Improving the Custom-Built Applications Computerized System Validation Lifecycle for a Medical Device Company

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Abstract

This research project was focused in the improvement of the Custom-Built Applications Computerized System Validation Lifecycle for a Medical Device Company. The Custom-Built Applications Computerized System Validation Lifecycle was improved by reducing the Production Lead Time from 502.66 days to 307.09 days. This improvement reduced the timeline by 195.67 days. This represents a reduction of 39% of the waste. Additionally, the amount of forms that are generated through the lifecycle were reduced from 26 forms to 13. The waste in form development was reduced by 50%. In the present, the Custom-Built Applications Computerized System Validation Lifecycle cost is $46,256.00. As a result, these improvements represent a saving for the Medical Device Company of $17,976.00.

Introduction

A Computerized System Validation is the process of documenting all the deliverables of a system with the purpose of showing fulfillment of the requirements. As per the Food and Drug Administration a computerized system undergoes a validation to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. This design project was focused in an improvement of the Custom-Built Applications Computerized System Validation Lifecycle for a Medical Device Company.

Background

Over the past years, this Medical Device Company site located in Juncos has been a role model in Computerized System Validation (CSV) for the other sites that this company has. The Medical Device Company has no global CSV procedure for all sites which means that each site develops its procedure based in their judgment of the regulation. As a result, many sites of this Medical Device Company consult with Juncos' site for advice during performance of a CSV Lifecycle. Juncos' site possesses a strong and solid Computerized System Validation procedure. This procedure had overcome many audit inspections with successful results. However, this procedure produces extensive timelines.

Problem

Juncos' site is being facing for more than nine (9) years the challenge to reduce the complexity of this procedure in order to decrease the validation timelines. Executing a complete CSV lifecycle consumes an average of 16.52 months. This situation stages Juncos' site in a position of disadvantage when comparing to other sites of this Medical Device Company. The Business Unit of this Medical Device Company evaluates the different sites for a better business strategy in new products. The extensive CSV lifecycle affect the timelines and is hurting the opportunities for Juncos' site to be selected for new projects. Finally, the purpose of this investigation is to achieve a reduction in CSV timelines to make Juncos' site an attractive place for future investment.

Methodology

A problem-solving approach was used to complete the goals stated for this project. The purpose of the project is to reduce the timeline in the Computerized System Validation Procedure for Juncos' site. As a result, the DMAIC data-driven quality strategy tool will be utilized to improve this procedure. The DMAIC Methodology (Refer to Figure #1) consists in five phases for completing the improvement project. The first phase is Define, in which the purpose of the project is established, the objectives and the customer's needs by applying diverse tools. The second phase is Measure, in which the data is gathered in order to identify the process performance. The third phase is Analyze, in which it the data collected in the measurement phase is examined to determine the opportunities for improvement. The fourth phase is Improve, in which the root cause is eliminated. Finally, the fifth phase is Control, in which an implementation plan, monitoring, documentation and training are performed for avoiding the root cause.

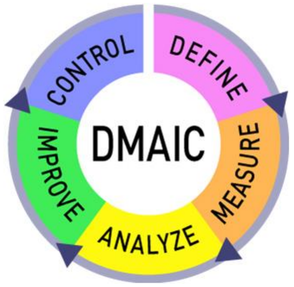

Figure #1 DMAIC Methodology

Define

During the Define Phase a Project Charter was created to provide a framework and objective for this Problem-solving Project. Additionally, the Voice of the Customer was evaluated to understand the problem and what the customer needs.

Measure

During the Measure Phase the actual Computerized System Validation procedure was established. Moreover, data was gathered to state the average time of completion of the entire actual CSV Lifecycle.

Analyze

During the Analyze Phase a Value Stream Map was developed to indicate the actual waste in the procedure and where are the areas of opportunity for improvement.

Improve

During the Improve Phase the new procedure was documented and compared with the actual procedure. As a result, a Cost/Benefit Analysis was performed to compare the financial impact of both procedures.

