First Pass Yield Metric Implementation for Validation Documents

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Abstract *— A regulatory compliance contractor in the life sciences industry desires to be distinguished from its competitors in terms of the quality of their services. To make it possible, the company intends to improve the validation test case development process in order to implement a metric that shows how much time they are saving their customers by delivering defect-free test cases to the approval process. This metric is known as the First Time Yield and measures the proportion of documents that are reworked during the approval process. To achieve this goal, the DMAIC methodology was used to gain a better insight of the process and the areas of opportunity. After following this structure, the baseline FPY value was improved from 66% to 80.5% with only the first stage of solutions proposed. This improvement reduced 6-15 hours of re-approving defective test cases. With this reduction, the client can allocate their resources into more valuable activities while complying with the project deadlines.*

Key Terms *— Defect, FPY, Rejections, Validation.*

PROJECT STATEMENT

A company wants to become the preferred regulatory compliance contractor in the life sciences industry with the improvement of the protocol generation process by reducing the defects that cause their rejection in the approval stage and implement a quality metric that provides the customer visibility of the quantity of test protocols that are approved the first time they are submitted to the approval process.

Research Description

XYZ, a company that manufactures a biological product is currently increasing the capacity in the purification process of its active product ingredients and huge validation efforts are needed on the modifications made to the Distributive Control System (DCS) software. In order to complete these validation activities on time, the manufacturer hires regulatory compliance contractor companies to provide support on the development and execution of approximately 2,000 test protocols which generate auditable evidence that the software performs as intended. ABC wants to exceed the client's expectations by delivering the greatest amount of documents that are approved the first time they are submitted.

Research Objectives

The expected objectives of this research to be accomplished are:

- Identify the defects in the rejected test protocols;
- Develop solutions to prevent the defect from occurring;
- Develop a metric that measures the first pass quality improvement.

Research Objectives

With the implementation of this Project, ABC will position itself as a more efficient and reliable solution for auditable document development by reducing both the client's and internal Full Time Equivalents (FTEs). This will result in lower, more competitive quotation of projects and improved on-time delivery.

Research Contributions

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LITERATURE REVIEW

In the life sciences industry, Computer System Validation (CSV) is the technical discipline used to help ensure that software systems meet their intended requirements. Through regulations and guidance, The Federal Drug Administration (FDA) has shaped Information Technology (IT) testing and analysis processes to match and requirements of the industries it governs. As a result, Computer System Validation has become an integral part of doing business in FDA regulated environments. XYZ has structured its Distributed Control System Software validation strategy according to the Industry Standard Architecture (ISA) S88.01 Batch Control Standard. Thus, the validation of the entire system will be divided by process cells, each one having their own Procedures, Unit Procedure and Phase Logic test cases that represent a real configuration in the production system once validated.

It should be noted that the test cases generation activities are not continuous since there is a discrete quantity of documents to be developed. Nonetheless, as more validation projects are absorbed by ABC Company, the improvement of this process will become more significant in terms of cost and time reduction.

Each of the test case document must comply with certain criteria stablished to comply with XYZ corporate quality standards, validation strategy requirements and 21 Code of Federal Regulations (CFR) part 11 compliance. To certify that the criteria are met, every test case shall go through the approval process before the execution of the software test case. The approval process consists of four individuals whose signatures certify the requirements of the document are met and is ready for execution. Each approver has a different role when reviewing the test case document. The approvers and their respective responsibilities are described below:

- **Document Reviewer:** The Document Reviewer signature indicates that the content in the test case is aligned with the title and number of the document.
- **Computer Systems Representative:** The Computer System Validation Representative signature indicates that the document satisfies XYZ Quality Practices and every test is aligned to the current Good Manufacturing Procedures.
- **Subject Matter Expert (SME):** The Subject Matter Expert signature ensures that the document was reviewed by the appropriate persons and to attest that test case/script is accurate, complete, and meet the technical requirements.
- **Quality Representative:** The Quality Representative signature indicates that this document satisfies XYZ Quality Practices, corporate policies, procedures, tools and local procedures.

Figure 1 represents the test cases approval process. It starts after the document was developed and submitted in the document control system used by XYZ to route the test cases through each approver, sending a notification by email that a document is waiting by their approval.

