Standard Work for Manufacturing Areas using Lean Methodology

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Abstract

Abstract *— Evaluating the structure of batch record review is an attempt to improve batch release time. Many researches have been implemented to reduce the cycle time by automating the documentation process, for example, using Electronic Batch Record (EBR). However, though the tool is offered for manufacturing process, there is still waste in cycle time for the offline Quality Assurance (QA) Batch Record Reviewer. For that, the purpose of this research was to design a standardization tool for the Batch Record review and for the reduction of the review cycle time. The principal problem was that the review process has many ways to be done and this could represent a problem since not everyone performs the batch record review in the same way. With the design of this standard work, we want to accomplish that everyone reviews with the same standard and verify the same critical parameters.*
Key Terms *— Batch Record Review, Cycle Time, EBR, Standardization.*

Introduction

In the past years, biotechnological investments in Puerto Rico have exceeded billions of dollars, in the creation of new pharmaceutical plants, new jobs and in the creation of new sources of income for the island's economy. With change and globalization in hand, biotechnology in Puerto Rico is heading towards high competitiveness in the world market. In this way, it is possible to work with greater inventiveness, while continuing to make improvements to products in order to achieve excellence in quality. It is for this reason that this investigative work focuses on the quality improvements of biotech industry on the island. In this design project you will be given an approach from the point of view of quality and continuous improvement.

For this reason, the process of constant improvement is vital for this type of company aimed at health. The purpose of this research is to design a tool that can help standardize the way Quality Assurance performs the Batch Record Review. A Standard Work tool was design as a guide to standardize the batch record review process. This is important since the batch record review is a critical part of the manufacturing process because ensures the quality and regulatory requirements are achieved. By reviewing the batch record, the Quality Assurance department has the opportunity to catch any errors before the product is released.

Background

This research work is oriented in part to investigate the history of industrial Pharmaceutical companies in Puerto Rico, when and how the biotech industries were established, the type of training that people need to work in this type of industry, the creation of new jobs and the economic contribution to the island. In addition, we will analyze the strategies used by the biotech industries such as: quality, one of the most important points of Edward Deming: constant improvement and the standards of the International Standard Organization (ISO 9000), which these industries use.
Bio-industries keep optimizing their processes. For this reason, the standardization of batch record review processes is extremely important.

Industries choose the island for the creation of their products, due to the amount of professional resources that are on the island. However, they know the quality with which these products will be created. These companies should know the terms of quality, based on quality strategies such as Edward Deming points, continuous improvement and ISO standards.

Deming's 14 Points, Quality, Continuous Improvement, and ISO 9000 are based on Shewhart's theory. These are paradigmatic; they are based on observations of what happens in industrial and service companies. Deming's observations are direct ones, hence the certainty of his knowledge [4]. Deming pointed out that top management must approve leadership as an effective way to achieve quality.

In the fifth of his 14 Points, Deming taught: "To constantly and forever improve the production and service system" [4].

It is for this reason that the biotech industries must be in a process of constant improvement, to ensure quality through the use of quality tools. When you improve a process, you in turn improve its time. In addition, this type of industry gets "feedback" from its customers on products and services. However, these industries must work on the most critical processes to determine the impact on quality.

According to reference [5], standardizing work methods reduces the probability of errors and improves baseline for continuous improvement. When the method of work varies among employees, error and wasted resources can often result. When everyone can access the current best practice for a task, it not only eliminates waste due to unshared knowledge, but also enables employees to improve the work further. When an employee learns the current best practice, they can see better opportunities to create change. When clarifying process and documenting current best practices, the benefits of standard work are numerous.

Problem

The main objective of this project is to create a tool for Quality Assurance department to standardize the batch record review, timeless of the eBR completion, approval and release, by everyone paying attention to the same details. It will consist of a Standard Work tool to reduce the waste of the Batch Record Review by everyone putting attention to the same details. Also, to reduce the Batch Record process review cycle time from 2 hours to 1 hour.

