Quality Improvement Process for Software Controls in Regulated Industry using Six Sigma Methodology

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Abstract *— A regulated industry at medical devices company, Software Control practices on Automated Processes are weak and not systematized. Several findings were found in past internal audits related to software revision changes. In order to achieve the compliance with Food and Drugs Administration, this project, the focus was in the areas related to software validation after a change, maintenance and software changes on automated processes. The principal interest is establishing a quality improvement process for the existing software control structure using DMAIC tool. DMAIC is the methodology used in this research as Define, Measure, Analyze, Improve and Control. DMAIC is a popularized continuous improvement method. The goal of this project is standardize and simplify the Software Control system while eliminating the probability of future observations. In this project were used different techniques to maintain a continuous improvement, demonstrating that the DMAIC methodology is a useful one to have an incremental improvement.*

Key Terms *— DMAIC, Finding, Six Sigma and Software Control.*

INTRODUCTION

Regulated Industry under Food and Drugs Administration (FDA), specifically Medical Devices Company, faces great challenges to achieve full compliance of Code of Federal Regulation (CFR) Title 21 Part 820 (21 CFR 820) Quality System Regulation for Medical Devices. In a global competitive environment to cover the high demand to a lower cost, the manual processes in the industry have become automated processes through the years. In order to ensure the quality of medical device product, FDA establish under 21 CFR 820.70 Production and Process Controls and the General Principles of Software Validation – Final Guidance for Industry and FDA Staff issued on January 11, 2002, show us that the Medical Devices Company under regulated industry is required meet computerized system validation activities and software control. In this project, the focus is to identify opportunities for quality improvement process in a regulated industry, since several findings were found in past internal audits related to software revision changes. This regulated industry understand that have a strong computerized system validation policy for the manufacturing of quality product, the areas related to software validation after a change, maintenance and software changes on automated processes are weak and not systematized. This project is going to determine what elements contribute a weak software control. The final goal of this project is find the main causes of weak software control to attack them and reduce the improper and unauthorized software management that could lead to regulatory observations.

PROJECT DESCRIPTION

The quality system for software control occurs in Medical Devices Company in regulated industry. The amount of findings in software control area causes an impact to the quality system for manufacturing of medical devices product. The findings affects directly to the quality system metrics, thus, support the emergence of a potential regulatory observation. This project is focus to reduce the risk of observations by internal audits

and strengthen the software control process giving excellent results using a useful DMAIC methodology.

PROJECT OBJECTIVES

This project has the main objective is considers and studies the impact in terms of quality system requirements related to software control practices after the establishment of this specific DMAIC Methodology. The specific goal is to standardize and simplify the software control system while eliminating the probability of future regulatory observations. Different tasks will be performed to reduce the risk of findings and optimize current software control structure.

PROJECT CONTRIBUTIONS

This project pretends to determined and provide improvement startegies with the Six Sigma implementation. Understanding the different regulatory aspects within an regulated industry after the implementation of Six Sigma principles following the DMAIC (Define, Measure, Analyze, Improve, and Control) approach. The regulated industry contribution, the principal idea is to reduce the risk in findings and in parallel stregthen the current software control structure at the same time the probabilities to bring quality products as results of a sistematized software control in full compliance with 21 CFR 820 requirements.

LITERARURE REVIEW

Six Sigma is a disciplined, data-driven methodology for eliminating defects in any process. To achieve six sigma quality, a process must produce no more than 3.4 defects per million opportunities. According to Devane [1], six sigma's basic value proposition is that principles for process improvement, statistical methods, a customer focus, attention to processes, and a management system focusing on high-return improvement projects result in continuous improvement and significant financial gains.

The prominent Six Sigma objective is to achieve greater revenue and profit for the business and high customer satisfaction. Properly executed, Six Sigma will achieve this through lower costs. However, achieving Six Sigma goals may require significant changes to the system. Change is perceived as a major source for disruption and higher costs. Although every associate in the organization should be a good change agent; Six Sigma assigns special roles to realize effective change. An executive-level manager in the role of champion acts as the official change agent, facilitating the management plans and change process.