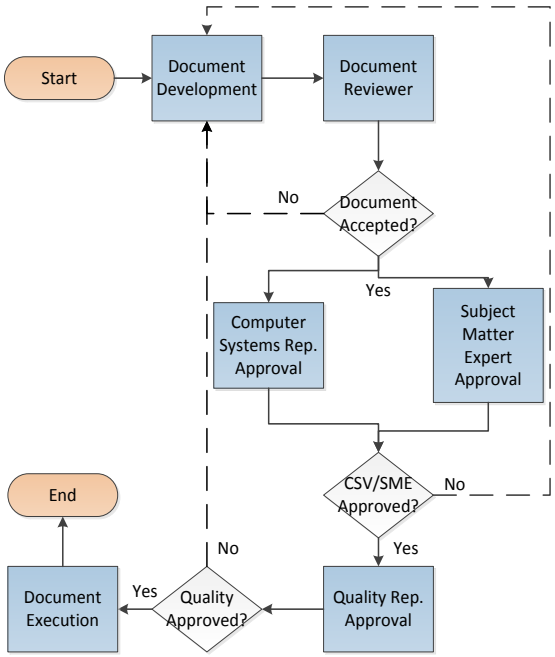


Figure 1
Approval Process Flowchart

Although the approval process does not "produce" defects, every signature required will be considered a process step that pass or fail decision will depend on how the test case document was generated in the development stage. The observed output in our process will be the ratio of approved and/or rejected documents, also known as process yield. Since the documents can be reworked when they do not meet the requirements, the process cannot be measured only at the very end of the process because the overall proportion of the acceptable results will be always 100%. This method fails to account for the cost of rework which consumed a significant portion of the value of the process. The metric that better describe the efficiency of the process is First Pass Yield (FPY). The FPY is considers the yields of each individual process without re-work (first pass) [1]. It is calculated by dividing the quantity of documents entering the process minus the defective documents, which eventually will be reworked, by the total number of documents entering the total process [2].

The selected problem-solving methodology to follow will be the DMAIC model. The rationale for this selection is that the document generation process is an existing one, it's also a data-driven process and the solution and root cause of the defects are not known. DMAIC is part of the Six Sigma approach which is focused on process improvement by reducing variation. Six Sigma is widely regarded as a world class level of performance achieved by only a few companies [3]. The mentioned methodology it's divided into five steps: Define Measure, Analyze, Improve and Control. In the Define step, the process and problem requirements will be properly stablished. The Measure step will characterize the key variables and provide the baseline data that will be further improved. In the Analyze step the main focus is to find the root cause(s) of the problem. Given the information in the previous steps, the improve step will attempt to find the solution that addresses the root cause of the process variability. At last, new controls will be implemented to make the process sustainable in order to ensure the improvements are maintained.

METHODOLOGY

The problem-solving methodology that will be followed in order to improve the First Pass Yield of the test cases development will be the DMAIC improvement strategy from Six Sigma. It is primarily based on the application of statistical process control, quality tools, and process capability analysis. This methodology uses a process-step structure that generally is sequential. The five steps which DMAIC is divided are:

- **Define Phase:** This step consists in defining the scope, goals and the work effort of the project. It will determine possible opportunities of improvement and the people that will be benefit from the overall results.
- **Measure Phase:** The objective of this step is the collection of the key aspects of current process performance. It this step the data available at its source will be identified. A data collection and detailed process flow diagram is often used. The tools to be used to show visual representations of the current state are graphs, charts, flowcharts and a SIPOC diagram.
- **Analyze Phase:** This step consists on identifying the root causes with the objective of isolate the problem. The key components of this phase include cause-effect, root cause and value- non value added analysis. It will used Value stream map and cause-effect diagram.
- **Improvement Phase:** The objective of this step is optimizing the current process based on data analysis. It is based on the identified root cause(s) in the prior step and directly addresses the cause with an improvement.
- **Control Phase:** This step includes designing and documenting the new controls and procedures, in order to hold the gains. Key components to this phase are visual workplaces, periodic audit exercises and training process to monitor the success.

RESULTS AND DISCUSSION

This section presents the findings of this research work.

