

Time Management Improvement for Computerized Systems Validations' Periodic Review Program

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Abstract — *In the Information Technology Department of Bristol Myers Squibb Manatí Site, the development of a Periodic Review Program was developed for the execution of the Periodic Review Reports for Computerized Systems. The periodic review program was developed for completing these reports months prior to their due dates; however, the program schedule is not being met. The DMAIC methodology (Define, Measure, Analyze, Improve and Control) was used to improve the program management. Ten completed reports were analyzed based on the complexity of their content and time of completion for each section. It was determined that one section of the report was delaying the entire approval process. The section affecting the process was related to another program in the Information Technology Department. To improve the schedule management of the Periodic Reviews both programs had to be aligned to avoid delays.*

Key Terms — *Computerized System Validation, Information Technology, Management, Periodic Review, Schedule*

INTRODUCTION

Bristol Myers-Squibb is a pharmaceutical industry that specializes in the manufacturing of medicine for rare diseases. Due to technological advances most processes are now being performed under automated systems. The Information Technology department is responsible for the validation of these automated systems under the Computerized Systems Validation (CSV) team. As established by the Food and Drug Administration (FDA) these systems must be periodically reviewed to ensure they comply and maintain their validated state. This falls under the CSV Periodic Review Program.

Motivation

This program is reviewed yearly; a schedule is developed to perform these reports on a timely manner. The schedule for this program was developed to perform these reports with two months prior to the due date of each report. This would guarantee that the report was evaluated and approved with time to spare in case any situation occurred. Currently, the program is running behind schedule, as these reports are being approved days prior to their due dates. Although the reports are not being approved after their due date, the established schedule is not being met. This affects the overall evaluation and approval process for each report. Additionally, this limits the productivity of the resources, time being spent on the completion of these reports impacts what other activities the resource could perform additional to the periodic review.

Objective

The objective of this project was to improve the periodic review program schedule management at Bristol Myers-Squibb Manatí Site.

LITERATURE REVIEW

Periodic Review Process

Periodic Reviews are conducted throughout the operational life of a computerized system to verify that it remains in a validated state, complies with current regulatory requirements is fit for intended use, and satisfies company policies and procedures. [1]. The time frequency in which they will have to be evaluated depends on the complexity of the system. For systems that are “commercially off the shelf”, meaning that no custom configuration must be made, and it works straight out of the box, the

system category is a 3, therefore; their periodic review frequency will be set for 3 years after they have been validated. For systems that are configured specifically for the company, these are considered a category 4; therefore, the frequency for their periodic review will be every 2 years after they have been validated. The category 5 consists of a system that has been custom made for the business, and the same rule as a category 4 applies. The periodic review will be performed after two years after the system has been validated.

The process of completing a periodic review report consists of filling out a template that contains the sections for assessing if the system maintains its validated state and it is suited for its intended use. These sections are made up of tables that contain questions the resource must answer based on what they find in the system's document Lifecycle, interviews they conduct, and any finding they may uncover while searching in the Quality Management Software. The review should confirm that operational controls are in place and are being effectively applied [1].

Schedule Management

The scheduling job has traditionally been addressed in the literature from the decision-making point of view [2]. Scheduling is an important part of organizing a plan within an organization. Managers often rely on schedules to help keep track of activities for a specific task. Scheduling is usually part of a production control structure, which encompasses planning, scheduling, and dispatching [2]. Having track of time management is crucial for the completion of a schedule.

Time management is an important skill managers need to master to be successful. This can be a difficult skill to acquire as time interpretation can vary from person to person. A person's perception and use of time is highly influenced by culture and in the globalized society of the beginning of the twenty-first century these cross-cultural differences must be analyzed to better understand them and therefore, organize effective

work teams [3]. It is important to note that changes often require an effort that goes beyond the technical knowledge an organization possesses.

For this case, following the schedule can ease the approval phase for these reports. Issues that may arise during the evaluation of these reports can be solved with more time for planification. Finally, resources can be distributed in other tasks to improve overall department productivity.

