not in aligned with Quality Standards. Such findings are detailed in Figure 3.

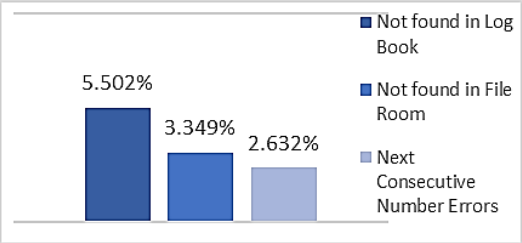

Figure 3
FMEA Quality Findings

Also, the process of generation and revision of FMEAs were monitored during a period of thee (3) months. Four (4) main roles were identified in the process. During the monitoring, it was observed that the average period of generation of the document through the approval could last 14.27 hours for a new document and 11.43 hours for a document revision.

On the other hand, for Design Documents, the worst-case scenario process was analyzed. In this case, two mayor documents were identified: The Functional Specification (FS) of the two mayor Computer Systems at the site. One of them contains approximately 3,000 pages and the other one 4,000 pages. The average quantity of revision for these documents per year is three times.

Analyze Phase

The Failure Mode and Effect Analysis processes two (2) major offenders, Costs and Document Quality Issues were analyzed. The Analysis was done using the DMAIC tool "Fish Bone Analysis".

During the analysis, Figure 4, it was noticed that Personnel, Method (process) and Environment, were key factors increasing Quality Issues. Because one is directly affected by the other, it was concluded that all these factors should be addressed to obtain the process desirable quality state.

On the other hand, FMEA and Design Document, the Method, Machine, Personnel and Environment were major offenders for Process costs as shown in Figure 5.

Approximately, one hundred revision of FMEA are performed annually, which means that 1248.97 hours are invested in the process resulting in an approximately annual cost of $45.4K. This estimate does not reflect the material costs.

The same cost analysis was performed for Design Documents. As mentioned, the worst-case scenario was taken into consideration for such analysis. An average of three revision per document are performed annually. As consequence, two hundred hours were invested during this process.

This means that three revisions per document (two documents) costs $15.7K, including material cost.

Also, during the analysis it was also noticed that during time, the quantity the revisions increased and the quantity of new document decrease. This factor was taken into consideration for the Improvement Phase.

Improve Phase

Using the results obtained in the Analyze phase, it was concluded that the procedure, machine, environment and the human factor directly influenced in the problem statement. Therefore, it was suggested a new system procedure to minimize Document Quality Issues and Costs. A document electronic system, already available on site was evaluated.

This document electronic system is used for Standard Operating Procedures (SOPs), Specifications, Bill of Materials, among others. This system and its procedures were studied, and it was concluded that it can be used for Validation Documents such as FMEAs and Design Documents.

