Improve the flow of sample analysis of manufacturing batches to reduce time and increase the capacity of the process.

Author: Vilmaris Colón Torres
Advisor: Rafael Nieves, Pharm.D
Industrial Engineering- Manufacturing Competitiveness

Abstract

This Research will focus on analyzing the flow of sample analysis of manufacturing batches to reduce time and increase the capacity of the process in the laboratories. A laboratory in the pharmaceutical industry receives many samples daily from manufacturing. This research aims to find how to mitigate the waste time factors in the flow of sample analysis in laboratories. With the incorporation of the new software, the laboratory can analyze many samples and use the equipment at a higher capacity and in less time. A significant improvement in the "takt time" of the process was observed from 50 minutes to 30 minutes. In turn, the flow of analysis of laboratory tests had an increase of 47%. Regarding the annual cost of licenses, a saving of $3,777 were obtained.

Introduction

This project Support and contributes to maximum efficiency in sample analysis in laboratories at an industrial level. In a company in which one of its goals is to provide quality products to its patients, it is essential to have an excellent quality department, and the Quality Control laboratories are part of that department. The contribution of these QC laboratories is of the utmost importance to provide quality products to clients or patients. With this project, the laboratory can analyze many samples and use the equipment at a higher capacity and in less time. This would represent significant improvements in the flow of processes and a decrease in waiting time. In an overview, the project seeks to install new software on specific laboratory equipment which were previously selected in order to maximize efficiency, reduce batch analysis time and reduce costs. The following are some of the advantages that this project will have. Create an individual's account: With this, it will be possible to enter new samples by different analysts without affecting the analysis of the other samples. Mitigate the waste of time: The flow of sample analysis in laboratories can be improved. Lower costs: Licenses for using this software are cheaper than the current software version available on the computer. Data integrity: Individual accounts for each user, the data is protected, and an individual analysis can be done (Audit trail).

Background

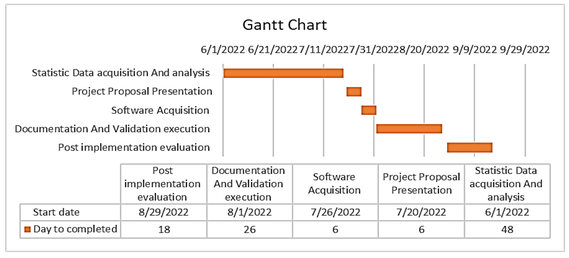
This project seeks to increase the flow of sample analysis in pharmaceutical industry laboratories. To achieve this project's objectives, we will use a Software (Transparent Screen Lock) that will be integrated into laboratory equipment to increase the capacity of the equipment. It is important that this software complies with the regulations of the pharmaceutical industry 21 CFR Part 11 code of federal regulations. In the US, the federal Food and Drug Administration (FDA) uses the rules in 21 CFR Part 11 to evaluate and enforce data integrity requirements for electronic records and signatures in drug manufacturing operations [1]-[5].

Problem

A deficiency was identified in the sample analysis flow process. The laboratories reported a significant number in the backlog of samples to be analyzed. Using the lean "standard work" methodology, a Takt time analysis was carried out to identify areas for improvement in our processes and to see how our Takt time could be reduced. With the integration of our new software, we seek to maximize the capacity to use laboratory equipment, minimize analysis time and, in turn, ensure compliance with 21 CFR part 11 regulations.

Methodology

Statistical analysis, implementation of lean manufacturing methodology, and validation processes were carried out to complete our project.



	Post implementation evaluation	Documentation And Validation execution	Software Acquisition	Project Proposal Presentation	Statistic Data acquisition And analysis
Start date	8/29/2022	8/1/2022	7/26/2022	7/20/2022	6/1/2022
Day to completed	18	26	6	6	48

Results and Discussion

For June and July, data was taken to compare the number of samples received by the laboratory vs. those analyzed.

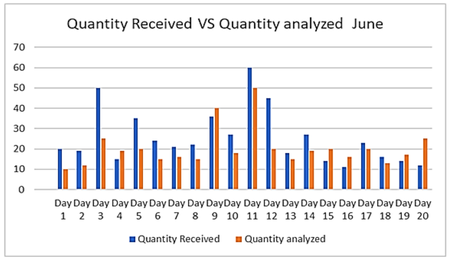


Figure 1
Quantities of sample received vs. analyzed (June)

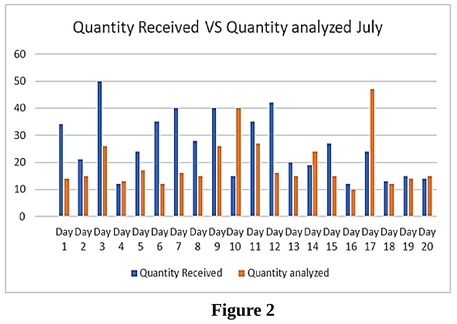


Figure 2
Quantities of sample received vs. analyzed (July)

Results and Discussion

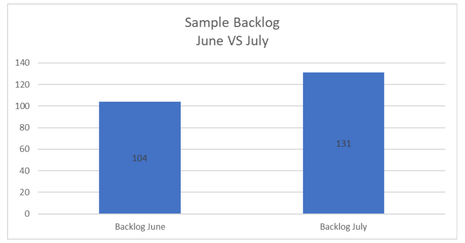


Figure 3
Sample Backlog

This graph shows the criticality level found in the flow of sample analysis in the laboratories. When comparing the samples received and analyzed (Figure 1) (Figure 2), we note that the number of Samples received is more significant than those analyzed. In these graphs, we can see the number of samples in backlog each month. For June, an amount of 104 samples were obtained in the backlog. On the other hand, for July, 131 backlog samples were obtained.

