Workflow Management in the Batch Record Review Process

Author: Michelle Velázquez Vázquez
Advisor: Maria M Garcia Sandoval, PhD
Industrial and Systems Engineering Department

Abstract

The review of Batch Records creates a story of the materials, manufacturing, and packaging involved in the production of biopharmaceuticals. The Master Batch Record details who, when, where, and how each process stage is carried out and how much of a product is produced. Most pharmaceutical companies need help to check batch data in time to provide medications to clients. However, a prolonged process time affects how quickly goods must be made available to the public. As a result, reviewing batch records is a laborious process that mainly occurs afterward. For the manufacturing purification processes of a chromatography column, viral inactivation filtration, viral filtration, ultrafiltration, diafiltration, and bulk filling for a high cholesterol drug, this project assesses the viability of an incremental batch record review in real-time. The DMAIC technique was used in this project's study to show how the queue time is decreased. The value-added time is increased, and other advantages.

Introduction

There are various reasons why process improvement activities are launched. Efficiency has traditionally been the main objective. A company can operate with fewer efforts thanks to increased productivity or efficiency. The system of batch record review has to be improved by the pharmaceutical sector. We need to be aware of options and resources that the business can use to boost productivity and cut costs. A batch record review is an essential tool for ensuring the quality of a pharmaceutical process. This subject is covered in many rules and standards for the pharmaceutical business, and it is a crucial stage before a Qualified Person may release a product. However, over the years, documentation has become more and more extensive, and the review can be very time-consuming.

Background

The research aims to standardize the document review process so that documentation is clear, accurate, and concise. With this, there can be a reduction of steps and resources in the document review process, safeguarding the quality of the process.

Problem

The main goal of this project was to speed up the delivery of the product onto the market by reducing the review and disposition times for batch records. The goal was to minimize batch record review from one month to seven days or less. This implemented the reduction of steps for the completion of batch record review. Another factor was to simplify the workflow cycle for the batch record review working together with all functional areas to reduce overworking the process of reviewing a batch record. This occurred by implementing controls to establish the completion of the steps in the batch record review process.

Methodology

Define Phase

For this project, the main focus was reducing the batch record review completion cycle time by working with QA, Manufacturing Associate, and all other functional areas involved in manufacturing a product. This would implement the reduction of steps for the completion of batch record review. Another factor was to simplify the workflow cycle for the batch record review working together with all functional areas to reduce overworking the process of reviewing a batch record. This would occur by implementing controls to establish the completion of the steps in the batch record review process.

Measure Phase

The following was Measured during this project:

- Alarm Assessments.
- Comments on BOM during execution.
- Data was acquired incorrectly in EBR.
- Data not obtained in EBR.
- Functional areas personnel not available.
- Communication problems between functional areas.
- Binders for supplementary documentation are only partially prepared.
- Right, First Time.
- Real-Time Review.
- Open Investigations.
- Open Work Orders.

Analyse Phase

- Evaluate different ways to perform batch record reviews.
- Perform batch record review following workflow and checklist.
- Analyze data obtained.
- Reduce cycle time by generating solution ideas and implementation requirements.

Improve and Control Phase

- Implement a simple and easy-to-execute batch record review system.
- Before effectiveness, document and train personnel.
- With project implementation, discuss final improvements and resolutior

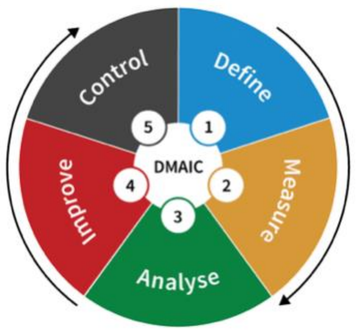

Figure 1
DMAIC Methodology

Results and Discussion

The research was carried out concerning the best batch record documentation review. The DMAIC technique was used in this project's study to show how the queue time is decreased. The value-added time is increased, and other advantages.

As part of the project, a checklist and a workflow were created as a guide in the batch record review.

Figure 2
Batch Record Review Workflow

Product: Batch #: BR ID:
SOP- FORM-
Start Date: End Date:

Batch Record Review Checklist

Task	Duration	Done	Comments
Create Binder	30 mns	☐	
Alarms in Smartsheet	1 hr	☐	
Alarm Assessments	1 hr	☐	
RT Report	15 mns	☐	
Audit Trail (Climet, Sartocheck, Solo VPE)	1 hr	☐	
Materials (Comment BOM)	10 mns	☐	
Trackwise, Maximo and Sparefox (Reference in SFO)	10 mns	☐	
Supplementary Documents	5 mns	☐	
MFG and PQA Review	5 mns	☐	
Circulate and Released	5 mns	☐	
		☐	

Figure 3
Batch Record Review Checklist

An improvement oportunity was identified during the process of Batch Record Review. According to all the analysis established in the results and discussion section, some of the batches used to execute this project had no problem releasing it in just 72 hours, following the due procedure and noting that there were no significant problems when making Batch Record Reviews. On the other hand, it was observed that there was a Batch in which the review took approximately 504 hours to complete because real-time review needed to be carried out. The real-time review help us identify the problem early in the Batch Record Review process and be able to solve it quickly. In this case, this did not happen, being released forty-eight hours before the disposition due date. This delay can cause the product not to reach the patients who need it on time for treatment.

Conclusions

One of the most crucial tasks at a pharmaceutical company is records review. These reviewers ensured that the batch was produced correctly and followed the protocol and legal standards. Reviewers must pay close attention to detail, be self-sufficient, and be well-versed in the manufacturing process they are evaluating. Reviewers should be conscious of the criticality of their work.
According to best practices, the BR must be error-proofed using a precise technique to ensure that the human and document interface is error-free. The BR should also reflect the operator's task order.

Future Work

To continue to improve the Batch Record Review process, a Sr. Associate Manufacturing created a Visual Aid to generate exceptions and a Flowchart to work with the Batch Record Review during the shift. The workflow, checklist, and visual Aid will help improve this process and will continue to find areas of opportunity and improve them.

Acknowledgements

Special thanks to Dr. Maria M. Garcia Sandoval for being my advisor during this time, Manufacturing colleagues, and functional areas such as Quality and Process Engineer.

References

[1] Schniepp, Susan. Pharmaceutical Technology. Aug 2017, Vol. 41 Issue 8, p65-66. 2p., Database: Business Source Ultimate.

[2] Solutions, M. (2022, June 30). Top 7 Benefits of Electronic Batch Records (EBRs). Merit Solutions - Empowering Growth & FDA Compliance. Retrieved from https:// meritsolutions.com/top-7-benefits-of-electronic- batch-records-ebrs/

[3] Monday, L. M. (2022). Define, Measure, Analyze, Improve, Control (DMAIC) Methodology as a Roadmap in Quality Improvement. Global Journal on Quality and Safety in Healthcare, 5(2), 44–46.

[4] PTD-400625: Evolocumab (AMG 145) HMP Purification Process Transfer Document for Commercial Manufacturing.

[5] SYDLE. (2022a, October 10). Checklist: What Are They? What Are the Benefits and How Do You Use Them? from https://www.sydle.com/ blog/.

[6] SYDLE. (2022, October 10). ¿Qué es el workflow y cómo puede aumentar la productividad? from https://www.sydle.com/.