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. A Computerized System Validation is the process of documenting the deliverables of a system with the purpose of showing fulfillment of the requirements. 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 per each Custom-Built Applications Computerized System Validation Lifecycle. This represents 39% of cost reduction.*

Key Terms *— Computerized System Validation, Custom-Built Applications, Medical Device, Software Tool Regulations.*

INTRODUCTION

The computerized system life cycle encompasses all activities from initial concept, and understanding the requirements, through development, release, and operational use, to system retirement [1]. 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 will be focused in an improvement of the Custom-Built Applications Computerized System Validation Lifecycle for a Medical Device Company.

PROBLEM STATEMENT

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.

The Juncos site CSV procedure consists in five phases: planning, specifications, verification, operation and retirement. The planning phase is a stage in which the system's requirements are established, the validation strategy is defined, and the scope of the 21 CFR Part 11 is defined. The specifications phase conforms a step in which the specifications describe how a system accomplishes the requirements and the software code is verified for consistency and applicability. During the verification phase all the necessary testing is performed to demonstrate that the system complies with the established requirements. Additionally, during the operation phase the software is tested for backup and restore purposes. Finally, the retirement

phase is used when a computerized system functions are no longer needed by the business.

As per the aforementioned description of the CSV procedure, is shown that the validation sustains a strong set of documentation that overcome the auditory inspections. Every requisite of the regulation is met with this procedure. However, the complexity that this procedure brings is being an issue for this Medical Device Company site. The main purpose of the procedure is to demonstrate that the system complies with its intended use but this purpose does not make justice to the vast amount of time that the validation consumes.

As a result, Juncos' site is being facing for more than nine 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.

RESEARCH DESCRIPTION

This research is about this Medical Device Company site CSV procedure and how it can be reduced to make this site an attractive place for future investment. This is an important approach because Juncos' site needs to offer striking timelines for new projects in order to be selected as business strategy. Having extensive timelines represents a disadvantage and a possibility of not being selected for new technology development.

RESEARCH OBJECTIVES

The objective of this research is to achieve a reduction in CSV timelines while fulfilling the regulation. The templates will be revised in order to accomplish less documentation during the CSV lifecycle. Additionally, CSV procedure contains tools for developing new systems. The procedure brings an extensive technical guidance for developing all the aspects of the equipment. The aforementioned tools are helpful for designing a new and complex equipment but at the same time represents a step back when analyzing the amount of time for completing a CSV Lifecycle. As per management opinion, these tools should be part of the engineering procedures since CSV procedure should have a focus of testing the intended use of the system. Therefore, an evaluation will be performed to analyze the possibility of eliminating equipment development from the CSV procedure. At the present time, a single CSV Lifecycle costs around $46,256.00 to the Juncos site. The main objective is to achieve a CSV timeline of 12 months which represents a savings of $12,656.00 per CSV Lifecycle.

RESEARCH CONTRIBUTIONS

The development of this research will contribute to reduce the CSV timeline. Additionally, it will contribute in simplifying the documentation process. Finally, it will help the engineering department to execute a CSV Lifecycle in a simpler way.

LITERATURE REVIEW

One frequently overlooked aspect of the U.S. Food and Drug Administration's (FDA) quality system regulation (QSR) for the medical device industry is the requirement to validate software tools that are used to develop, verify, or validate medical device products [2]. Software tool validation records are inspected by the FDA. The FDA's inspectors expect to find the necessary evidence that demonstrates that the software tool was tested for its intended use. If the software tool validation records fail to demonstrate the intended use, the FDA could issue a warning letter. Therefore, in order to avoid a warning letter from the FDA, a strong procedure for these types of validations need to be develop.

The Code of Federal Regulations (CFR) Title 21, Section 820.70(i), establishes that "When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented [3]." Additionally, Section 820.75(a) establishes that "Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented [4]." Furthermore, the FDA guidance, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" explains that any software used for automated processes to manufacture devices falls under the aforementioned regulations. Hence, even the "off-the-shelf" software tools need to be validated for its intended use.

As per the FDA guidance, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" the ideal exercise is to provide evidence of testing from each phase of the lifecycle. A typical model for system development and verification is the V-model. The V-model is a type of Software Development Lifecycle in which the process is executed in a sequential manner (V-shape). The main goal of this model is the association of a testing phase for each corresponding development phase.