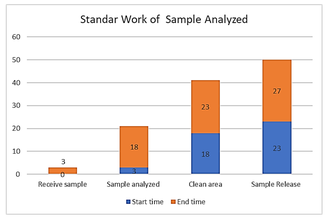


Figure 4
Takt time (Pre- implementation)

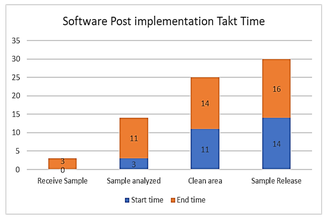


Figure 5
Takt time (Post implementation)

As seen in the graph (figure 5), the total time from when the samples are received until they are released is 30 minutes; this shows us the "takt time" of the process. Here we can observe a decrease in time compared to the data obtained in figure 4 with a "takt time" of 50 min.

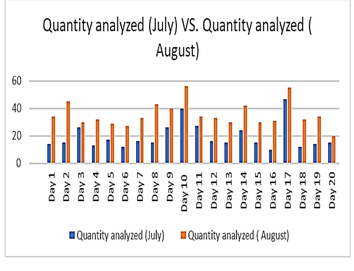


Figure 6
Quantity of sample analyzed Pre vs Post implementation

The number of samples analyzed by the laboratory in August exceeds those analyzed in July. Based on the data presented, the increase in the flow of sample analysis was a significant one.

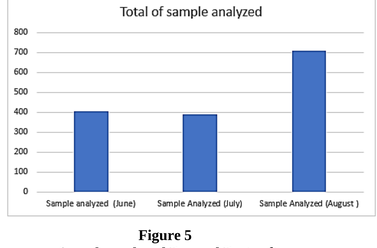


Figure 5
Sample analyzed Pre and Post software implementation

As we can see, the flow of analysis presents a significant increase of 47% in the flow of analysis of samples in our laboratory. The data is obtained based on the three shifts, which is equal to 24 hours of work in the laboratories.

Results and Discussion

Table 1
Annual economic impact

Annual license fee	
Old Software	New Software
$ 580.00 each	$ 67.45 each
x 10 (license) = $ 5,800	x 10 (license) = $2,023
Total Annual Savings	$ 3,777

*Data based on licenses purchased for TOC instrument.

Based on the calculations obtained, our new software not only complied with the regulations required in the pharmaceutical industry but also had a positive economic impact, since the company acquires savings of $3,777 annually.

Conclusions

The purpose of carrying out this project was to create an evaluation of productivity in the analysis laboratories of the pharmaceutical industry. It seeks to identify if there is indeed a need for improvements in the sample analysis flow process. As an improvement, we identify a new software to implement (transparent screen lock). The advantages of implementing this new software are as follows: software implementation is more cost-effective, unauthorized access to analysis systems is prevented, multiple user accounts can be created all these accounts are 21 CFR compliant Part 11 code of federal regulations, which guarantees a quality standard and compliance with data integrity. A comparison of the number of samples analyzed pre- and post-implementation of our new software were made there was a significant increase of 47% in the number of samples analyzed after the implementation of the new software. Another factor analyzed was the Takt Time of the sample analysis process. Initially, our Takt time was 50 minutes, after the implementation, a reduction in our Takt time was obtained with a total of 30 minutes. Both the increase in the flow of analysis and the reduction in Takt time observed in our data, we can conclude that indeed our software created improvements in our process as expected.

Future Work

The next year it is expected to integrate the software into 5 additional units of TOC equipment. In addition, in the future, an analysis of the laboratory equipment compatible with our software will be carried out in order to implement a new productivity project in the same way.

References

[1] U.S. Food and Drug Administration. 2022. Part 11 Electronic Records Electronic Signatures Scope and Application. [online] Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application> [Accessed 21 May 2022].

[2] Resources.perkinelmer.com. 2022. Data Integrity and CSV Compliance Solutions for Drug Manufacturers. [online] Available at: <https://resources.perkinelmer.com/lab-solutions/resources/docs/WHT-167896-Data-Integrity-and-CSV-ComplianceSolutions-for-DrugManufacturers.pdf> [Accessed 20 May 2022].

[3] Ramachandran, J., 2022. Designing Security Architecture Solutions Library PUPR | Database Login. [online] Ezproxy.pupr.edu. Available at: <https://ezproxy.pupr.edu:2408/ehost/ebookviewer/ebook/bmxlYmtfXzc0MTE5X19BTg2?sid=b64f66bd-2521-463d-b5bb-37cf81c549d4@redis&vid=0&format=EB&lpid=lp_i&rid=0> [Accessed 21 May 2022].

[4] Ibm.com. 2022. IBM Docs. Transparent Screen Lock support in Windows 7 and later [online] Available at: <https://www.ibm.com/docs/en/samfess/8.2.2?topic=features-transparent-screen-lock-support> [Accessed 15 May 2022].

[5] E-motional.com. 2022. e-motional.com software -- Transparent Screen Lock Windows. [online] Available at: <https://www.e-motional.com/TScreenLock.htm> [Accessed 21 May 2022].