Validation Documents Process Optimization and Cost Reduction

Arelys Simonetti Roche
Carlos González, PhD.
Industrial and Systems Engineering Department

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.

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)

Background

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

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

Problem

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.

Methodology

Lean Six Sigma is a methodology that combines the benefits of Lean and Six Sigma Strategy. 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. [2]

DMAIC model covers five (5) different stages where specific tools are applied to achieve them. These stages must be performed in sequential order. [3]

Results and Discussion

Define Phase

In the Validation Department, the generation and revision of FMEAs and Design Documents are performed at least, on a weekly basis. 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. Refer to Figure 1 for the Process SIPOC.

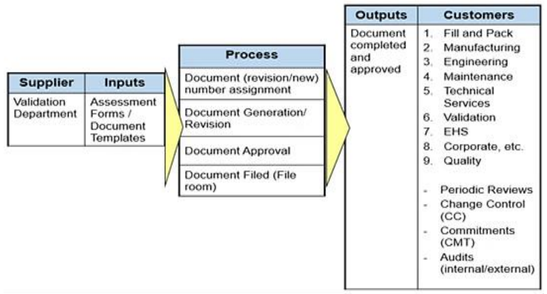

Figure 1
FMEA and Design Document SIPOC

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 aligned with Quality Standards. Such findings are detailed in Figure 2.

Also, the process of generation and revision of FMEAs were monitored during a period of three (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 major documents were identified: The Functional Specification (FS) of the two major 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.

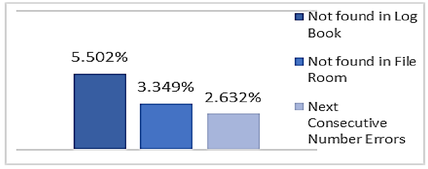

Figure 2
FMEA Quality Findings

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, 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.

Results and Discussion

On the other hand, FMEA and Design Document, the Method, Machine, Personnel and Environment were major offenders for Process costs. Approximately, one hundred (100) revisions 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.

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 (3) revisions per document (two (2) 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.

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.

The use of a document electronic system to generate FMEA and Design Document will 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.

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 3. The reduction of man hours had an estimated annual saving of $21.5K. 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 4.

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 is performing any job in a different site location.

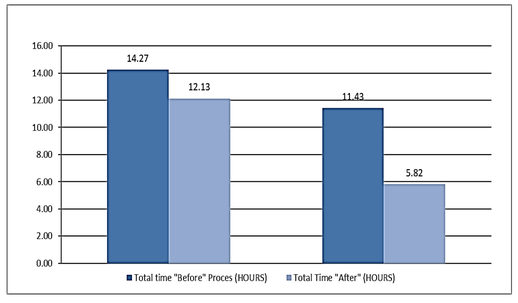

Figure 3
FMEA Man hour Reduction for new and revised documents

Control Phase

As part of the Implementation Process, SOPs were revised to maintain the process of generation, routing and approval alignment. Training is provided to the customers and users of the FMEA and Design Documents during every revision.

Results and Discussion

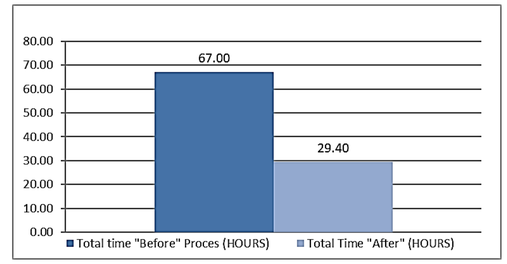

Figure 4
Design Document Man hour reduction for revised documents

Conclusions

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 these 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.

Future Work

It is recommended to extend these efforts to additional Validation Documents such as Validation Protocols, more Design Documents, Periodic Reviews, among others. Considering the time of the document generation and material costs, the benefits can be multiplied for the area.

Acknowledgements

The author acknowledges Dr. Carlos González for your outstanding professionalism. Also, want to express gratitude to Graduate School Faculty and the Polytechnic University of Puerto Rico for the educational engagement during the process.

References

[1] American Society of Quality (ASQ), Failure Mode & Effects Analysis (FMEA), 2019. [Online]. Available: https://asq.org/quality-resources/fmea.

[2] M. Boulanger, Six Sigma Standard, American Society for Quality, 2018. [Online]. Available: https://asqasktheexperts.com/tag/dmaic/.

[3] S. A. Carleton, "Six Sigma Academy and GOAL/QPC", The Lean Six Sigma Tools Memory Jogger, Massachusetts: GOAL/QPC, 2016.