As a result, each organization must possess a protocol that define the steps to follow in order to complete a validation for a software tool. The protocol acts as a work instruction to establish the minimum requirements of the computerized system. The protocol shall establish that the validation activities must deliver documented evidence with a high-degree of assurance that the computerized system will consistently operate meeting its pre-determined specifications and quality attributes. Furthermore, the International Society for Pharmaceutical Engineering provides a guide (GAMP 5 – A Risk-Based Approach to Compliant GxP Computerized Systems) that offers a step-by-step approach for developing a software tool's validation protocol. The GAMP5 documents are guide and not standards [1], however, organizations (pharmaceutical and medical devices) often use this guide to meet regulatory requirements when validating computerized systems.

Moreover, the first step in validating a software tool is to define its intended use. During this step a description of how the tool will be used must be made. The next step is to perform a risk analysis. The purpose of the risk analysis is to determine the impact that any of the situations identified may have in the medical device safety / effectiveness and the patient. Some of the key elements that can be considered in such analysis are: 1) the amount of damage which can result from a failure, 2) the likelihood of such an event occurring and 3) the cost-effectiveness of existing or potential safeguards. The following step is to define the user requirements specification of the tool. The user requirements specification describes the intended use, key hazards and the most critical functionality. The user requirements are written before the system is created. This document acts like a guidance for the system's developer in order to manufacture the tool by following such requirements. Next, if the system is used to create or maintain electronic records and/or electronic signature, per 21 CFR Part 11, additional validation testing must be performed to demonstrate that all Part 11 requirements have been met [2].

Once requirements are done, the next step in the validation process is to create a test protocol with test cases that address each of the requirements established. The FDA guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" recommends, "Test cases should address error and alarm conditions, startup, shutdown, all applicable user functions and operator controls, potential operator errors, maximum and

minimum ranges of allowed values, and stress conditions applicable to the intended use of the equipment. The test cases should be executed and the results should be recorded and evaluated to determine whether the results support a conclusion that the software is validated for its intended use [5].” As a result, the level of validation effort should be proportional to the risks. Finally, the test results must be documented during a validation summary/report that confirms the software tool was tested for its intended use.

In Computerized System Validation, each system tool receives a categorization that addresses to a specific Computerized System Validation Lifecycle path (amount of documentation needed). There are four software categories: 1) Infrastructure Software, 2) Non-Configured Products, 3) Configured Products and 4) Custom Applications. The Infrastructure Software are infrastructure elements link together to form an integrated environment for running and supporting applications and services [1]. The Non-Configured Products include both systems that cannot be configured to conform to business process and systems that are configurable but for which only the default configuration is used [1]. Additionally, the Configured Products provide standard interfaces and functions that enable configuration of user specific business processes [1]. Moreover, Custom Applications are systems or subsystems developed to meet the specific needs of the regulated company [1].

In conclusion, independently of the Computerized System complexity, all software tools need to be validated and test results documented for concluding that the system meets its intended use. It is important that the organizations develop a strong Computerized System Validation protocol that complies with regulatory requirements. The U.S. Food and Drug Administration agency seeks for compliance in software tool validation. If the validation records do not offer enough evidence for testing the intended use of the software tool, a warning letter can be issued to the organization. Warning letters are public records and are not a favorable acquisition for the company impacted. Therefore, when designing a Computerized System Validation protocol, it is imperative to follow all the regulatory requirements to avoid observations from the federal agency (FDA). Even more important, developing a strong Computerized System Validation protocol leads to the manufacturing of high-quality products that save and improve the lives of patients.

PROJECT METHODOLOGY

A problem-solving approach will be 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 (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.

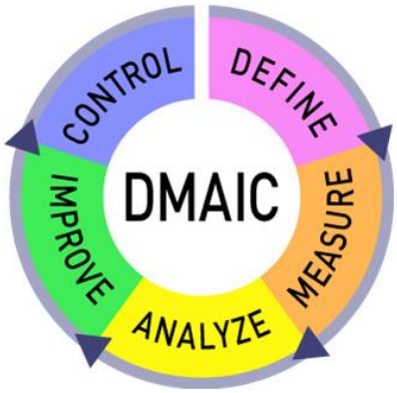

Figure 1
DMAIC Methodology

Define

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

Measure

During the Measure Phase the actual Computerized System Validation procedure will be established. Moreover, data will be gathered that states the average time of completion of the entire actual CSV Lifecycle.

Analyze

During the Analyze Phase a Value Stream Map will be 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 will be documented and compared with the actual procedure. As a result, a Cost/Benefit Analysis will be performed to compare the financial impact of both procedures.