According to George [2] Motorola recognized there was a pattern for improvement (and use of data and process tools) that could naturally be divided into the five phases of problem solving, usually referred by the acronym DMAIC. Phase I (Define) this phase is to clarify the goals and value of a project. Phase II (Measure) the purpose of this phase is to gather data on the problem. Phase III (Analyze) this phase is to examine the data and process maps to characterize the nature and extent of the defects. Phase IV (Improve) is to eliminate defects in both quality and process velocity. The last one is Phase V (Control) that the purpose of this phase is to lock in the benefits achieved by doing the previous phases.

The following Figure 1 tell us where is the most causes that generate weak software control practices.

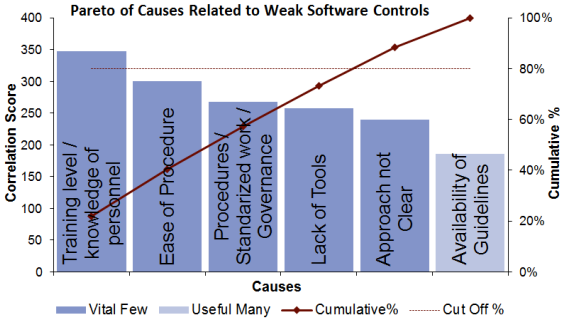


Figure 1
Pareto of Causes Related to Weak Software Controls

The most causes is concentrated in the gap of training level / knowledge of personnel, easy of procedure, procedures / standarized work / governance, lack of tools and approach not clear . These causes are the one that would be analyzed. The first five (5) causes cover 88.4% of the total correlation score. In this design project, the historical data will be collected to be measured and analyzed. Once the data is measured and analyzed it will make various recommendations to improve the process for software control in regulated industry.

Lean Manufacturing Philosophy

This project consists of the design, explanation of the tools to be implemented and the reason for the implementation. It also established the type of analysis and how the data was collected. This project design is intended to implement different six sigma tools in order to standardize and simplify the regulated industry software control system while eliminating the probability of future observations. The methodology of Six Sigma basics in essence creates improvements by managing variation and reducing deficits in the processes of an enterprise. DMAIC these five elements focus on significant process improvements. You may ask how this process relates to the everyday man or woman. Using data from every conceivable source, the statistical formulas used by the process of the Six Sigma methodology can effectively calculate this data into productive applications. From the time allotments for pizza delivery, to the analytical processes used by insurance companies, statistics play a large part in daily affairs, and this approach enables productivity and profit for businesses without neglecting consumer input. The processes of Six Sigma with its statistical perfections that allow increased profits, less defective products, and millions in the bank, is impressive to those that gain such windfall, but the lingering question to ask may be too little, too late[1]. Six-Sigma is a 21st century concept. It represents a process-focused, resource-based and customer-driven concept. Enterprises implement the Six Sigma business concepts to achieve processes and activities perfection. The essence of Six Sigma concepts is that customers' satisfaction can be provided by increasing the quality of products. The quality of products can be increased by increasing the quality of processes. Finally, the quality of processes depends on resources and capabilities and on their combination. Six-Sigma is more than just a business concept. It is a management philosophy that signifies how expensive defects are. Six-Sigma can be implemented through Six Sigma projects, which involve five phases shown in Figure 2. However, the mentioned phases of improvement in Six Sigma ways include very detailed, concrete measures, instruments and techniques. This makes it possible to call them methodology. Six Sigma methodology (DMAIC) helps to improve any process. It suggests that it is usually possible to improve processes' efficiency, not by changing the combination of resources and capabilities, but by eliminating variation and defects, which appear as a consequence of variation. In summary, the Six Sigma basics of statistical findings for business and consumer advancement, heralds as the ultimate process for achievement, yet leaves the mind to ponder its effectiveness upon the human race [2].

