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Abstract

In the Information Technology Department of Bristol Myers Squibb Manatí Site, the development of a Periodic Review Program was created for the execution of the Periodic Review Reports for Computerized Systems. The objective of the periodic review program was completing these reports months prior to their due dates; however, the program schedule was not being met. The DMAIC methodology (Define, Measure, Analyze, Improve and Control) was used to improve the program management. 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.

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.

Background

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. The review should confirm that operational controls are in place and are being effectively applied [1].

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]. Time management is an important skill managers need to master to keep track of the different activities that are being performed under them. 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].

Problem (Cont.)

The periodic review program was designed to complete reports two months prior to their due date. The program was running behind schedule, as these reports were being approved days prior to their due dates. This affected the evaluation and approval process for each report. Additionally, this limited the productivity of the resources performing the reports.

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

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.

Define Phase 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.

Methodology (Cont.)

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

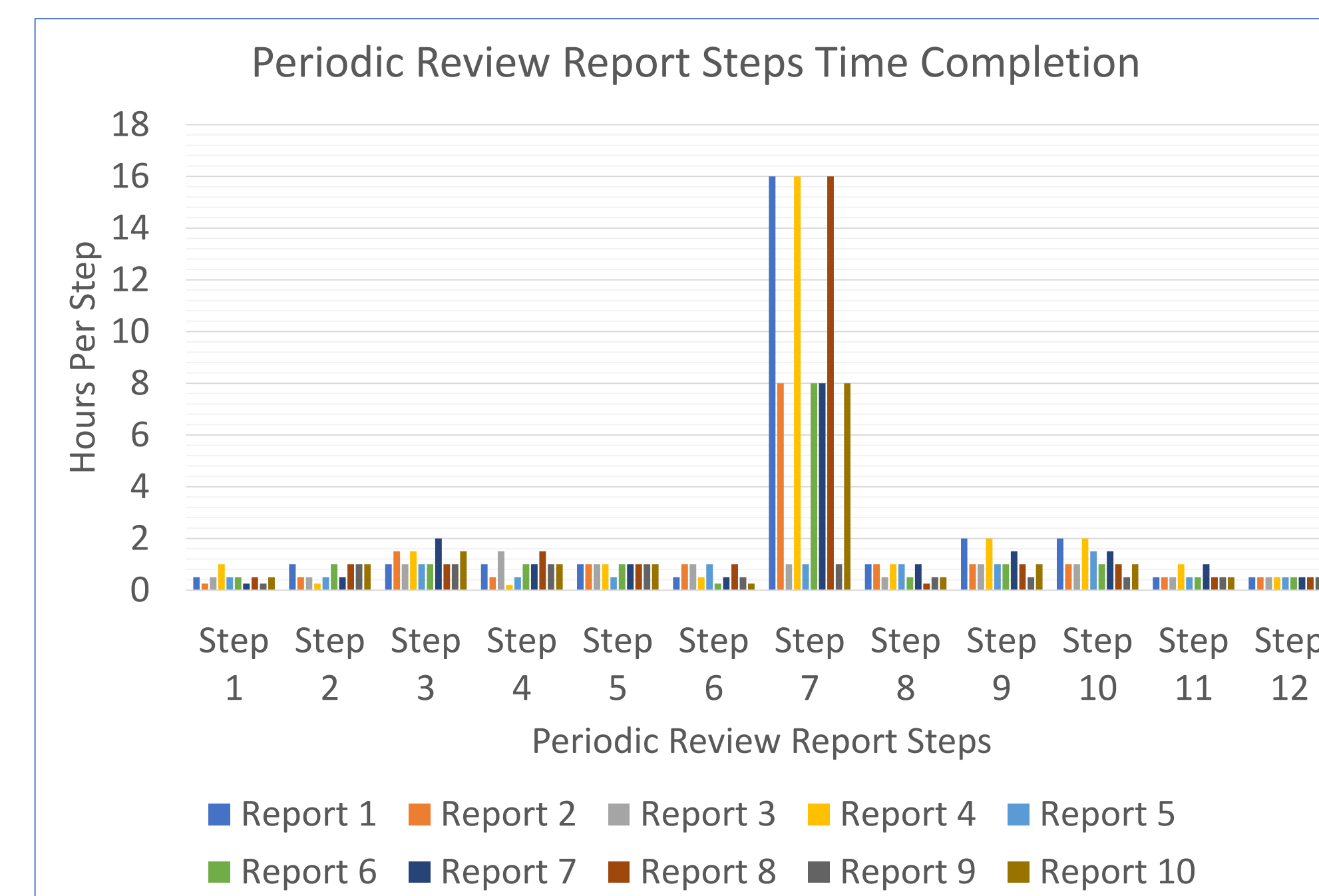


Figure 1.
Periodic Review Report Steps Completion

Improve Phase The initial problem the periodic review team faced was the lack of resources by the beginning of the year. By adding more members to the team this problem was mitigated. 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. 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 The number of resources should be maintained at four individuals executing these reports. 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.

Methodology (Cont.)

Control Phase (Cont.) 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.

Results and Discussion

The analysis regarding the process was conducted and it 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 process steps of the report it was determined an external program was affecting the completion and approval phase. That is why a harmonization between the two programs was recommended. To help keep both programs on track, an automized tool was recommended.

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.

Conclusion

The team executing these reports needs to maintain four members to guarantee a consecutive execution for these reports. A harmonization between the User Access Review and the Periodic Review Program must be maintained by scheduling their reports accordingly. An automate tool was recommended to keep track of the Periodic Reviews and at the same time aid the User Access Review Program keep in track. These changes will ensure the Periodic Review Program falls back in schedule and prevents it from falling out of schedule in the future.

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

References

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