Control

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

RESULTS AND DISCUSSION

During this section it will be discussed the results after performing the five phases of the DMAIC Methodology.

Define Phase Results

During the Define Phase, a Project Charter was created to provide a framework and objective for this Problem-solving Project (table 1).

Table 1

Project Charter

Element	Description	Specifications
1. Process	Name of process to be improved.	Computerized Systems Validation Procedure
2. Project Description	What practical problem will be solved? What is project's purpose?	Juncos' site is being facing for more than nine (9) years the challenge to reduce the complexity of the CSV 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. Therefore, the purpose of this investigation is to achieve a reduction in CSV timelines to make Juncos' site an attractive place for future investment.

Finally, the last tool used during the Define Phase was Voice of the Customer (VOC). The VOC helps to visualize the customers' expectations and opinions. This exercise was conducted with the management of the different engineering departments. The VOC was developed to understand which areas of the procedure needed improvement as per management observations (table 2).

Table 2

Voice of the Customer

Voice of the Customer Translation Matrix		
Customer Comment	Identifying the Issue	Customer Requirement
Actual CSV Procedure takes too much time for completion	*Extended Procedure*	*Reduce actual CSV Lifecycle to make Juncos' site an attractive place for future investment.*
Tools for developing new systems should not be part of the actual CSV Procedure	*Unnecesary tools that do not test the equipment's intended use*	*Reduce complexity of the actual CSV Procedure.*
Actual CSV Procedure was developed more than 9 years ago.	*Outdated CSV Procedure*	*Update actual CSV Procedure in order to reduce CSV Lifecycles timelines.*
Actual CSV Procedure requires requires the development of many of documentation	*Merge or eliminate documentation from the CSV Lifecycle*	*Reduce the amount of documentation per CSV Lifecycle*
Resources executing the CSV Lifecycles do not have the required knowledged.	*Additional training needed*	*Give additional training to the resources in order to have them more prepared for performance*

Measure Phase Results

The Measure Phase consisted in evaluating the actual Computerized Systems Validation Procedure. The Computerized System Validation Procedure for Juncos' site contains five phases: Planning, Specifications, Verification, Operation and Retirement (figure 2). Each phase requires a set of documentation depending of the category of the equipment.

