Implementation of an Optimized Electronic System in a Manufacturing Industry

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Abstract *— The pharmaceutical industry plays a vital role in global health, improving people's wellbeing, so time delivery is critical. That is why companies are implementing automation in their processes. Hence, this research project intended to enhance productivity within a pharmaceutical company by implementing an optimized electronic system. The focus was to keep the deviation rate at 7% or below and keep consistent cycle times. Data from 2022 was analyzed, and it exhibited high deviation rates and cycle times that were not consistent, indicating the need for improvement. Upon the implementation, results showed that the deviation rate remained below 7%. In addition, cycle times remained stable and low. A comparison of pre-and post-implementation data revealed significant improvements in both deviation rates and cycle times. However, continuous monitoring is crucial to validate the sustainability of these improvements and to identify possible trends and further improvements in the process.*

Key Terms *— Cycle Time, Deviation Rate, Manufacturing Electronic Systems, Process Improvement.*

INTRODUCTION

The pharmaceutical industry is responsible for the production and distribution of medications that impact people's health. Therefore, it is important to keep a constant flow of products without impacting the production time. To maintain the flow, it is essential to have standardized and optimized processes.

The overall product flow in the pharmaceutical where the researcher work is the following: drug preparation, filling process, inspection of the product, and packing. It has been observed that when the product arrives at the inspection area, it arrives with incomplete units. These discrepancies cause the inspection process to stop to conduct investigations and find the root cause of the discrepancies. Once the investigation is closed, the batches have to be reprocessed, which causes a delay in production. Therefore, the main purpose of this project is to optimize an electronic system that automatically enters the number of units per box into the system and generates labels with the total quantity. This will reduce the discrepancy of units found in the inspection area probably caused by human errors and will avoid stoppages, maintaining a continuous flow of the process.

LITERATURE REVIEW

Pharmaceutical industries are sectors focused on researching, developing, making, and delivering medicines and medical equipment. They "are playing an extreme important role in global health system by diagnosing, curing, treating, and preventing diseases" [1]. These industries contribute to economic growth and scientific progress and help to make life better, by improving people's well-being all around the world.

To be able to improve people's well-being, these industries have to time delivery. Time delivery in the pharmaceutical industry is important because it directly impacts the patient's health. This is because these patients depend on a consistent supply of drugs or medical devices to manage conditions or recover from illness. Therefore, a delay in this delivery can risk patient outcomes and even be lethal in some cases. In addition to the impact that time delivery has on patient's health, it also has an impact on the loyalty of customers and staying competitive internationally [2].

According to an article from the journal Review of Management & Economic Engineering,

"two of the biggest challenges for the manufacturing company are to fulfill the customers increased demands and to keep a high level of competitiveness on the market by increasing the level of productivity and efficiency" [3]. Also, in a manufacturing company, each step in the production and distribution process is important and demands attention to detail to ensure safety, efficacy, and compliance. Therefore, one way of increasing the level of productivity and efficiency without affecting safety and quality is by optimizing the processes.

One of the most transformative approaches to process improvement is to change the processes from manual to automatic. The automation process "is often seen as a tool to use when trying to go leaner, reduce waste, and optimize the production process" [4]. Transitioning from a manual process to an automatic one can significantly reduce cycle time in pharmaceutical industries and boost productivity. This is because manual processes sometimes cause delays and inefficiencies in the process because the processes depend on human interventions, which can be prone to errors because they are likely to fatigue or have distractions. Thus, when the processes are changed from manual to automatic, it eliminates delays in the process by using technology to make things run smoother and with more consistency, boosting productivity.

A report from the Zapier Editorial Team conducted a survey to find out if automatic or manual processes are used in their workplace and how both processes impact their productivity. The following are some of the key findings that the Zapier Editorial Team stated:

- 88% of small business owners say automation allows their company to compete with larger companies.
- 2 out of 3 knowledge workers say automation has helped them be more productive at work.
- 65% of knowledge workers are less stressed at work because they automate manual tasks [5].