Figure 2
DMAIC Methodology

Methodology

In this competitive world, each organization needs to fight for a place at the top. To sustain competitiveness, each organization needs to produce and deliver defect free products. In order to do so, organizations follow many different business

management strategies witch one of the most popular strategy is six-sigma. Six-Sigma is a business management strategy that involves betterment of the organization's existing products, to make them defect free. The following paragraphs will help you understand this methodology in detail.

DMAIC Methodology Tools

DMAIC is an acronym which stands for Define, Measure, Analyze, Improve and Control. These are tools of DMAIC, and are used in order to find and eliminate defects in the product. A team of experts is formed which uses the DMAIC methodology to find and eliminate the root cause of defects. This team has a leader with a six sigma black belt certification. Other members of the team hold six sigma certifications too. These are experts who look at processes and the products. The outcome of their study helps the organization to raise its position in the market, and cut off competition by producing defect free products. Let us proceed to understand the DMAIC methodology [1].

D - Define

The team is formed with a specific purpose in mind. This is what the define stage is all about. The team needs to sit together and define the scope, goal, budget, duration and the problem. The leader of the team makes a charter document where they mention all the above aspects in complete detail. Then, work begins. The team defines the problem and then sets about finding the root cause and finding ways to eliminate that cause. The understanding of business process management helps the team at this stage of DMAIC methodology [2].

M - Measure

Here, the performance of the process is measured. The feedback of people who manufacture products, feedback from customers who use the products and the way the product is processed, are all measured. The team also takes a look at business growth strategies. At this phase, the problem statement and project contract are commonly refined as a result of establishing an accurate baseline for the metrics being targeted. This can be known as the data collection step too. All relevant data, important to the product, and the processes followed to manufacture the product is collected at this stage [2].

A - Analyze

The next step in DMAIC process, analyze, as the name suggests, is analysis of the data collected in the previous phase. It is important to analyze the feedback given by customers, as they are the end users of the product and the product needs to match their needs. In this stage, the root cause of the problem is identified. A process chart, here, helps the team in understanding where the process of manufacturing the product has gone wrong.

I - Improve

The process chart helps the team in redesigning the process, after elimination of problems. A complete new process chart is then made, which highlights the changes and improvements to be incorporated, in order to do away with defects. The concepts of total quality management and lean manufacturing are used in this stage. Documentation accompanies the new process chart, which provides the changes made in the process, in detail. Work at this stage becomes easy, if the team has collected enough data [2].

C - Control

This is the last stage in DMAIC model. After the new process is designed, the organization replaces the old process with the new one. The team closely monitors the working of the new process and ensures that there are no problems in the new process. They monitor the performance of the new process and ensure that products manufactured are defect free. If there are any further changes to be made, the team makes changes and again measures the performance of the process. Under proper guidance and observance of the team, new process is adopted by the organization [2].

RESULTS AND DISCUSSION

This section discusses all the phases of DMAIC methodology to go to the entire process and capture all the variables using the Six-Sigma Manufacturing Principles.

Define

In the Define phase, the Project Charter (Table 1) was used to document the vision, objectives, scope, deliverables, organization and the implementation plan to strengthen the software controls in a regulated industry. This tool gives a breakdown to recognize all variables of gaps that generated weak software controls practices. The Project Charter set the direction and ensures the buy in from all the stakeholders.

Table 1
Project Charter

Project Charter	
Project Title	Quality Improvement Process for Software Controls in Regulated Industry
Problem Statement	Software Control practices on Automated Processes are weak and not systematized in regulated industry. This could result in improper and unauthorized software management that could lead to non-conforming production processes and by consequence Regulatory Observations.
Project Goal	Standardize and simplify the regulated industry Software Control system while eliminating the probability of future observations.
Project Leader	Software Quality Engineer (Team Leader)
Resources	**Project Team:** • Information Technology Director (Sponsor) • Quality System Manager (Sponsor) • Manufacturing Engineer (Team Member) • Validation Specialist (Team Member) • Quality Engineer (Team Member) • Manufacturing Manager (Coach) **Subject Matter Experts (SME):** • Computerized System Validation (CSV) Resource • Information Technology Resource **Stakeholders:** • Plant Managers
DMAIC Timeline	**Phases** — **Due Date** Define — JUN 12 Measure — JUL 12 Analyze — AUG 12 Improve — MAR 13 Control — OCT 13
Audit & Gap Analysis Findings (Source & Quantity)	Several findings were found in past internal audits related to software revision changes.
Failure Modes (findings) addressed by this project	• Inadequate software control procedure • Software not protected (access control) • No restriction to folders/files • Inadequate Software Intervention • No up to date Backup • No Backup available • No Source Code Review for Part Programs
In Scope	• Control of Software Category 3 (Non-configurable), Software Category 4 (Configurable) and Software Category 5 (Custom) • Control of Part Programs / Program Logic Controller (PLC) Programs
Out of Scope	• Electronic Records • Manufacturing Executive System (MES)