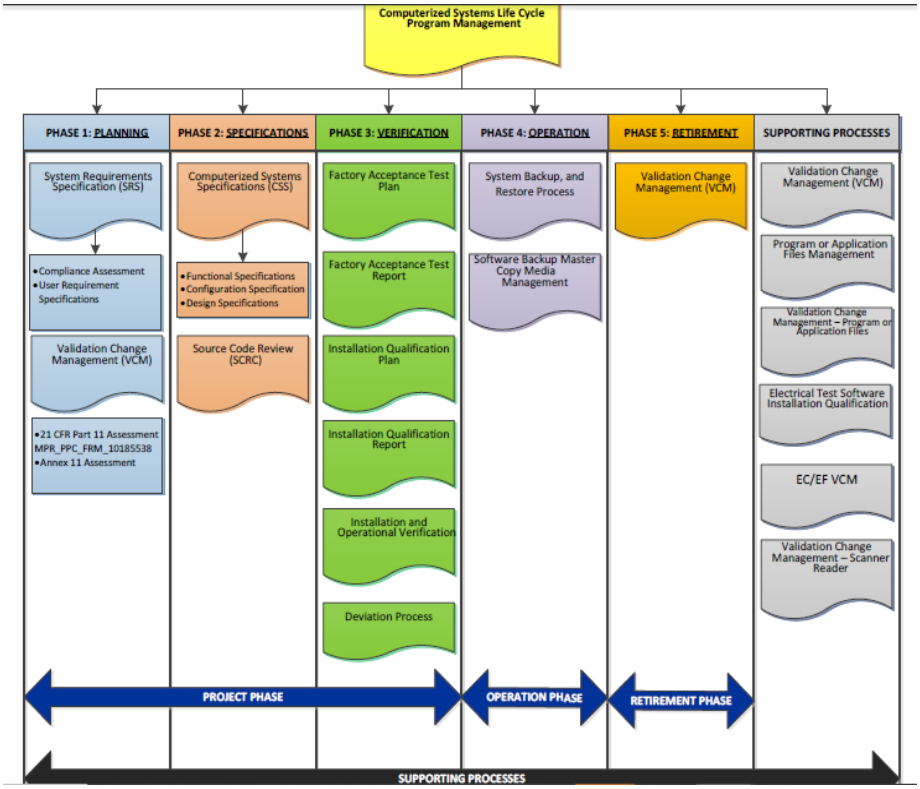

Figure 2

Computerized Systems Lifecycle Program Management

For the purposes of this research, only the Custom Product category will be analyzed. The Custom-Built Applications are developed to meet the specific needs of the user company. Custom development may be a complete system or extension to an existing system. This type of equipment is the most used in Juncos' site since the business needs are very specific. This category possesses the longest validation path. The necessary documentation needed for this category is: 1) System Requirements Specification (SRS), 2) Validation Change Management Plan (VCM), 3) Computerized System Specifications (CSS), 4) Source Code Review, 5) Factory Acceptance Test (FAT) Plan, 6) Factory Acceptance Test (FAT) Report, 7) Installation Qualification Plan (IQP), 8) Installation Qualification Report (IQR) and 9) Validation Change Management Report (VCM).

Moreover, thirty Custom CSV Lifecycles were evaluated to understand the average completion time for this type of lifecycle. The Custom-Built Application category was selected because represents the worst-case scenario in terms of quantity of documentation and because is the most used category in Juncos' site. For this data gathering, each CSV Lifecycle was evaluated from the beginning to equipment release. As a result, 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 (table 3).

Analyze Phase Results

The Analyze Phase consisted in the development of a Value Stream Map. A Value Stream Map provides a visual representation of a system's process by illustrating its various stages and cycle times [6]. This lean-management method tracks a product from the origin through its end user.

On the other hand, the Value Stream Map developed for the Custom-Built Applications CSV Lifecycles studied shows that the Production Lead Time of the procedure is 502.66 days with a Non-Value Added time or Processing Time of 303.98 days. As shown in figure 3, there are several areas of

Table 3

Average Time of Completion of a Custom CSV Lifecycle

CSV Lifecycle Number	CSV Lifecycle Started	CSV Lifecycle Ended	Total Days for CSV Lifecycle to be Completed	
1	4/10/2017	7/11/2017	92	
2	6/14/2016	1/24/2018	589	
3	9/9/2016	8/24/2017	349	
4	10/25/2016	4/12/2017	169	
5	1/11/2017	8/22/2017	223	
6	6/1/2016	8/10/2017	435	
7	5/5/2017	12/27/2017	236	
8	6/22/2017	3/13/2018	264	
9	11/22/2016	5/16/2017	175	
10	11/22/2016	5/16/2017	175	
11	11/30/2016	5/23/2017	174	
12	9/9/2015	7/12/2016	307	
13	11/24/2015	3/30/2016	127	
14	6/8/2015	4/26/2017	688	
15	4/22/2015	4/25/2017	734	
16	4/22/2015	4/25/2017	734	
17	11/30/2015	4/29/2016	151	
18	11/7/2014	3/19/2015	132	
19	11/7/2014	6/2/2015	207	
20	2/16/2012	11/6/2014	994	
21	6/26/2013	11/6/2014	498	
22	5/23/2013	11/6/2014	532	
23	2/16/2012	11/6/2014	994	
24	2/16/2012	11/6/2014	994	
25	6/26/2014	11/6/2014	133	
26	2/16/2012	11/6/2014	994	
27	2/16/2012	11/6/2014	994	
28	2/13/2012	11/6/2014	997	
29	2/16/2012	11/6/2014	994	
30	2/15/2012	11/6/2014	995	Average Months:
Average Time (Days) of CSV Completion			502.6666667	16.52