STUDY

DMAIC Methodology

For the execution of this project, the DMAIC Methodology was chosen. This methodology allows for the project to be divided into phases. The name itself is an acronym for all the phases the project goes through when using this methodology. DMAIC stands for Define, Measure, Analyze, Improve and Control. The define step is where the problem of the project was identified, and it also helped determine the project goal for the problem at hand. Afterwards, this methodology moved on to the measuring step where the process of the periodic review was evaluated. With the definition of these variables, data was gathered to move on to the Analysis phase. This phase helped create a foundation for the determination of what was needed to improve the schedule management for the Periodic Review Program. The Improve step was tackled once the analysis of the data gathered had been completed. This step sought to improve the process by getting rid of defects found in the measuring and analysis steps. Finally, the last step for the methodology is the Control step. This step determined a method to be used to avoid the Periodic Review Program falls behind schedule again.

Definition Phase

For this project the definition phase was where the problem was identified as well as the goal. From the start it was identified that the Periodic Review schedule was behind. Although the team had managed to complete them before their actual

due date they were not complying with the established schedule. That is why the goal for this project was to improve the management of the Periodic Review schedule.

Measure Phase

The execution of the periodic review report consists of filling out a pre-made template that contains the necessary information to guarantee the success of the periodic review. To be able to determine where the fault was, it was important to determine what needed to be measured for the process being studied. It was determined that to assess the process, the variables to be measured had to be the process variables, and the time it took to complete each one.

Analysis Phase

A total of 10 reports were analyzed with the purpose of determining ways to improve the current scheduling management for the periodic review program. To execute this analysis the periodic review report had to be studied, therefore, it was divided into sections to determine the time it took to complete each one. This helped identify if the problem laid within the process itself. A total of 12 sections were identified for this process.

Table 1 provides a description of the 12 steps identified during the periodic review report execution. Figure 1 illustrates the time each step took for completion. From what can be seen in this figure it can be identified that step 7 has the most delays. On average this step takes about 8.3 hours to complete. This step has an overall impact on the Periodic Review completion process. Overall, the other steps are aligned and take an average of 0.84 hours to complete.

Additionally, during the interviews conducted to the periodic review team it was also noted that by the beginning of the year, only two resources oversaw the execution of these reports. The initial delay in the schedule was attributed to the lack of resources vs. the number of reports that needed to be completed and approved.

Table 1
Periodic Review Template Sections

Step	Definition
1	System Description
2	Change Controls related to the system
3	Summary of the documentation regarding the system's lifecycle
4	Quality Events, which include investigations or actions opened for the regulatory system
5	Standalone action items
6	Incidents report
7	User access review
8	System's capacity for Electronic Signatures
9	System Backup Configuration
10	Data Integrity Requirements
11	Summary of Findings
12	Conclusion