The completion of project charter and its presentation helped with management the project scope and addressed the quality improvement process for software controls.

Measure

In the Measure phase, the main purpose is to objectively establish current baselines as the basis for software control improvements. The Process Map (Figure 3) was used to understand "what does the process look today?" and "how do inputs flow into that process?" for software control to obtain full compliance with applicable regulations.

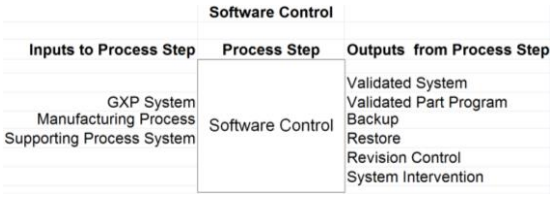


Figure 3
Software Control Process Map

The Baseline Capability (Table 2) show us "how does the output perform now?" based on failure mode identified in the project charter. The baseline risk with the highest score is when the system was not validated and not restriction to folders/files.

Table 2

Baseline Capability (Risk)

Process or System: Production Process Control - Software Control			
Failure Mode	Effect	Occurrence	Baseline Risk Evaluation Score
Inadequate control procedure (revision change)	3	2	6
System not validated	9	1	9
System not protected (access control)	3	2	6
No restriction to folders/files	3	3	9
Inadequate System Intervention	3	2	6
No up to date Backup	1	3	3
No Backup available	3	1	3
Lack of qualification evidence for Part Programs	3	2	6
		Overall Risk Evaluation	48

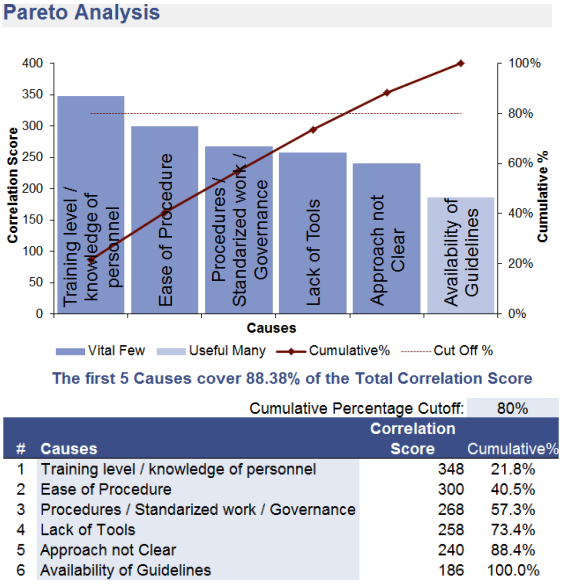
Effect Scoring	Frequency scoring	Risk Evaluation
Critical = 9	Far Too Often >20%=5	Effect = Frequency
	High Probability 10-20%=4	
Major = 3	Moderate Probability 5-10%=3	
	3-5%=2	
Minor = 1	Low Probability 1-3%=1	
No Risk = 0	3.4 ppm or better=0	

The Cause and Effect Matrix was used as tool to understand quantitatively the relationship between the impact of inputs (gaps of software control process = Xs) on the outputs (finding needing to be resolved = Ys) of a given process. In the Figure 5, the most-influential factor contributing to weak software control is "Training Level / knowledge of personnel.

