COMPUTER SYSTEM VALIDATION CYCLE OPTIMIZATION

Omar A. Torres #48400
Masters in Engineering Management
Polytechnic University of Puerto Rico

Advisor: Prof. Héctor J. Cruzado, PhD, PE
Department of Civil Engineering and Land Surveying
Polytechnic University of Puerto Rico

Abstract

Excessive amount of deviations in a documentation of a manufacturing process creates a deficient time consuming procedure that can delay a project and contribute to go over the projected budget. As the root cause of a current distributed control system migration project this unnecessary quantity of deviations that were submitted to the quality assurance department (QA) were identified to be due to a deficiency in the document generating process required by the company and the proper regulation agencies. An additional step in the review process of the documentation was implemented. To effectively reduce deviations in the testing cycle an engineering subject matter expert to review the documents was added as a peer reviewer before forwarding the documents to QA. Upon verifying the data the deviations were reduced to the point of having significant savings towards project managing events. Thus confirming that by having a technical peer review after the generation of the document the amount of deviations was reduced to half of what was expected originally.

Introduction

Computer System Validation (CSV) is a highly regulated process in which the system gets documented and tested according to requirements. It ensures that any technology component (software or hardware) is fulfilling its purpose in line with the regulatory guidelines of that industry [1]. The Food and Drug Administration (FDA) requires following the Good Automated Manufacturing Practice Model 5 (GAMP5) guidelines for documenting the manufacturing process in the automation section of engineering as part of Current Good Manufacturing Practices (cGMP) [2]. These practices contain the requirements for manufacturing methods, types of facilities, controls used in the manufacture, quality, purity, and the packing of the products. Figure 1 represents the documentation and testing in automation for manufacturing cycle for a product [3]. GAMP5 also includes reporting any deviation from the established procedure.

A deviations is any event or finding that fails to reflect the expected result. These could be anything from missing information, having a discrepancy in parameters while testing, bad wording, unapproved changes or not properly document changes. The original process started with the integrator who was responsible of the code migration from one system to another. This code was documented by the document generator who specified the code according to functionality or design. Once the document was generated it was uploaded into a document review workflow which involves a CSV representative, a Quality Assurance (QA) and an project lead engineer . By adding an extra review step in the process it is expected a significant reduction in deviation and an increase in project savings.

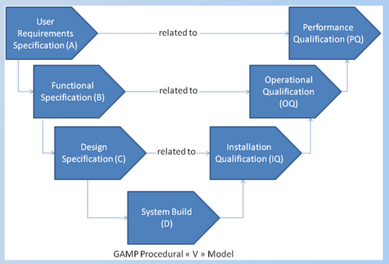

Figure 1: GAMP5 Model

Project Objectives

Optimize the document generation process to generate high quality documentation that accurately represents the functionality and configuration of the system by minimizing deviations and saving money that can potentially be redistributed to other processes within the project.

Engineering Analysis

Methodology-Following the corrective actions of implementing a step of engineer technical review, it can determined that documents being generated were lacking a lot of the technical details. These details were missing because the document generator lacks the experience or knowledge to identify gaps in the information edited in the document regardless of functionally or design. This layer was implemented after the March 22, 2018 test that resulted in six (6) deviations. These deviations included lack of data in tables, failure to portray complete configuration and typographical errors in parameter transcripts from the production code.

Deviation Analysis- During the investigation, It was found that in a period of 19 days before the implementation, only 28 documents were recorded which yielded 8 deviations in different events. These deviations triggered revision to the documents that fine-tuned the details and content of the original document.

Turnaround time- the engineering team took multiple days for the review and correction of the content in the documents. the engineer committed around 2 hours performing review by day since there were activities considered higher priority in the project to include coding and hardware configuration.

Investment cost for rework-The engineer review team consisted of four (4) members that were part of the workflow in the approval of a document. The first member was the document generator that created the document or incorporated changes to it, this activity was followed by the engineer performing the content review. After the document had been reviewed for content a QA engineer reviewd the document for formatting errors and compliance with site procedures. Lastly the document will go to the document controller which will upload the document and start the approval process all over again for the new version.

Results

After the initial assessment multiple things were noticed, sample size was not equal before and after only 28 documents were recorded before the implementation, the threshold stated by the Project Manager was 40% as represented in Figure 2. This forecast was higher than what was encountered and 8 documents contained deviations out of the 28 documents.

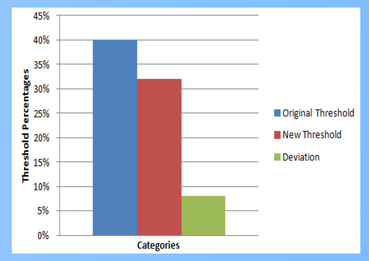

Figure 2: Deviation Thresholds Before Implementation

After the implementation documents receiving deviations were lower than expected as represented in Figure 3. Only 4 deviations were recorded surpassing the percentage of expected threshold by 7%.

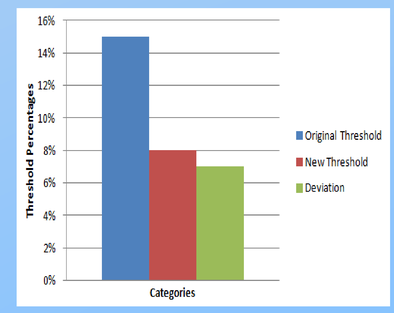

Figure 3: Deviation Thresholds After Implementation

Savings After the implementation

The Project Manager was able to justify the implementation due to the large reduction of costs per document with deviations Following Figure 4 . With this exercise the project manger had an estimate of over $29,000 in savings.

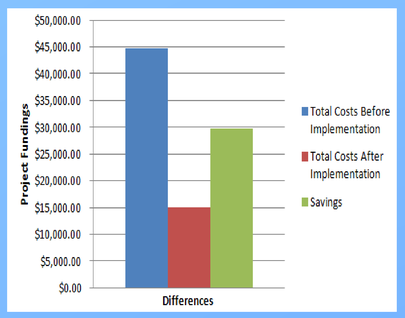

Figure 4: Cost analysis and savings

Conclusion

With these results it can be decisive that the implementation of this layer provided a better quality product that the validation team can rely on and that the company can utilize as a new standard of requirements across the board for the new system implementation.

References

1. What is Computer Systems Validation (CSV)? (2018, March 31). Retrieved from https://www.getreskilled.com/what-is-computer-systems-validation-csv/
2. GAMP 5 Guide: Compliant GxP Computerized Systems. (n.d.). Retrieved from https://www.ispe.org/publications/guidance-documents/gamp-5
3. The Why and What of Computer System Validation in Pharmaceuticals -. (2018, April 13). Retrieved from http://www.rscal.com/the-why-and-what-of-computer-system-validation-in-pharmaceuticals /