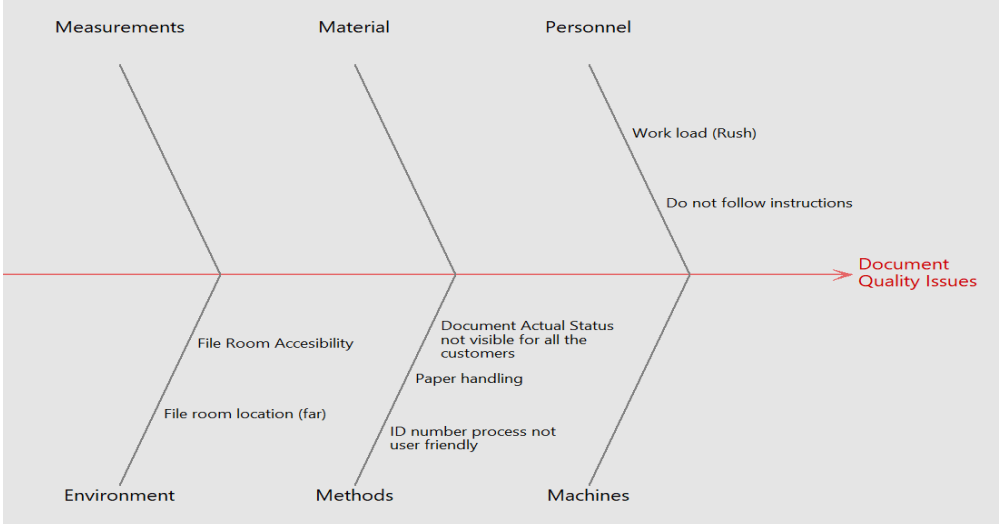

Figure 4

FMEA Quality Issues Fishbone Analysis

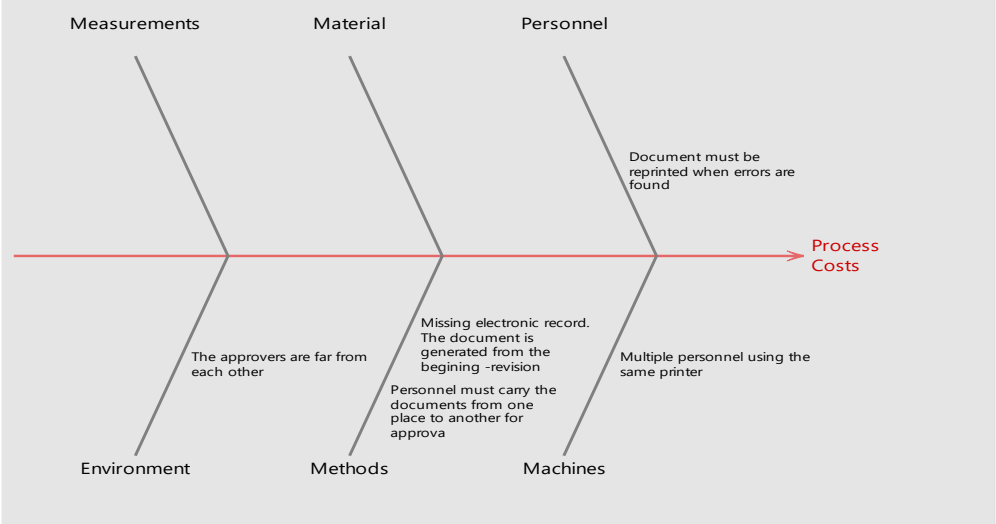

Figure 5

FMEAs and Design Document Costs Fishbone Analysis

The use of a document electronic system to perform FMEA analysis is to help the personnel that needs to revise the document to follow the actual identification number and revision of the FMEA, eliminating the possible errors in documentation. Also, the routing will be performed electronically, reducing man hours, material costs and document storage costs.

A Validation Protocol was generated to document the uploading of the already generated and approved FMEAs. One hundred and forty-two documents were identified and uploaded to the Document Electronic System. The last available revision was used for this execution.

Also, four (4) Standard Operating Procedures (SOPs) were revised to add instructions for the generation, routing and approval of these documents in the document electronic system.

The implementation of this new process was monitored during a year. The reduction in man hours was estimated in 20% for new FMEA documents and 52% for revision of FMEA documents as shown in Figure 6. The reduction of man hours had an estimated annual saving of $21.5K.

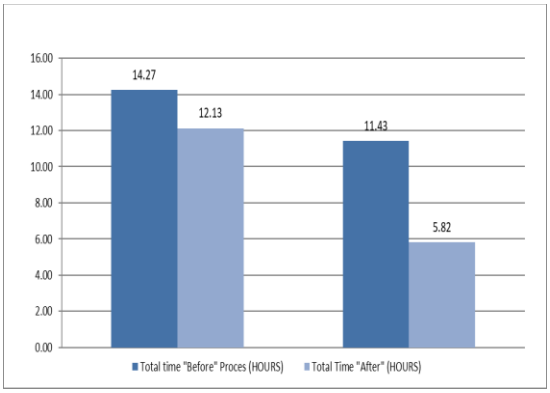

Figure 6
FMEA Man-hour Reduction after the Implementation of a Document Electronic System

On the other hand, for Design Documents, the new process benefits an annually estimated man hour reduction 56.7% ($8K) and $1.5K of material cost in the document revision process as shown in Figure 7.

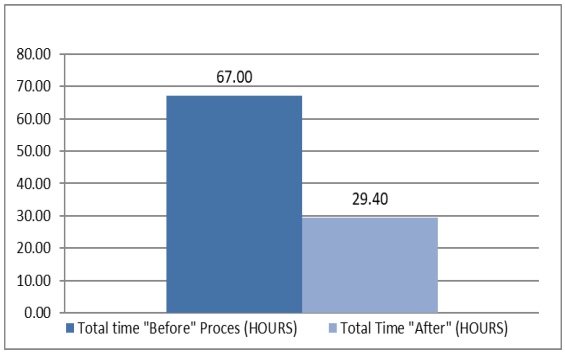

Figure 7
Design Document Man-hour Reduction after the Implementation of a Document Electronic System

Other benefits were found during the implementation: these documents can be accessed from anywhere, inside or outside the plant. This gives the availability of documents when the personnel are performing any job in a different site location.

Control Phase

As part of the Implementation Process, SOPs were revised to maintain the process of generation, routing and approval alignment. These SOPs are modified when areas of opportunity are found. Training is provided to the customers and users of the FMEA and Design Documents during every revision. Also, it was recommended to extend these efforts to additional Validation Documents such as Validation Protocols, More Design Documents, Periodic Reviews, among others.

CONCLUSION

The Lean Six Sigma methodology scope is to reduce process variations among to possible process waste. Quantitative and qualitative tools are provided by this methodology to achieve the desire process state becoming an important process for continuous improvement and cost reduction throughout any site.

The main objective of this project was to reduce 100% of document errors (Quality Issues), reduce 100% of material expenses (Costs) and reduce at least 50% of document approval time

(Time Efficiency) for FMEAs and Design Documents.

FMEAs and Design Documents are documents frequently used in any manufacturing and regulated site. The process of generating this documents are constantly handled manually. The implementation of an electronic process can be used to reduce the consumed man hour and material costs generated by these processes. In this case, an estimated overall reduction of over $31K supports this statement.

The major contribution of this study was the optimization of the generation, approval and routing of Validation Documents and the possibility of extension of benefits in the area by applying this process to additional documents.

REFERENCES

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