Define Phase

The tests case development process has been consuming in terms of time and resource allocation. A test case is not a piece of work that could be scrapped, their creation suffers from a significant amount of waste every time one of these documents fail to be approved because of the rework performed. Since the validation of the control software is a requisite for restarting production, additional costs may be caused by this process if it impacts the timeline of the project.

The scope was to evaluate the test cases development process in order to reduce the defects that cause their rejection during the approval phase. The objective of this improvement is to provide ABC the tools to prevent the delivery of defective test cases allowing XYZ to reduce their approval efforts and allocating those resources in other tasks that add more value. ABC will be able to make accurate forecasts of their document development projects and less uncertainty in their quotations.

A team composed of a CSV coordinator and two test case developers, with the assistance of a quality representative of XYZ, will participate on the data collection of the test case development process in order to address the root causes of the problem. The project goal pursues to reduce the percentage of test cases rejections in the approval process by a 25%. An internal system should be implemented to gradually reduce the shipment of defective documents on the approval process.

Measure Phase

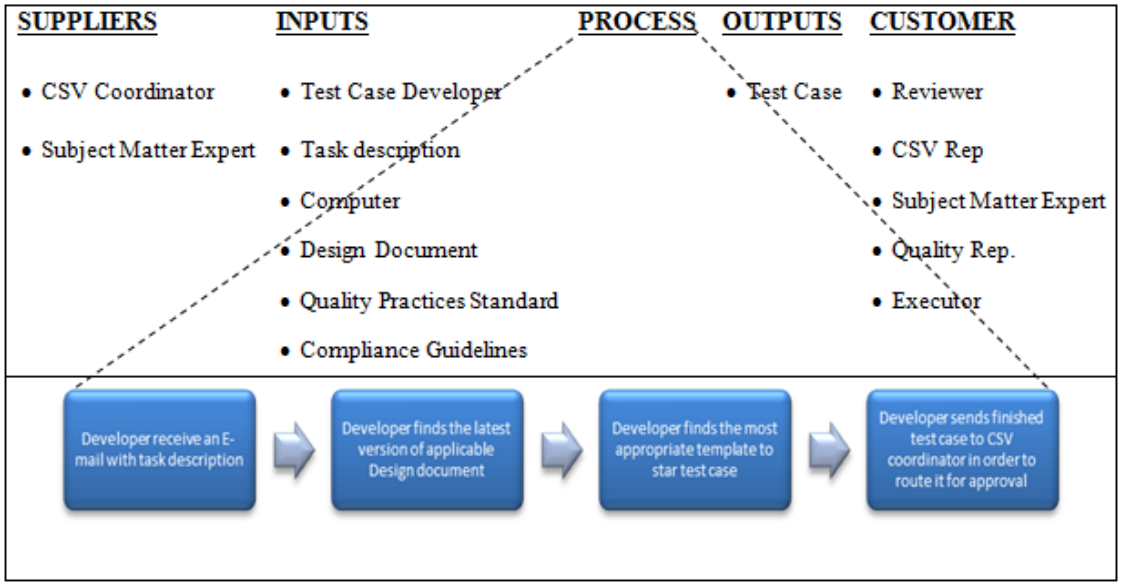
The Figure 2 shows a high-level perspective of the test case development process and its respective suppliers, inputs and outputs, and ultimately who will receive the test cases after their development. This diagram is known as the SIPOC diagram.

In order to obtain a better understanding of the process that is intended improve, a data collection process will be performed in the measure phase. The baseline data of the process will be gathered by the team by inquiring on the document control system where the routing of the document though the approvers takes place. The system provides information regarding the upload dates of the documents, the time the approver downloads the document to review it and the comments that describes the reason rejection.

The first data that is collected is the time that each approver takes to evaluate the test case document for the second time it passes through the approval process. This information is important because it determines the amount of waste that a rejection of a document creates. The time consumed in the evaluation process was calculated based on the time it took the approver from downloading the document to the time that same person approves the document in the system.

Since a rejected test case has to go through each of the approver regardless their feedback their first time it went through the approval process, the rejection criticality increases as it occurs further in the process. For example, a rejection in the review step, which is the first one, is not as critical as a rejection in the quality step because the test case document will have to pass through every approver again until it reaches the quality representative to approve the corrected document.