Analyze

In the Analyze phase, the purpose of this step is to identify, validate and select root cause for elimination. A large number of potential root causes (in our case, the gaps of software control process) of the project problem are identified via root cause analysis. The top 3 or 4 potential root causes are selected using multi-voting or other consensus tool for further validation.

Based on data of cause and effect matrix obtained in Measure phase, the Pareto chart is tool to analyze the "what are the predicted relationships between inputs and outputs?" and the true root causes. In the Figure 4, show us that the first 5 causes cover 88.38% of the total correlation score, eliminating the cause #6 that is "availability of guidelines".



Cumulative Percentage Cutoff: 80%

#	Causes	Correlation Score	Cumulative%
1	Training level / knowledge of personnel	348	21.8%
2	Ease of Procedure	300	40.5%
3	Procedures / Standarized work / Governance	268	57.3%
4	Lack of Tools	258	73.4%
5	Approach not Clear	240	88.4%
6	Availability of Guidelines	186	100.0%

Figure 4

Pareto Analysis Related to Causes of Weak Software Control

Based upon evidence, which of the inputs (causes) determine output capability (Risk), the cause #5 "Approach not clear" is not identified in Table 2, suggesting the elimination it of key causes. The team, based on the causes of weak software control, identifies the potential root causes of each one. In the Table 3, the causes of major weak software control are identify and are: training level / knowledge of personnel, easy of procedure, procedures / standarized work / governance and lack of tools. Each one of these causes has some potential root causes that cause the problem in each one. From the data collected and the analysis that the team did to each potential cause of weak software control the potential root causes were identified in the Table 3.

Input (cause) - Output (effect) ranking scale	0 = No Correlation 1 = Slight Correlation 3 = Moderate Correlation 9 = Strong & Direct Correlation								
	Outputs or Findings needing to be resolved								
Relative Risk Ranking 1-10 Based upon RPN (10 = Highest) ---->	10	10	8	8	6	6	6	4	
Inputs from Process Map *(Rank Correlation of Input to Finding)*	Inadequate Control Procedure	System not Validated	System not Protected	No Restriction to Files/Folders	Inadequate System Intervention	No Up to Date Backup	No Backup Available	Lack of Qualification Evidence for Part Programs	**Correlation Score**
Training level / knowledge of personnel	9	9	9	9	1	3	3	3	348
Ease of procedure	9	3	9	9	3	3	3	3	300
Procedures / Standarized work / Governance	9	1	9	9	1	3	3	0	268
Lack of Tools	9	0	9	9	1	3	9	3	258
Approach not Clear	9	3	3	9	3	1	1	3	240
Availability of Guidelines	9	1	1	9	1		3	0	186

Figure 5
Cause & Effect Matrix

Table 3
Potential Roots Causes

Offender	Potential Root Cause
Training level / knowledge of personnel	Roles and responsibilities not clear for obtain software control process
Easy of Procedure	No specific procedure for minor or major changes in software control process
Procedures / Standardized work / Governance	Non standard procedures for software control management
	No official software inventory
	Non-standard security for software control process
Lack of Tools	No official tool for software inventory
	No adoption of information technology procedure and tools for the software control process

Improve

In the Improve phase, the purpose of this step is to identify, test and implement a solution to the problem; in part or in whole. Identify creative solutions to eliminate the key root causes in order to fix and prevent process problems. In our case, this phase is used to establish actions for the significant root causes related to weak software controls. In this phase is the step to demonstrate that the potential causes of the problem are the correct. Basically, it is used to recognize findings addressed by this project as potential modes, determine their effect on the software control process, and establish actions to reduce the failures. In summary, this improve phase will show the implementation of the diverse tools to ensure that the causes that were found in the analyze phase, these are managed with correct solutions.

In the Analyze Phase, the team recognized the major potential root causes for the causes of weak software controls.