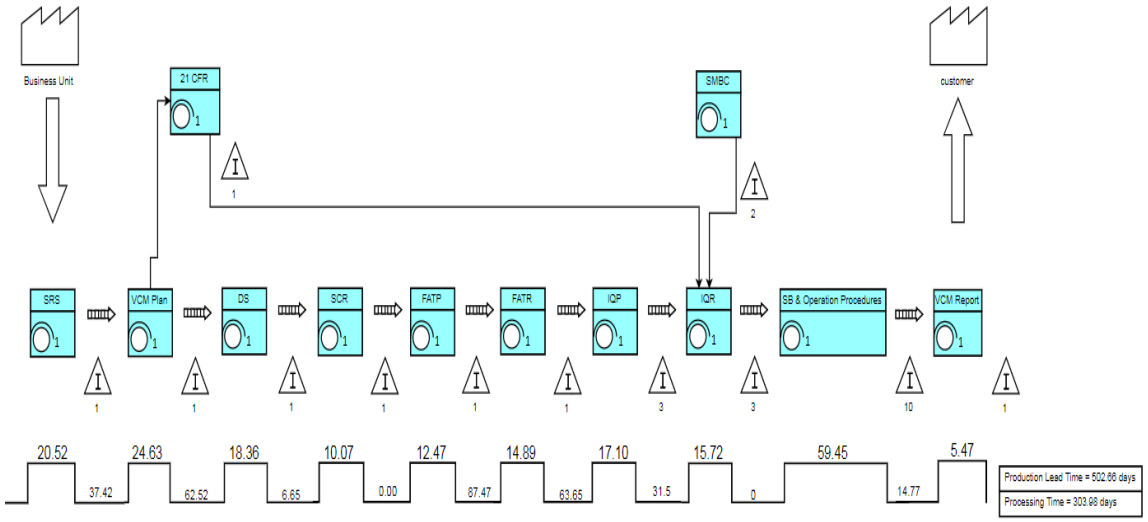

Figure 3

Actual Value Stream Map, Improve Phase Results

the process that produces waste in wait-time which are: 1) from approval of SRS to starting VCM Plan, 2) from approval of VCM Plan to starting DS, 3) from approval of FAT Plan to starting FAT Report and 4) from approval of FATR to starting IQ Plan. Those waste in wait-time represents areas of opportunities for improvement.

The first waste in wait-time occurs because the SRS is the official document that the Medical Device Company sends to the equipment supplier. The equipment supplier analyzes the requirements and sends a response to the Medical Device Company in terms if it's possible to construct the equipment as per requested. This is the stage of negotiation and brings a waste in wait-time for both parties to agree.

The second waste in wait-time occurs because equipment supplier documentation takes time to be developed. The equipment supplier's documentation provides all the technical information for maintaining, re-programming and using the equipment. This documentation is used for the development of the DS in order to specify all the technical requirements of the equipment.

The third waste in wait-time occurs during the Verification Phase, which produces more waste because is the stage of the lifecycle in which the software is tested, and errors occur. After FAT Plan approval, a designated engineering team goes to the supplier's factory site and test the equipment utilizing the agreed and established requirements (SRS). During this visit, the software related issues are solved at the moment or are agreed to be stated in a Punch List to solve them prior shipment.

The fourth waste in wait-time occurs during Installation Qualification Plan development. This document has a total of three forms that requires a high degree of technical knowledge to be able to develop the necessary tests that challenge the established requirements.

Additionally, as shown in figure 3, there is a process in the timeline which is a Value Added item that is consuming 59.45 days. During this stage of the process occurs the development of the Software Backup and Restore Procedure and Operation and Software Security Management Procedure. These procedures take time to get approved because they require a long list of approvals such as the quality engineer, document owner, manufacturing engineer, regulatory, reliability, Business Unit product Design designee, engineering manager and document control. These two procedures are approved under the same Record Change Order and require a total of ten documents to be developed. Otherwise, starting these procedures produces no waste because this task needs to be drafted before IQ Report closure.

As a result, this process contains approximately (there are cases that require more documentation) 26 documents to be developed.

The Improvement Phase consisted in eliminating the waste to reduce the Production Lead Time. The following FDA regulations and guides were revised to ensure compliance in the new design: Part 820 Quality System Regulation (specifically the Subpart G – Production and Process Controls), General Principles of Software Validation; Final Guidance for Industry and FDA Staff and GAMP 5 - A Risk-Based Approach to Compliant GxP Computerized Systems.

As per GAMP 5, "regulated companies should seek to maximize supplier involvement throughout the system life cycle in order to leverage knowledge, experience, and documentation, subject to satisfactory supplier assessment. For example, the supplier may assist with requirements gathering, risk assessments, the creation of functional and other specifications, system configuration, testing, support, and maintenance [1]." As a result, the Design Specifications was decided to be leveraged (provided by the supplier) since the supplier has all the technical knowledge of the system. The supplier will have seven days after VCM Plan closure to provide the Design Specifications. This mandatory action will be established in the contract. Moreover, having the Design Specifications document out of the timeline, causes a reduction of 80.88 days in the Production Lead Time.

Additionally, the first communication with the supplier in which the System Requirement Specifications are sent, it was decided to establish in the contract that the response in terms if it's possible to construct the equipment must be on or before 14 days. This agreement eliminates 23.42 days of Processing Time.