Control

During the Control Phase an Implementation Plan was performed. The Implementation Plan establishes what is needed to be documented and how the personnel will be trained in this procedure.

Results and Discussion

Define Phase Results

During the Define Phase, a Project Charter was created to provide a framework and objective for this Problem-solving Project. Finally, the last tool used during the Define Phase was Voice of the Customer (VOC) that provided guidance about customer's expectations.

Measure Phase Results

After evaluating the data gathered, it was concluded that the average time of completion of a Custom CSV Lifecycle is 502.66 days or 16.52 months.

Analyze Phase Results

The Analyze Phase consisted in the development of a Value Stream Map. Refer to Figure 2.

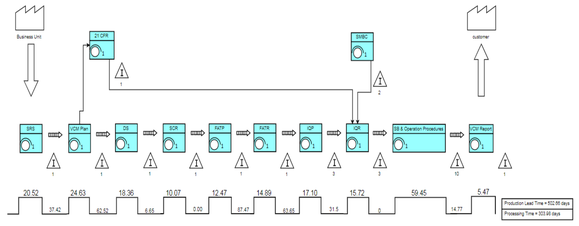

Figure #2 Actual Value Stream Map

Improve Phase Results

The improved Custom-Built CSV Lifecycle will cost $28,280.00. This represents a savings of $ 17,976.00 for each Custom-Built Applications CSV Lifecycle, which represents 39% of cost-reduction. Refer to Figure 3 and Table 1.

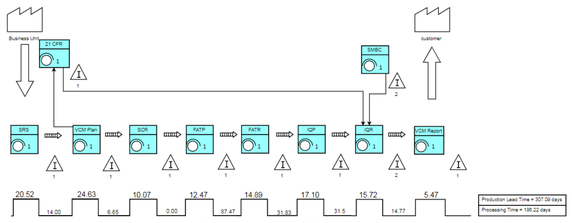

Figure #3 VSM for Improved Custom CSV Lifecycle

Table 1
Comparison of Documentation Required – Actual Custom CSV versus Improved Custom CSV

CSV Lifecycle for Custom-Built Applications				
Documentation Required (Quantity of Forms)	Actual CSV Lifecycle		Improved CSV Lifecycle	
	Yes	Leverage	Yes	Leverage
SRS (1)	✓		✓	
VCM Plan (1)	✓		✓	
21 CFR Part 11 (1)	✓		✓	
DS (1)	✓			✓
SCR (1)	✓		✓	
FAT Plan (1)	✓		✓	
FAT Report (1)	✓		✓	
IQ Plan (3)[1]	✓		✓	
SMBC (2)	✓		✓	
IQ Report (3)	✓		✓	
SB and Operation Procedures (10)	✓			✓
VCM Report (1)	✓		✓	
Quantity of Forms:	26		13	

Note[1]: Only 1 form is required for the Improved CSV Lifecycle.

Control Phase Results

The Computerized System Validation Procedure are being revised to incorporate these changes for the Custom-Built Applications. Additionally, the procedures for Software Backup and Restore, and Operation and Software Security Management are being created for having a standardized procedure which is applicable to all future validations. Furthermore, training will be given.

Conclusions

The Custom-Built CSV Lifecycle timeline was reduced from a Production Lead Time of 502.66 days to 307.09 days utilizing the DMAIC Methodology. This represents a reduction of 39% of the waste. The templates were revised in order to accomplish less documentation during the CSV lifecycle. As a result, the Installation Qualification Plan was reduced from 3 forms to 1 form. Also, after improving the CSV Lifecycle a reduction of 50% of the forms was achieved.

Future Work

The Computerized System Validation Procedure contains the following categories: 1) Infrastructure Software, 2) Non-Configured Products, 3) Configured Products and 4) Custom Applications. Since Custom-Built Applications category was part of the scope of this research, the remaining categories will undergo through the same methodology in order to reduce all the waste possible while fulfilling the regulation.

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