This improvement in productivity is what the companies are looking for, and it can be measured by using cycle time. Cycle time is a crucial parameter that helps to optimize whenever the manufacturing sector seeks to enhance efficiency, productivity, reduce costs, and improve responsiveness to customers [6]. According to Lean Scape, cycle time is defined as the total amount of time required to complete an individual process or task from start to finish [7].

But changing the processes from manual to automatic does not only benefit to improve productivity and reduce the cycle time; it also reduces errors in the process that cause deviations. Deviations are defined as "any unwanted event that differs from the approved processes, procedures, instructions, specifications, or established standards" [8]. Deviations can happen when manufacturing, packing, sampling, and testing drug products [8]. It can be measured with a deviation rate, and companies want to keep deviations low because it means they are doing things right. A tool to monitor the errors in the processes is the deviation rate.

To keep a low deviation rate, it is best to have a controlled workflow in manufacturing processes. Manufacturing processes can be defined "as a sequence of consecutive process steps that are performed on some input in order to produce an output [9]. To ensure smooth and automatic manufacturing processes, electronic systems like Manufacturing Execution Systems (MES) are used. MES are software tools that help companies make things better and faster, while maintaining quality and efficiency [10]. This software works by connecting different parts of the company, like people and machines, to keep track of what is happening and make sure everything works well together [10].

In conclusion, people live in an automatic era, and to stay competitive in the pharmaceutical sector, automation is essential to boost the efficiency of its processes. Switching from doing things by hand to using automatic systems helps companies to reduce their cycle times by speeding

up the processes. Automation, besides improving efficiency, also improves consistency and data management, helping companies to keep up with the changing market while maintaining the highest standards of quality and safety. In addition, automation helps to reduce human errors and deviations in the processes, which contributes to cost savings and improves overall competitiveness. As pharmaceutical work keeps changing, using automation will definitely remain a cornerstone of success for companies that want to continue growing. Therefore, considering the importance of automation in pharmaceutical industries, this research project attempts to reduce the deviation rate (keeping it in 7% or below) and cycle time in a pharmaceutical company by implementing an optimized electronic system.

METHODOLOGY

To develop the research project and accomplish the objectives established about how the implementation of an optimized electronic system can boost productivity by reducing reprocessed lots and minimizing stoppages in the production flow, the following methodology was used:

- Understand current challenges and processes by gathering data on the number of reprocessed lots, reasons for reprocessing, and the frequency and causes of stoppages.
- Define key metrics as deviation rate, cycle time and ANOVA.
- Train operators, managers and quality personnel by providing comprehensive training on how to effectively use the news features in the electronic system to minimize reprocessed lots and manage production schedules.
- Implement the optimized electronic system that consist in shifting a process from manual to automatic.
- Ensure that the electronic system is well integrated into the existing system and production environment.
- Collect data of discrepancies found after shifting the process from manual to automatic.
- Analyze the data collected before and after the implementation to compare the deviation rate and cycle time.
- Prepare a summarized report/presentation about the methodology, data collected, analysis conducted, and the results obtained.
- Illustrate how the optimized electronic system has positively influenced productivity by reducing discrepancies found in lots and minimizing stoppages, leading to on-time delivery.

RESULTS AND DISCUSSION

This research project attempted to improve productivity in a pharmaceutical company by implementing an optimized electronic system. To achieve this, the researcher collected and analyzed the data of lots inspected and discrepancies found in units during the year 2022 (see Graph 1 and Graph 2). Then, implemented the optimized electronic system and collected the same data from December 18, 2023 to March 31, 2024 (see Table 1). Metrics such as cycle time and deviation rate were used to measure productivity and compare it after the electronic system optimization.