Although until at this moment the Execution category was not mentioned, it is the most critical of rejections and the most wasteful in terms of process. The execution rejection means that a test case was approved when it had a nonconformance and it was not detected until the executor noticed it in the middle of the execution of the test case. The procedure to follow in that situation is that the executor has to create a deviation describing the expected results against the observed results. Then, this deviation report must go through the evaluation of the subject matter expert and the CSV representative and there is when they will conclude that the test case document was developed and approved mistakenly and it has to be corrected and re-approved.



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After knowing the different categories of rejections in the approval process, the quantity of rejections must me known. The approval reports in the document control system are evaluated to identify the defective test cases and the corresponding category of rejection. It is important to clarify that not every rejection is due to an error committed by the test case developer. There are also other reasons why a document could be rejected such as the document was not needed and inadvertently was requested by XYZ validation representatives, or another design document version was released during the test case approval and per management decision the document was rejected to align it to the design updates.

The team gathered key information from a sample of 50 test cases submitted for approval per week in order to characterize the approval process. A table was created to fill the following information regarding the documents:

- Process Cell
- Test Case Author
- Rejected (Yes, No)
- Stage of rejection
- Reason for rejection

After gathering the historical data, different charts were created to visualize the proportions of defective test cases from different perspectives. Control charts were created to help visualize the periodic proportion of rejected test cases, while a pie chart of the cumulative measure of rejected test cases will show how much hours were wasted in reworking the rejected documents.

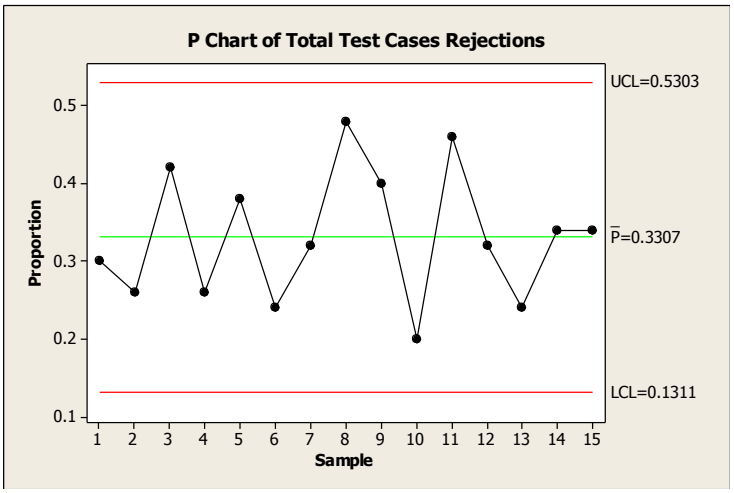

Figure 3
Average Proportion of Overall Rejected Test Cases

The type of control chart used to display the rejections rates on a weekly basis is a P chart, which shows the proportion of failure of an event with respect to the sample size. The graphic below shows the proportion of rejected test cases due to development errors on a sample of 50 test cases. This chart includes the rejections of all of the approvers over the studied time period. It shows that, on average, one third of the generated test cases are rejected due to test case development errors, causing rework both in the development and the approval process. Control charts of rejection rates by each approval stage were created in order to have a better understanding on what approver is the most impacted by these defects.

The reviewer stage in the approval process has the highest rate of rejection compared to the other approvers. It is common that the reviewer rejects the majority of the test cases because it is the first one of the approvers to see the document and could capture errors that could fall under the category of the other approvers if they are obvious enough

Table 1
Rejection Justifications in Reviewer Stage

Reason for Rejection	Count
Incorrect Title or Title Format	41
Incorrect approver names	33
No Signature Log	21
Incorrect Version Number	18

The control chart of the CSV approval stage shows a more stable process having an average of approximately 6% of the rejections. At this point the more visible errors were already detected by the reviewer, but the CSV representative has the expertise to detect less visible details.