This is important since the batch record review is a critical part of the manufacturing process because ensures the quality and regulatory requirements are achieved. The situation that originated this research is that the review process has many ways to be done and this could represent a problem since not everyone performs the batch record review in the same way. With the design of this standard work, we want to accomplish that everyone reviews with the same standard and verify the same critical parameters.

Methodology

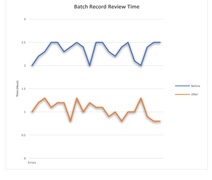
The methodology of this research consists of developing a Standard Work tool using a excel spread sheet. This tool will organize tasks to achieve stability and consistency in the daily operations also will allow identifying a process's true capability. First, we must review all the data to determine what steps are key and should remain in the review, also we will review the cycle time of the actual review. Then we create the spread sheet that will contain the specific steps that Quality Assurance team must review. By developing this tool, we will have the opportunity of write clear and precise instructions to follow for the review. We will define each task and step that is important and need to be review. After creating the spread sheet, we must set a standard time so the Standard Work becomes useful and can be measure. We will measure cycle time, waste and costs with this tool. It is important to keep in mind that the objective of measuring working times is to define the capability of a workstation. This also allows to monitor standard work to know is we must make adjustments or if it is working. At last is the implementation, after allowing people use the tool so they can start familiarizing with it and making the necessary changes, comes the implementation, and this is where the challenge is. Change the concept of how people do the review to standardize it through a Standard Work establishing a performance improvement challenge.

Results and Discussion

The purpose of this research was to standardize the Batch Record Review process of a bioindustry in the central east area of Puerto Rico. This chapter will present the results obtained throughout the study.

Reviewing the data, we found that we have an amount of data that do not add any relevance to the review process. Chart # 1 shows the amount of data previously reviewed versus the amount of data currently reviewed. Here we can see how it was possible to decrease by 57% the data that was reviewed before in the Batch Record Review. This amount of data was very high compared to the data that is now reviewed with the Standard Work tool. With this, the way in which it was going to be included in the Standard Work tool to optimize the revision was determined.

Also, we can see in Figure # 2 how the Batch Record Review cycle time decreased from 2.3 hours to 1.0 hours, this is a decrease of 1 hour and in turn we had a decrease in costs of $ 19,264 per year.



Results and Discussion cont.

With the creation of the Standard Work Tool, we reduce waste since all QAs will review the Batch Record in the same way, thus avoiding errors and, most importantly, standardizing the way to do it. Annual reviews were analyzed in terms of accumulated time.

Standard Work

Product Name: | Batch No.:
Material No.: | Start Date:

BR's	Description	Yes	No	N/A	Discrepancy / Comments
Tank Preparation	System No.: _____				
	For Tank Preparation, verify the information is recorded in the logbook is correctly and accurate.				
	Process Activity Documented correctly?				
Solution Preparation	Ensure the Batch Recipe was created correctly.				
	Confirm with the report and logbook the start time of the recipe.				
	Confirm the latest date/time the transfer out recipe should be completed.				
	Ensure transactions were performed for the required materials.				
	Ensure that the total quantities of ingredients used throughout the batch record match the actual quantities reported in the ERP system.				
	Confirm the Batch Report is attached.				
Transfer Tank Preparation	System No.: _____				
	For Tank Preparation, verify the information is recorded in the logbook is correctly and accurate.				
	Process Activity Documented correctly?				
Transfer to Supply Tank	Ensure the Transfer Recipe was created correctly.				
	Confirm with the report and logbook the end time of the recipe.				
	Ensure preparation time acquire is within limits of the eBR.				
	Ensure the Final Volume meets acceptance criteria as specified in the eBR.				
Sampling	Confirm samples were collected according to the corresponding sample plan.				
	Ensure equipment is calibrated and standardized within the correct range.				
	Confirm the test results are within limits.				
Good Receipt Information	Ensure that Expiration dates assigned to the solution is correct.				
	Confirm the actual yield data meets acceptance criteria as specified in the eBR.				
	Confirm the Label is attached.				
Batch Record Review	Review all "Events/Exceptions".				
	Ensure all the supporting documentation attach is reviewed, present and complies with good documentation practices.				
	Confirm the reports contain the correct product batch number.				
	Confirm all materials are released and used within expiration date.				
	MFG and QA reviewer must sign the applicable checklist including the supporting documentation.				