The following items provide specific solutions (Table 4) under the new software control structure:

- **Roles and Resposabilities** – The roles and responsabilities established within each document or procedure in software control process. The training matrix for Information Technology (IT), Subject Matter Expert (SME) and Document Control personnel were modified in software control process. Improvement the training for engineers, IT and documentation personnel on specific task.
- **Standard Procedures –** Several current procedures and work instructions (WI) were complemented with software control inputs. Software control was aligned with the established computerized system validation policy.
- **System Security –** Security guidelines were established to define requirements for current and new systems.
- **Inventory –** Systems with quality impact in the product were listed in a Information Technology (IT) asset management database.
- **Information Technology (IT) Integration** – IT procedures were referenced through the

computerized system validation documentation**.** Also, the ServiceDesk Plus application was leveraged to store the system inventory.

Table 4
Potential Roots Causes with Resolution

Offender	Potential Root Cause	Resolution
Training level / knowledge of personnel	Roles and responsibilities not clear for obtain software control process	Roles and responsibilities defined / Training
Easy of Procedure	No specific procedure for minor or major changes in software control process	Standard Procedures
Procedures / Standardized work / Governance	Non standard procedures for software control management	Standard Procedures
	No official software inventory	Inventory
	Non-standard security for software control process	System Security
Lack of Tools	No official tool for software inventory	Inventory
	No adoption of information technology procedure and tools for the software control process	Standard Procedures / System Security / Information Technology (IT) Integration

The following items provide general solutions for the causes (offender):

- **Training level / knowledge of personnel –** In order to strengthen the knowledge of personnel, the training plan was established to retrain the engineers, quality representative, Information Technology personnel and Documentation Control personnel in the software control topics. These topics are computerized system validation overview, software backup and restore procedure, software backup media copy procedure, system operation and security management, change management, operational qualification, performance qualification and software audits. New procedures related to software revision control and program management, and computerized systems inventory management were implemented and the same personnel was trained.
- **Easy of Procedure –** This cause was managed establishing clear, defined and detailed guidelines under standard procedure for system backup and restore requirements, backup management requirements, software audit adding questions for the system integrity and control, access level and system security requirements, impact of changes on systems to other control elements (software inventory, backup and procedures) and software inventory management.
- **Procedures / Standardized work / Governance –** The software control procedures were implemented under existing Computerized System Validation umbrella in order to: use existent gonvernance, reinforce current procedures and practices, and one procedure for an specific element (for example system security and inventory). Also, the procedures were revised to obtain a cross reference between Information Technology, Process Validation and Computerized System Validation.
- **Lack of Tools –** New and existing tools and application were used to obtain software control, such as:
  - Create software and system inventory using the IT ServiceDesk Plus application.
  - Implement security tools (IT Production Image Control and Registry Editor).
  - Implement software and system audits using the existing audit policies, procedures and work instructions (WI).

In Figure 6, show us a Software Control Structure resolves each potential root cause.