Table 2
Rejection Justifications in CSV Stage

Reason for Rejection	Count
No Test Problem Report Table	14
Incorrect Test Format	13
Replication Error	11
Incorrect approver names	8
Incorrect Test Objective	3

The Subject Matter Expert has the responsibility to compare the technical content in the test cases against the design specifications document. Unlike the CSV and Quality content, the SME will be the only one able to detect the great majority of the errors in this area. However, the rejection rate for the SME approval stage is very similar to the CSV stage even though the majority of the CSV-type errors were detected in the review stage.

Table 3
Rejection Justifications in SME Stage

Reason for Rejection	Count
Incorrect Technical Content	38
Statement Is not divided in Sub-classifications	8

The Quality Stage of the approval process is has a lower average rejection rate yet more intermittent than the other stages. The lower rejections may be due to high detectability of the reviewer regarding quality related errors.

Table 4
Rejection Justifications in Quality Stage

Reason for Rejection	Count
Incorrect Design Document Number	12
Incorrect Design Document Version	10
Incorrect Version Number	2

At last, the execution errors chart displays the rate of approved test cases that reach the execution stage and the executer of the test cases notices that there is a test step that fails to match the expected results, leading the executer to fill a Test Problem Report (TPR).

Table 5
Rejection Justifications in Execution Stage

Reason for Rejection	Count
Incorrect Technical Content	15
Expected Result Missing	3

A cumulative First Pass Yield measure is represented in the following chart to demonstrate the baseline of the process and the wasted Full Time Equivalents over the studied period of time:

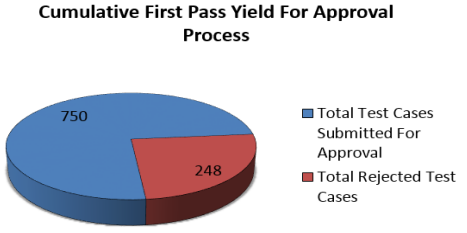

Figure 4
Cumulative Proportion of Rejected Test Cases

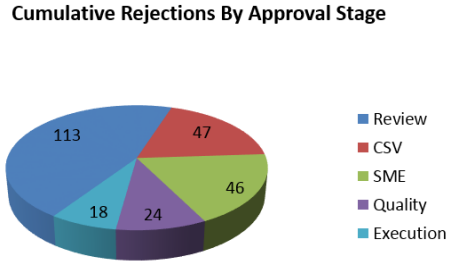

Figure 5
Cumulative Proportion of Rejected Test Cases per Approval Stage

Analyze Phase

After measuring the baseline data for the approval process for a time period of 15 weeks, The goal in the analyze phase is to identify the possible root causes of the defective test cases and categorize the most critical errors found in the test case generation process based on that causes.

As presented in the measure phase, an average of 33% of the submitted test cases is found to be defective across the approval process. Since the waste caused by the test case depends on the stage rejected and the frequency that the error occurs, priority should be given to the most critical in terms of time wasted and frequency of occurrence.

A value will be attributed to each of the errors encountered in the measure phase that will be calculated by multiplying the cumulative count of the error and the criticality based on the step that the defective test case was rejected. For the errors that are detected in more than one stage, the frequency will be first multiplied by their corresponding criticality and the results then will be added. The value assigned to each error will be presented in a Pareto chart, which will be used to graphically summarize and display the relative importance of the differences between groups of data. While the limited time will not be sufficient to address all of the errors in the test cases document, the 80/20 rule of the Pareto principle will help to focus on the key items that will make a significant improvement in the process. However, the other unattended errors may be reduced with the controls that will be stablished after the improvement phase. The figure 6 is a Pareto chart which shows the grouped causes of test case rejections in the approval process.

The Pareto chart does not reflect on which stage that error is detected but instead is classified by the time, in hours, wasted when rejected by the approver. It shows that the most critical error in the approval process is the “technical content” classification.