A Batch Record from a manufacturing area was used as a sample to determine opportunities for improvement.

In addition, the results of the changes made in the process were evaluated, in order to establish the vital characteristics to which it is important to pay attention. A trend between the reviews could be observed, indicating that the greatest potential is the review cycle time since there was no standardization tool as a guide and each QA towards the review in their own way and of the entire process, whether relevant and irrelevant items in the review. Though the goal was to reduce cycle time by three (1) hour, it is safe to establish that modifying the Batch Record Review with a Standard Work for QA advantage will help reduce BR cycle time.

Number of Times Use	Time Before Standard Tool	Time to Complete the Revision
1	2	1
2	2.2	1.2
3	2.3	1.3
4	2.5	1.1
5	2.5	1.2
6	2.3	1.2
7	2.4	0.8
8	2.5	1.3
9	2.4	1
10	2	1.2
11	2.5	1.1
12	2.5	1.1
13	2.3	0.9
14	2.2	1
15	2.4	0.8
16	2.5	1
17	2.1	1
18	2	1.3
19	2.4	0.9
20	2.5	0.8
Standard Time Set = 1.0 hour	Average Time = 2.3 hours	Average Time = 1.0 hour

Conclusions

The biotechnology industry in Puerto Rico has been on the rise in the last decade, being a world center for the manufacture and export of medicines. These industries are redesigning their processes daily to optimize them. Quality and continuous improvement are key to optimizing these bio-industries. As the purpose of this research, optimization of one of the most important processes to ensure quality, such as the Batch Record Review, was achieved.

This research sought to optimize and standardize the way the Batch Record Review is carried out. After carrying out the necessary studies to optimize this process, it was identified that it could be improved by just creating a tool where it specified what had to be reviewed. In this way, the process was optimized, reducing the review time to continue with the biopharmaceutical production batches in less time. In summary, given the findings, this research was successful since its objectives, optimization and standardization of the Batch Record Review process were achieved.

Future Work

- Develop tools to standardization of all areas.
- Reduce BR documentation by adding verification signatures in EBR during the in-line process.

There are many opportunities in eBR system's design that can be an advantage for QA.

Acknowledgements

I want to thank and recognize the support from my family and professors throughout my journey in Manufacturing Competitiveness graduate program. Also, I want to thank my project advisor Dr. Rafael Nieves for his availability, commitment, dedication and passion for teaching and directing me in this journey.

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Gantt Chart

Task Name	Duration	Planned Start Date	Planned Finish Date	Percent Complete
Research design and planning	3 days	3/2/20	3/4/20	100%
Finalize research problem/questions	1 day	3/2/20	3/2/20	100%
Develop research design	1 day	3/3/20	3/3/20	100%
Prepare research proposal	1 day	3/4/20	3/4/20	100%
Literature Review	7 days	3/9/20	3/16/20	100%
Search and synthesize relevant literature	4 days	3/9/20	3/13/20	100%
Prepare draft literature review	3 days	3/13/20	3/16/20	100%
Data collection	9 days	3/17/20	3/26/20	100%
Develop data collection instrument (Standard Work Tool)	3 days	3/17/20	3/20/20	100%
Pre-test/pilot data collection instrument	3 days	3/21/20	3/23/20	100%
Data Collection	3 days	3/24/20	3/26/20	100%
Data analysis	5 days	3/27/20	4/1/20	100%
Prepare data for analysis	1 day	3/27/20	3/28/20	100%
Analyze data	2 days	3/29/20	3/30/20	100%
Draw conclusions/ recommendations	2 days	3/31/20	4/1/20	100%
Writing up	12 days	4/2/20	4/14/20	66%
Final draft of report	3 days	4/2/20	4/4/20	100%
Review draft with supervisor	5 days	4/5/20	4/10/20	100%
Final editing	3 days	4/11/20	4/14/20	100%
Final submission	1 day	4/14/20	4/14/20	100%