Design of Workflow and the Identification of Waste in the Reinstatement Process

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Abstract

The reinstatement process is the procedure and has documentation of shutdown in pharmaceutical, activities that arise when a system facility fails. The documentation process involves how to return the manufacturing facilities to the controlled conditions. This documentation involves the manufacturing, validation, microbiology, quality, and maintenance-engineering departments. It was designed a workflow process diagram of the reinstatement documentation process and identified steps that involved a waste of time of motion and waiting. It was collected data on how much time passed since the microbiology department delivered its reports to the final closure of the reinstatement documentation process. The reasons that cause this waste of time involve errors in documentation, the evidence required is not complete, and people forgetting to start the process for the final approval. The project emphasized and brought a future research recommendation of developing a manufacturing electronic system to document the whole process.

Key Terms *— Documentation process, Reinstatement process, Shutdown, Waste time.*

Problem Statement

The reinstatement release process for manufacturing operations consumes much time and needs the collaboration of diverse teams. This can take hours and days until the report is completely approved. The report includes data from housekeeping, the microbiology department the results of samples, reports of sanitizations performed by manufacturing personnel, information about the status and what was performed in work orders, and data about the parameters such as temperature, pressure, and humidity that are measured in each manufacturing room.

The reinstatement document is developed in hard copy. The initial approval requires the signature of the departments mentioned previously. The offices of these departments are on different floors, and the manufacturing personnel needs to give the document to each person in the office. Also, unplanned activities can occur at any time, if occur during the night. Some of the people are in their house and need to call them for verbal approval of the document. On the final approval, all signatures are required, and each department must see all the data in the package document. This is a waste since only one person can see the document. If the industry moves to a digital process, the system can obtain the data need as microbiology sample results, housekeeping, and work order details. In a digital process, all people can see the data at any time and approve it more quickly the document and this includes approving the initial document when unplanned activities on nights or holidays.

Methodology

The reinstatement process as is right now takes hours and days in the different steps of the process. The focus of this project is to identify waste in the process and make improvements to the process. The reinstatement document is pre-approved and post-approved by five departments.

The process of reinstatement will be evaluated by observation to obtain data on how each step of the documentation process is conducted. This step involves the initialization of the document, until the final approval for closing the document package. This will allow to design of a process flow diagram to determine what type of waste time is identified and at which steps are identified. The second part of the project is to look at the reinstatement process documents that are currently open to identify how much time passes from when the microbiology department delivers its final report to the final approved date. The identification of wastes of time will be analyzed to determine their possible causes.

At the moment of identifying waste that causes it to take more time to approve the document, the investigator will analyze, compare, and introduce how a paperless system for this process can reduce the time consumed on each step.

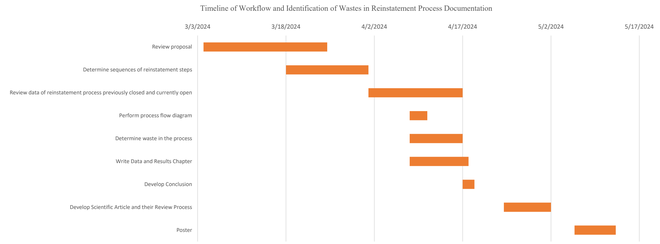

Figure 1 . Timeline of reinstatement process research.

Results and Discussion

Figure 2. Reinstatement Process Workflow

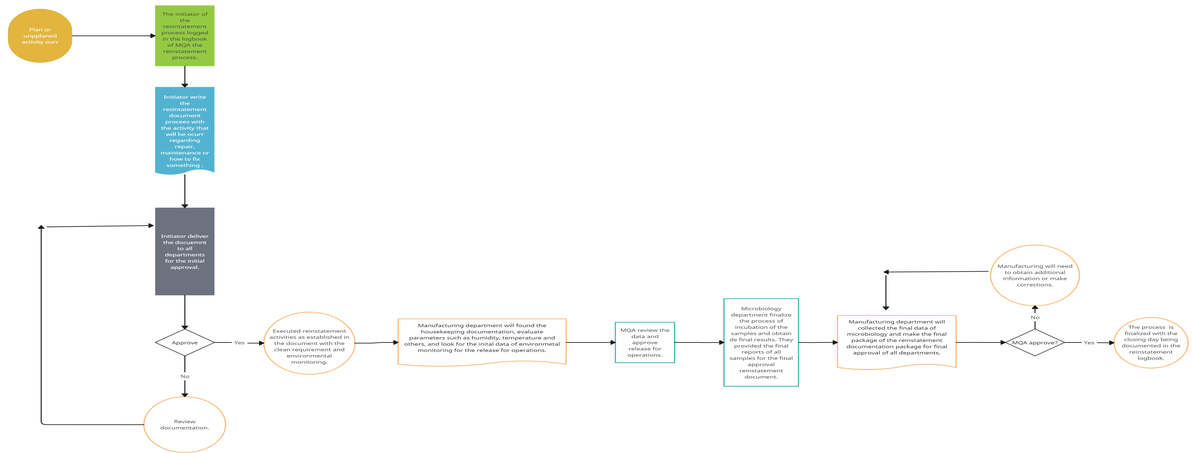

Table 1 Amount of Days Passed from the Microbiology Department to Deliver the Final Report to the Final Closure of Reinstatement Documentation

Reinstatement	Days from being Delivered Microbiology Report to Final approve
A	77
B	17
C	49
D	8
E	47
F	45
G	49
H	37
I	36

- Reasons for the amount of time for closing the reinstatement documentation process:
- That the engineering department did not close the work orders in the system. Is a requirement of the procedure that all work orders related to the reinstatement must be found in a close state in the system.
- MQA determined that some samples were not included in the final report. This means that the Microbiology department with the initiator, reviews the reports and makes others with the missing in the first report,
- The initiator forgot to start the closure. This is because the reinstatement document stays in the logbook of the MQA, and the initiator does not have it. MQA personnel need to make a reminder to the initiator to close the document.
- Errors in the process of making page control, and people are not in the plant to make corrections.
- A revision of the reinstatement was written before and during the execution of activities that changed the final documentation requirements and was not included.
- MQA finds that was not included all room's sanitizations documentation in the final documentation and the initiator must find that for including

Conclusions

This section will focus on the benefits that can be obtained by implementing an electronic manufacturing system for the reinstatement process. As demonstrated, the reinstatement process has steps that consume a lot of time, because has waiting and motion waste that can delay the process for hours and days. Also, was demonstrated that the process for closing the reinstatement took on average forty days in the data presented. The most probable reason for this number of days is that people forgot to manage the documentation and the errors in the documentation as presented in the previous section. These errors are made, because all documentation is in hard copy and is not being reviewed electronically which will omit the errors performed in sample reports and sanitization that are not included in the documentation package.

One goal of this project is to show the need for an electronic system to document the reinstatement process. The electronic system for this process must involve electronic data from housekeeping personnel, and communicate with the electronic system of equipment and machines for retrieving the data of their sanitization. The reinstatement document must be written in the platform and communicated with the electronic system of the microbiology department to look at the results of the samples collected as part of the reinstatement. These features described will accelerate the reinstatement of initial approval, and manufacturing releases after the activities are performed, and will send notifications to the initial approvers after obtaining the microbiology results for the final approval.

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