Furthermore, the Installation Qualification Plan Forms were revised to reduce the complexity. This deliverable, as established before, consisted of three forms. These forms were Installation Qualification Plan Form (in which utilities, environmental conditions, adjustable parameters, Electro-Static Discharge, Calibrations, etc. are verified), Computerized System Installation and Operational Verification Form, and Traceability Matrix. Some tests were repeating among these forms. Hence, these forms were combined into one and the content was edited to avoid testing duplicity and to add

simplicity to testing development. As a result, it is expected that these changes reduce waste in this stage of the process by at least 50%. Therefore, the waste in wait-time for developing the Installation Qualification Plan was reduced to 31.83 days.

The last improvement made for the Custom-Built Applications Lifecycle was to leverage the Software Backup and Restore Procedure and Operation and Software Security Management Procedure. These procedures do not need to be created for each system. The Software Backup and Restore Procedure can be created to provide general instructions on how to create an image backup utilizing a Ghost Image Software and where to store the image. These instructions can be applied to almost all Custom-Built Applications and the exceptions (i.e., Programmable Logic Controllers) can be explained in this Standard Operating Procedure. Also, general instructions to substitute the Operation and Software Security Management Procedures can be created to state how to create users with different levels of accessibility, accounts and system security. Having those procedures standardized means that future CSV Lifecycles can leverage these procedures. As a result, this improvement reduces 59.45 days of Value Added Time.

After performing all the improvement for the Custom-Built Applications CSV Lifecycle, a new Value Stream Map was created for comparison (figure 4). This new VSM shows a shorter CSV Lifecycle with a Production Lead Time of 307.09 days and a Processing Time of 186.22 days. This improvement reduced the timeline by 195.67 days. This represents a reduction of 39% of the waste.

Moreover, the improvements for the Custom-Built Applications CSV Lifecycle reduced the amount of forms to be developed during the process. The actual CSV Lifecycle produces a total 26 forms. On the other hand, since the DS and the procedures are going to be leveraged, the waste in form development was reduced by 50% (table 4).

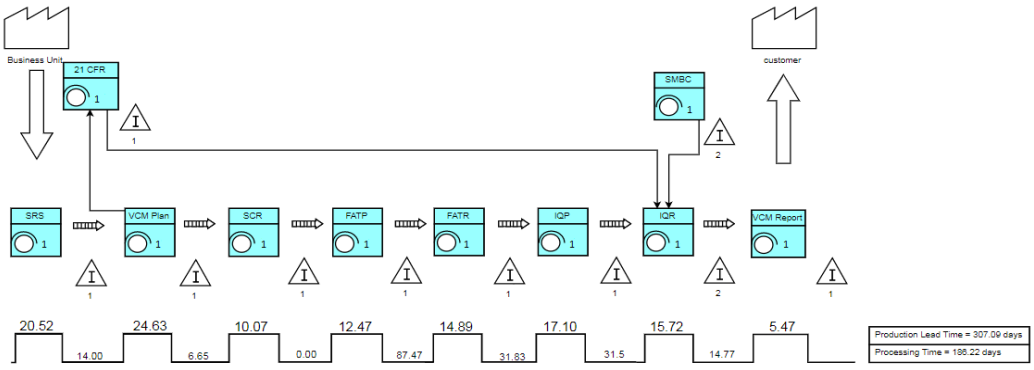

Figure 4
VSM for Improved Custom CSV Lifecycle

Table 4
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.

Additionally, the actual Custom-Built CSV Lifecycle costs for Junco's Site $46,256.00. This is based only in the cost associated to the resource (consultant engineer) that executes the CSV Lifecycle. In Junco's Site, the CSV Lifecycles are executed by consultant engineers with an average of $35 billable hour. Nevertheless, 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.

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. After all procedures are approved, an intensive training will be given to explain to the affected population the changes performed in the Computerized System Validation Procedure.

CONCLUSION

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.

Additionally, an evaluation was performed to analyze the possibility of eliminating equipment development from the CSV procedure. This goal was not achieved since the General Principles of Software Validation; Final Guidance for Industry and FDA Staff establishes that "The device manufacturer (user) needs to define the expected operating environment including any required hardware and software configurations, software versions, utilities, etc. [5]." Therefore, all the documentation that defines the equipment development needs to be present in a CSV Lifecycle to be in compliance with the regulatory agency.

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