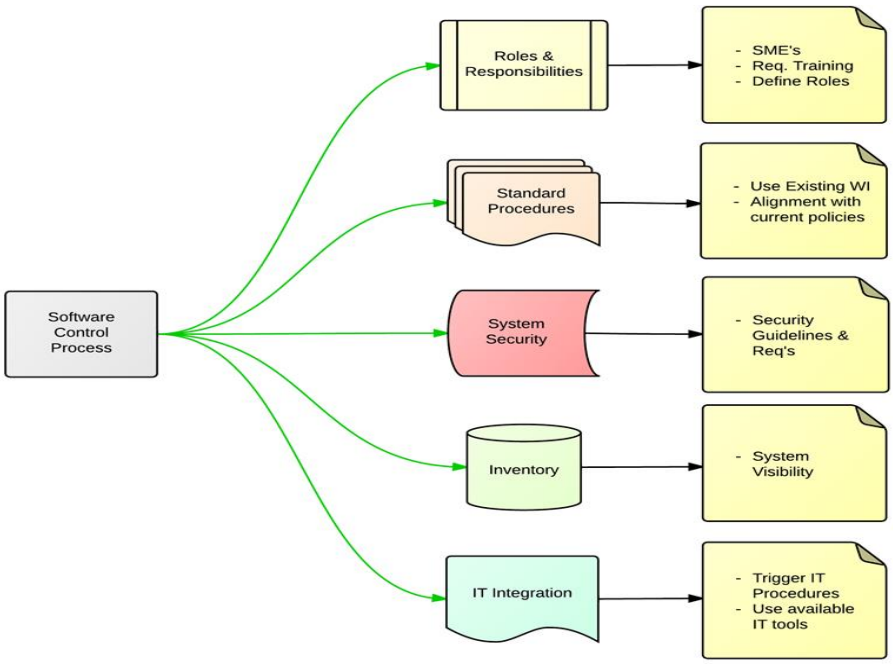


Figure 6
Software Control Structure

Table 5
Quality Improvement Process (QIP) Control Plan

Quality Improvement Process Control Plan for Software Control - Key Parameters Indicators								
					Months			
Failures Modes	Sample	Description	Verification Method	Frenquency (D,W,M)	1	2	3	Result
Inadequate software control procedure	1 Completed Change Control	Change Control Forms/ Inventory Forms	Document Review	M	X	X	X	
Software not protected (acess control) and/or no restriction to	1 New / Revised Work Instructions	Work Instructions (WI) creation	Document Review	M	X	X	X	
No up to date Backup	1 Completed Change Control	Change Control for Software Restore	Document Review	M	X	X	X	
No Backup available	1 Backup forms (revised) 1 Software Audit	Backup Forms (revision)/ Software Audit	Document Review	M	X	X	X	
No Source Code Review for Part Programs	1 Completed Qualifications	Operational Qualification/ Performance Qualification	Document Review	M	X	X	X	
Not Meet Goal		Meet Goal					Exceed Goal	

Control

In the Control phase, the purpose of this step is to sustain the gains. It is in this phase is monitored the improvements to ensure continued and sustainable success. In other words, the objective of this phase is control management of the improvement done. An implementation plan was elaborated to provide direction and tracking tool to complete several tasks. The main problem identified were weak software control practices that are caused by training level / knowledge of

personnel, easy of procedure, procedures / standardized work / governance and lack of tools are the offenders that contribute the failure modes.

This control plan in Table 5 is used to ensure the member of team is making satisfactory progress to the project goals using key parameters indicators. Once has been implemented the strategies under implementation plan in previous Improve phase, it is very important the monitoring of the progress for the improvements that are in place and running. As we can see in Table 5, a sample was taken per three month consecutives to verify if the implementation plan was effective, sustainable and meets the goals.

CONCLUSION

The quality system for software control practices was improved by the implementation of quality Improvement process for software control in regulated industry using six sigma methodology. Software Control practices on automated processes per Food and Drug Administration regulation under 820.70(i), indicate 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. Also 820.70(i), specify that all software changes shall be validated before approval and issuance, and these validation activities and results shall be documented. Thus, software control is a critical area in order to achieve the full compliance with computerized system validation policies.

In this project was identifies the causes of weak and not systematized software control practices that has been noted by audit finding and defined in this project as failure modes. The main problem identified were the weak software control that are caused by training level / knowledge of personnel, easy of procedure, procedures / standardized work / governance and lack of tools that are the offenders of the weak software control process. With the data obtained and analyzed, the potential causes for these offenders were the following: training level / knowledge of personnel – roles and responsibilities not clear, easy of procedure – no specific procedure, procedures / standardized work / governance – non standard procedures / no system security / no inventory, lack of tools – no inventory / non standard procedures / no system security / no information technology integration. Based in the results, improvement recommendations were presented, addressing the causes mentioned above, including the development of an improvement plan, where the causes were strategically organized under software control structure. It is important to monitor the progress of the software control process after these improvements are in place and running. After three (3) months of project the goal in terms of strengthen the software control practices was accomplished.

The improvement already established gave satisfactory results to the regulated industry strengthening the software control structure. The deliverables and project charter goals were achieved with adequate confidence, providing a periodic method of review for computerized system elements identified as part of failure modes. These improvements reduce the risk of future regulatory observations.

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