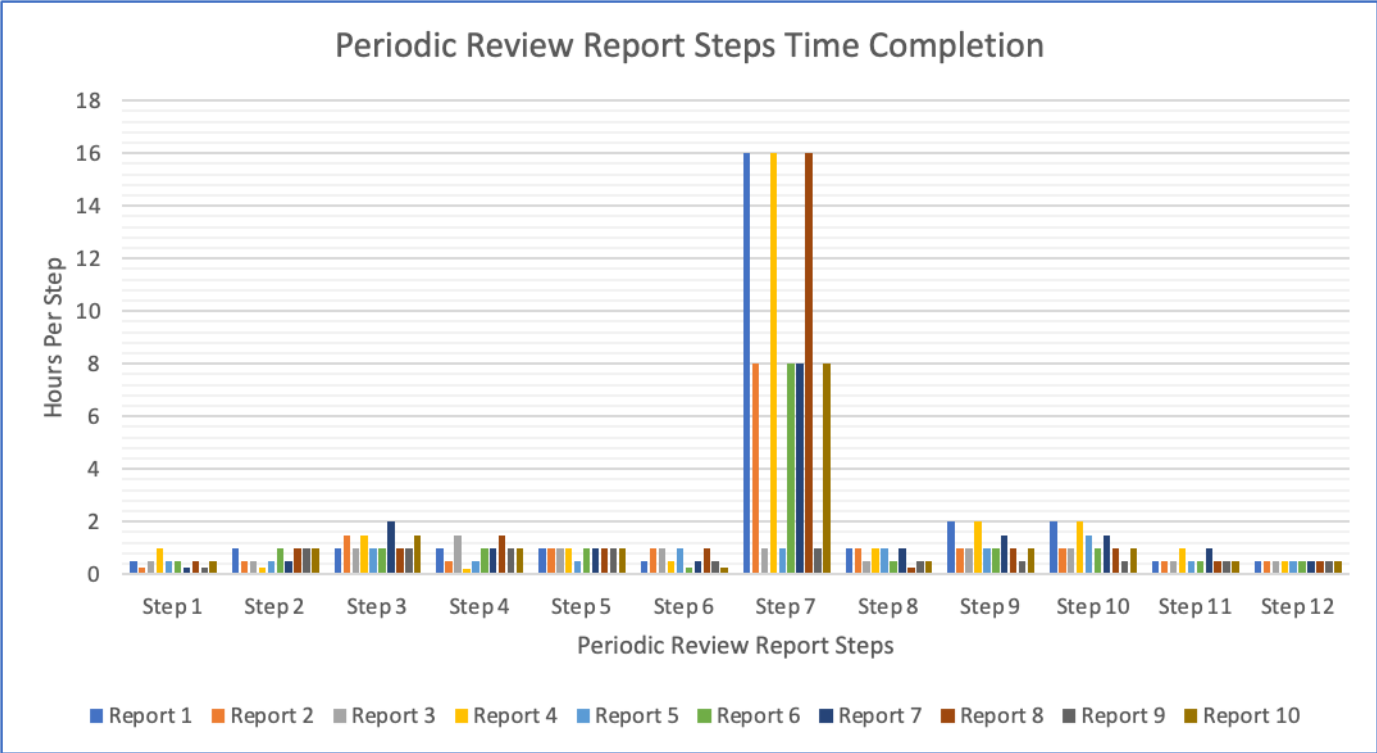


Figure 1
Periodic Review Report Steps Completion

Improve Phase

The initial problem the periodic review team faced was the lack of resources by the beginning of the year. However, this problem was mitigated by adding more members to the team. A total of four resources were assigned for the execution of these reports. This left the problem regarding the process itself, during the data evaluation it was determined that step 7, User Access Review, was taking the longest to complete. The information regarding this step, is provided by another team assigned to the completion of the User Access Review for the systems. The user access review of a system evaluates the system’s users and whether they comply the requirements to have access to the system. To obtain a balance between the two programs and avoid the delays with the periodic reviews the remaining schedule for the periodic review was evaluated and sent to the User Access Review team to harmonize both programs. The harmonization for both these programs would mean

that the periodic reviews would be completed as originally planned.

Control Phase

To prevent the Periodic Review program from falling behind schedule again it was determined that the number of resources should be maintained at four individuals executing these reports. That means the load of work would be divided between more resources and would avoid overworking them. Guaranteeing that they could be more efficient in completing other tasks as well.

Because part of this delay was due to not having the availability of the User Access Review report, a meeting was held for the harmonization of both programs. With the updated schedule they could prepare the User Access Review reports prior to the execution of the periodic review. To guarantee they keep up with their schedule, an automated scheduling system was recommended. This tool would be a validated excel spread sheet that must have the capacity to calculate the periodic

review due dates automatically. Access to this tool would be granted to the team executing the User Access Review reports for their use to prepare for the execution of their program.

CONCLUSION

The Information Technology department at Bristol Myers Squibb Manatí Site was behind in their schedule for their Computerized Systems' Periodic Review program. An analysis regarding the process was conducted and it was determined that the initial delay for this schedule was due to lack of resources executing these reports. The integration of more resources provided some aid in the execution of these reports; however, after closely analyzing the actual steps regarding the report it was determined an external program was affecting the completion process for the reports. That is why a harmonization between the two programs was suggested. To help keep both programs on track, an automized tool was suggested.

Additionally, it was determined that the periodic review team should be a minimum of four individuals. This way the reports would be constantly being generated, and the resources could help assist in other tasks as well. Improving the overall efficiency of the Computerized System Validation (CSV) Team.

Future Works

The periodic review template should be evaluated closely to determine if the process could be simplified all while maintaining its integrity. The team should look to standardize their completion time for the reports making the approval process easier.

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