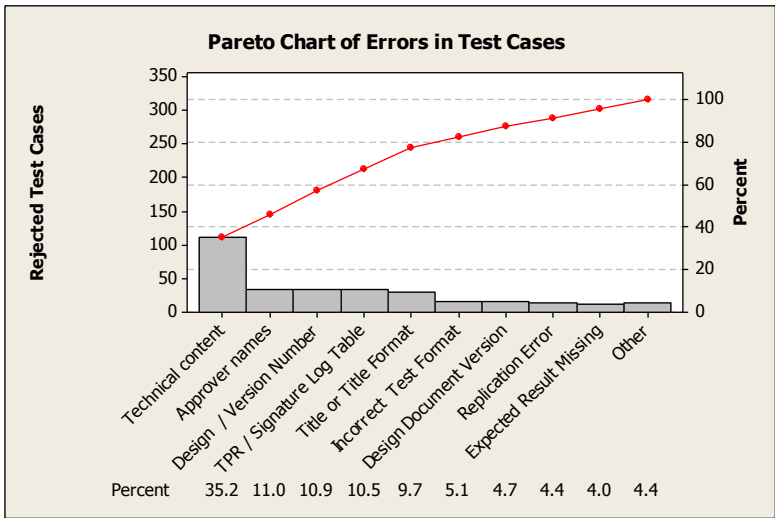

Figure 6
Cumulative Proportion of Rejected Test Cases per Approval Stage

The reason behind the criticality of this error is that it is not only detected by the SME, but also is the primary reason of the execution failure which is the most critical step. The next four errors, Approver Names, Design / Version Numbers, TPR / Signature Log Table, and Title or Title Format are the source of 80% of the test case generation errors. This means that the improvement phase will be focused on the best solution to address these sources.

Before finding a suitable solution for these errors, a root cause analysis has to be performed in order to identify their root causes. The team gathered to observe the current document generation process and the current controls to find the potential root causes. To summarize those findings, a cause-and-effect diagram was used. Figure 7 shows the result of the brainstorming session:

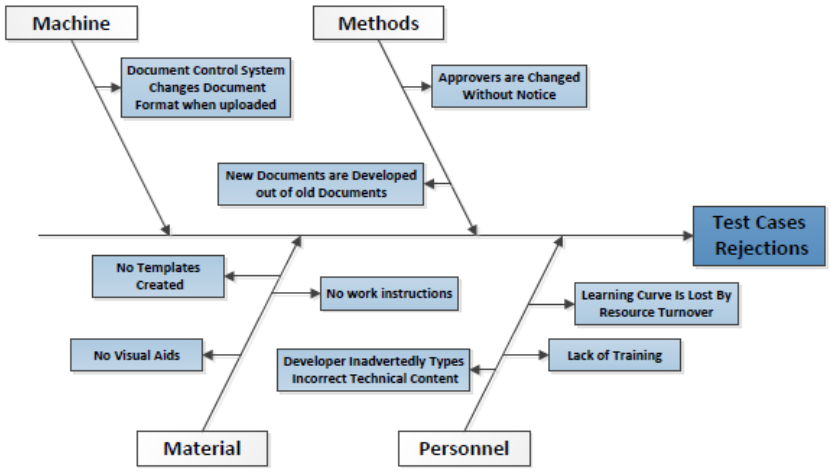

Figure 7
Cause and Effect Diagram for Test Cases Rejections

Several findings were made during the process walk down, providing visibility of the flaws in the process. These findings will be used as a start point to improve the process and reduce the test cases rejections. Since all of the possible improvements cannot be done at one time, these improvement opportunities will be evaluated in terms of implementation difficulty and impact on the

process. In order to make the most meaningful improvement possible under the scope of the project, the efforts will be focused on the lower difficulty and higher impact areas of opportunity.

Improvement Phase

The goal in this phase is to implement the proposed solutions during the team problem-solving process. The priority will be given to the areas of opportunity with highest impact in the approval process. The list of improvements is described below:

Incorrect Technical Content: This error occurs when one of the test case developers types the incorrect content from the design document. The improvement proposed to mitigate this error is to give the developer the instruction to only use the "Copy" and "Paste" tool instead of manually typing the statement on the test case. Even though it is a simple solution, it prevents the developer from creating errors.

Wrong Approver Names: As stated in the cause-and-effect diagram, the reason for this error is usually that one of the approvers of the test case documents is changed without notice, causing the former approver to reject the test cases when he/she gets the request for approval. Initially, it was proposed that this problem could be addressed with a visual aid showing the current approver by process cell, but the approach was different at the end. After discussion with the quality department, it was found that removing the names of the approvers does not generate any compliance-related problem. The resolution was to remove the name of the approvers from the beginning of the test cases in order to eliminate the possibility of writing the name of the wrong approver.

