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.*

INTRODUCTION

The pharmaceutical industries have one procedure regarding shutdown activities, and unplanning activities, such as a rupture of a pipeline, floors that need polishing, and others. The process used on this project in a bio-pharmaceutical is called reinstatement. The reinstatement procedure involves all important departments of the manufacturing industry such as manufacturing, microbiology, validation, manufacturing quality assurance (MQA), maintenance, and engineering. These departments will evaluate the activity (ies) that will be performed under the reinstatement, what control they will take when performing the activities to minimize the risk of contamination, and how many sequences of cleaning will need to be performed to return the facility to manufacturing conditions. The return of the manufacturing process is guaranteed once the microbiology personnel take the number of samples required by the reinstatement document and their results are within parameters according to microbiology and validation procedures. The approval of release for returning to manufacturing operations is finally approved by MQA.

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 more quickly the document and this includes approving the initial document when occur unplanned activities on nights or holidays.

Research Description

The topic of the project emerges after the process of reinstatement being precise in the time consumption that takes to approve it. The project will demonstrate the need to implement the use of a digital process through a validated platform for the reinstatement process that will reduce the time of initial approval for performing the activities under the reinstatement document and the final approval for closing the document after all activities being performed and all data is collected. The project will analyze the data of the reinstatements currently and previously performed and determine the time that took for the final approval after the microbiologist completed all his reports, the manufacturing department completed the reinstatement package for the evaluation of MQA. MQA determines if all documentation is completed or if needs something else and returns the package to the manufacturing department for their completion and goes back to MQA. The data obtained will be analyzed and used to demonstrate that there a is need for the implementation of a digital process to reduce the time of closing the reinstatement document package.

Research Objectives

The objectives of the project are:

- Determine the amount of time that a reinstatement process is being closed after the microbiology department finishes its reports.
- To determine the causes of wasted time by using the hard copy process.
- Demonstrate that is necessary the implementation of a digital process.

Research Contributions

The main objective of the research is to demonstrate the importance of implementing an optimized reinstatement process. The project will demonstrate the waste of time consumption using a hard copy process. If the company implements a validated digital process the activities required as part of the process will be executed in less period, as all people involved in the initial approval of the document can be read at all times instead of only one at a time. The final closure documentation will be performed faster.

LITERATURE REVIEW

The main objective of the project is to demonstrate that the reinstatement process as being conducted has a lot of time lost as waste. The document is written on a computer, but all the signs needed, and supporting evidence are done manually. Exits seven types of waste: overproduction, unnecessary inventory, transport, process, defects, waiting, and motion [1]. The activities that are performed with these types of wastes add cost to the final product but do not change the product into one more sophistically [1]. Motion waste is the type of waste that is caused by the distance traveled by people during the operation that consumes [1]. In the reinstatement process, the document is approved by five departments, and the originator document's department must go to each office to obtain the signatures. In this step are identified motion and waiting wastes, which increase the time of approval of the document and the execution of activities. Later, during the execution of the activities related to the reinstatement, the documentation of the housekeeping personnel of the daily cleanings must be taken out of the rooms to make a copy for an attachment to the reinstatement document. This step also adds motion waste, the documentation of each room must go outside, make copies of each room, and then turn back the original to the proper rooms.

Reference [2] established that waste needs to be reduced or eliminated because they did not add value to the product and customers. The objective of the project is to demonstrate the need to optimize the documentation process of reinstatement by going through a digital process. This will help by reducing

or eliminating the wastes of motion, defects in terms of something missing in the documentation and waiting, to obtain an approval document of reinstatement, and to reduce the time of post-approval, resulting in lower time returning to normal conditions of operations.

The paperless term refers to the use of digital software for documentation. In pharmaceutical manufacturing is called Manufacturing Electronic System (MES). Reference [3] established that some advantages of the paperless system are efficient business processes, fast service, reliable document management, and productivity increases. The final goal of the project is to demonstrate that the industry organization to pursue the use of digital/paperless system documentation for reinstatement to reduce the time that took to approve it.

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.

RESULTS AND DISCUSSION

As established in the previous section, the first step of the research is the design of a workflow for the reinstatement process. It looked at the process of how the documentation of the reinstatement starts until the end, when the document has the final approval, for developing the workflow process in Figure 1. The first step of the reinstatement process is the design of a planned activity for repairing, installation of equipment, maintenance of some manufacturing equipment, or an unplanned activity that affects the conditions of the manufacturing rooms. When the activity occurs unplanned, this can happen on the night shift. This creates a waste of time in waiting for people who answer phone calls from every department (Microbiology, Validation Engineering, MQA) to obtain their evaluation and decision of the activity that occurred. In the second step, the person who will oversee the activities that will occur to return the facilities to normal condition will go to the MQA department to obtain the number of the reinstatement document. On this step, is identified motion waste, since the engineering department is located in another building, and they are most of the time the initiator of the reinstatement process. Then, in step 3, the initiator will write the activities that will be handled to reestablish the normal conditions of the manufacturing areas. In this step, the initiator needs to obtain the signatures from the other departments (Microbiology, Validation, Area owner, and MQA). If the initiator is the engineering department they need to move to the other plant and go to the first and the third floor to obtain the signatures. This is a waste of time in motion. Also, in this step, MQA can reject the document, and the initiator must add the information that MQA personnel understand is missing and then go back to obtain the signatures.