By addressing the "Incorrect Technical Content" and "Wrong Approver Names" problems, which where the two most frequent reasons for rejection, more than 40% of the causes for rejection were solved. These improvements were performed with little or no effort since it only took to make a decision and provide the developers these new instructions. The greatest benefit of these improvements is that the methods prevent the error from occurring at all. Of course, the process must remain under observation to validate the success of the improvement and to verify if there is no other error coming from the improvement itself. For that reason, the control phase shall provide a method to characterize the improved process.

Even though at the closure of this research no other improvement was implemented, the team is still working on solutions to address other high-impact areas of opportunity but with higher difficulty. One of them is to provide training to all of the current developers and make it as a requirement for every other resource that begins developing test cases. Also, some tools from the Microsoft Word software, which is used in the test case development, will be taught to help prevent common errors in the test case format.

The other future improvement is to develop a "Job Tool" that will serve as a Standard Operating Procedure (SOP) to the developers. This document will contain a step-by-step instruction of how a document should be developed in a specific order that will prevent the developer from committing errors. At last, templates for the different types (Alarms, Interlocks, Procedures, etc.) and configurations (Special Cases, If Statements, etc.) will be created for the use of the developers when starting a test case. The developer will not be allowed to start a new test case out of another test case document because it could increase the probability of leaving incorrect design document versions or document versions due to developer's forgetfulness.

Eight weeks after the implementation of the first two improvements and several talks to the test case development team to increase awareness of the impact that causes the errors in the test cases, new data was gathered by taking a weekly sample of 50 test cases. The results were compared with the baseline data to verify that the improvements made an effect in the process.

In the baseline process, the First Pass Yield was 66%.and after the initial improvements; the FPY of the test case development process has

increased to 80.5 %. The total percentage increase of the test case development process after the improvements is 22%. At the beginning of the process the average rejections per week in the execution stage was 2.3% and after the improvements that percentage decreased to 0.25%. It was estimated by the team that these initial improvement saves approximately 6-15 hours per week from being wasted approving reworked documents. Even though the initial improvements made a significant improvement, the process must be kept monitored to analyze its behavior. The control phase will provide the team with the tools to keep this (and future) improvements sustainable.

Control Phase

The purpose of the control phase is to provide the process owners the tools to maintain the results of the implemented improvements and gradually continue with the reduction of the rejections in the test case development process. In addition, a chart will be created to help the management of XYZ the improvements achieved by ABC.

The figure below represents the graphic that will track the progress of the test case development process in terms of the mentioned metric:

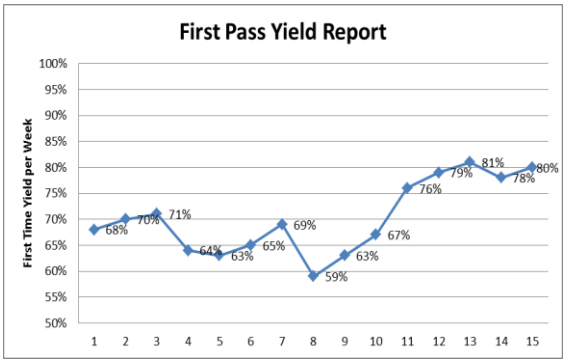

Figure 8
First Pass Yield Report

CONCLUSIONS

Through the DMAIC methodology, it was possible to provide a structure to the First Pass Yield Implementation, from identifying the purpose and scope of the project to verify the success of the proposed improvements. After gaining enough insight of the test case development and approval processes, significant improvement could be possible due to the tools of the methodology. A First Pass Yield metric could be stablished for the test cases rejections allowing visibility of the waste of the baseline process. The baseline FPY value was improved from 66% to 80.5% with only the first stage of improvement proposed. This increase in FPY means that 6-15 hours a week (depending on the total test cases generated in that week) were recovered from wasteful tasks due to the rework made to defective test cases. Controls were stablished to gradually increased the already successful improvement in order to achieve unprecedented quality in the test case generations process, granting contractor ABC a better standing in the life sciences industry in Puerto Rico.

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