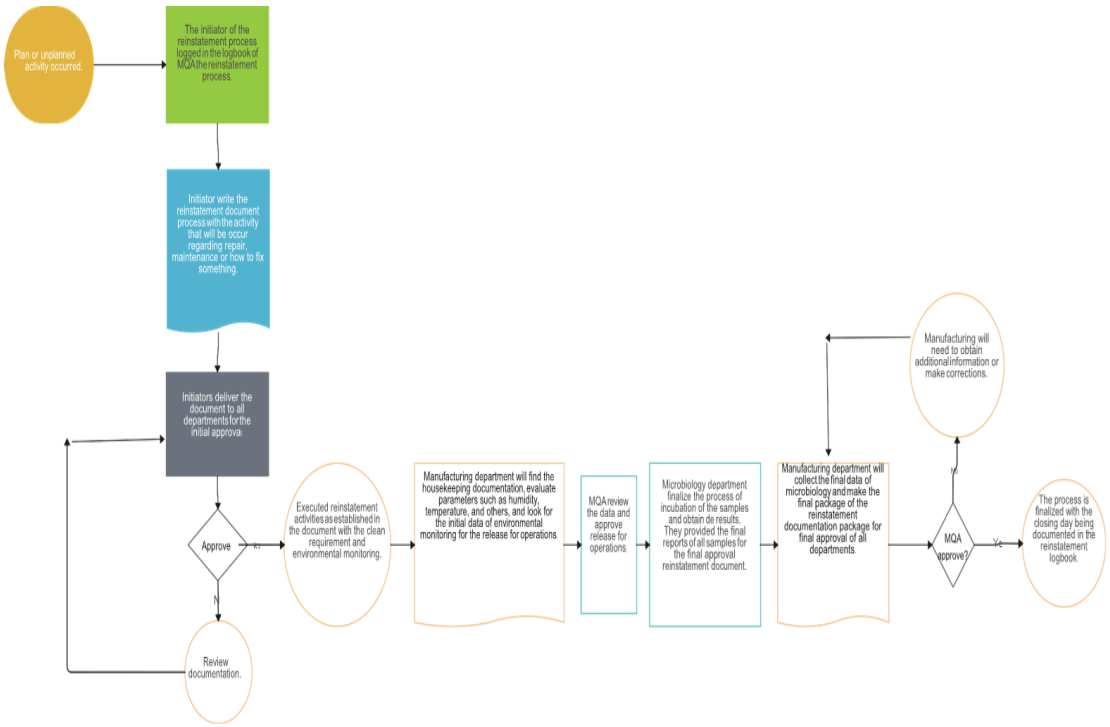

Figure 1
Reinstatement Workflow Process

After the reinstatement document's initial approval is obtained, the activities for reestablishing controls in manufacturing rooms can be executed. At the moment all activities are concluded, the manufacturing personnel start the sanitization of equipment and posterior the housekeeping personnel perform the sanitization of the rooms. After that, the microbiology department will collect samples that include particles in the air and samples for incubation. Most of the time, the release for returning to operations is performed with the results of air particles. The release document is a section of the reinstatement document and the owner needs the results of the air particle, evidence of the sanitization performed by manufacturing and housekeeping personnel, and with these, MQA evaluates the data and gives the release. The data of the microbiology department and housekeeping is hard copy, the owner area needs to obtain it. The microbiology department depends on whether they have a sample auditor on the shift to review the data for approval. This is a time-consuming step because the owner's area needs to go to every room to obtain the document of sanitization for each room and wait until the microbiology department's data is approved and they develop a document for agglomerating all samples of air monitoring for delivery to him.

After sample results of incubation were obtained, the microbiology department prepared an official report for the initiator of the reinstatement. This report is the start of the closure of the reinstatement process. When all documentation regarding the closing step is performed, the initiator will again deliver it to each department for evaluation and approval. On this step, as in hard copy, only one person can begin reviewing the data and perform the approval. This step is a time-consuming process because being performed in hard copy has waiting waste because the person from each department can perform other tasks as being in meetings makes him unable to review the document package at the moment is delivered.

The results of the analysis of eight reinstatement documentation packages for obtaining the amount of time that passed from when the Microbiology department delivered their final reports to the final approval of the reinstatement are shown in Table 1.

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

It was found that only one reinstatement was closed before passing ten days, and the data obtained was that the risk of the activities performed was medium and the impacted area was isolated rooms and not the entire plant. In the other documentation process that took from seventeen to seventy-seven days for closure, it was found that the risk classification was medium-high and high. The evaluation of risks depends on the classification of the manufacturing room, the activity needed to repair the equipment for improvement to the facility and what controls need to be taken. The risk evaluation determines the amount of sanitization that needs to be performed for the facilities and equipment and the amount of microbiology samples to collect.

The evaluation risk and the controls taken in each reinstatement process, were not the cause for the number of days that took for closure, because the quantity of days presented in Figure 1 is after the microbiology departments delivered the final reports of the samples. Some causes found during the reviewing of the reinstatement documents and conversations with people of the different departments for the amount of time for closing the reinstatement document process were:

- 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.

The waste identified during the workflow and the reasons that make the reinstatement closure process take a lot of days, are the indicators that an electronic system is needed to avoid delays in the reinstatement initial approval, manufacturing release, and final closure.

CONCLUSION

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.

FUTURE RECOMMENDATIONS

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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