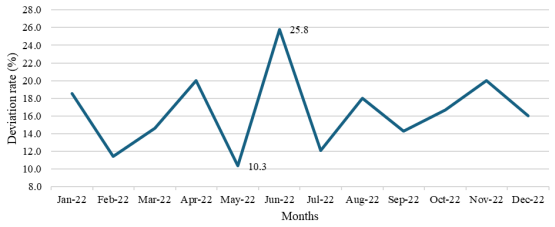
Table 1

Data recollected from Dec 18, 2023 - Jan 19, 2024

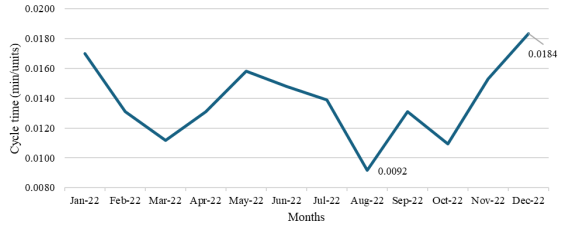
Month	Lots inspected	Discrepancies found	Deviation rate (%)	Cycle time (min/units)
Dec-23	20	1	5	0.0102
Jan-24	40	2	5	0.0093
Feb-24	43	0	0	0.0095
Mar-24	47	1	2	0.0094

From Graphs 1 and 2, the researcher can conclude that the deviation rate and cycle time were not consistent; that is, it did not have an increase or reduction pattern. During 2022, the deviation rate was high, with the highest at 25.8% and the lowest at 10.3%. In this project, the researcher attempt to maintain a deviation rate of 7% or below by implementing an optimized electronic system. Something similar occurred with the cycle time. Since the process was manual, human errors were

inevitable, causing stoppages in the process and, therefore, a lack of consistent cycle time. The lowest cycle time achieved in 2022 was 0.0092 min/units, and the highest was 0.0184 min/units. After the implementation, the researcher observed a reduction in stoppages, which will lead to consistency in the cycle time.

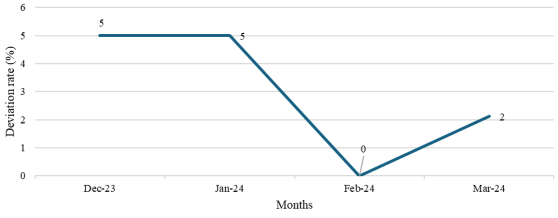


Graph 1
Deviation rate during 2022



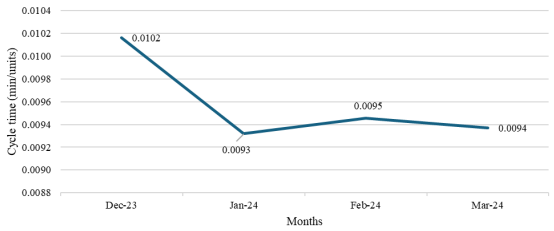
Graph 2
Cycle time during 2022

Graph 3, show the deviation rate behaved from December 2023 to March 2024. It is clear that, after the implementation of the optimized electronic system, the discrepancies found in the lots inspected were reduced. This reduction can be observed in the deviation rate (7% or less could be maintained). The highest deviation rate observed was 5%, and the lowest was 0%. This means that changing process from manual to automatic worked, and it is shown in the data collected.



Graph 3
Deviation rate from December-23 to March-24

In terms of cycle time, Graph 4, show how the cycle time behaved once the process has been optimized by converting a manual process into an automatic one. This division went from a cycle time of 0.0102 min/units in December 2023 to a cycle time of 0.0092 min/units in March 2024. Although the reduction is not constant, it has more consistent cycle time compared to the data from 2022. This consistency can be attributed to a more structured process with fewer external factors (human errors) that can affect the cycle time by causing stoppages in the process. This reduction is beneficial to the pharmaceuticals because now they can have a well-established workflow that contributes to having a faster process, which leads to faster delivery and meeting customer demands.



Graph 4
Cycle time from December-23 to March-24

Furthermore, to confirm that the implementation of the optimized electronic system was beneficial for the process and see if there is a statistically significance difference in the deviation rates and cycle times after the implementation, a hypothesis test was carried out. To measure if changing from manual to an automatic process was significant, the data collected was analyzed by analysis of variance (ANOVA) using Minitab.

The ANOVA results (Figure 1) show that there is a significant difference in means between the groups tested for deviation rate. The *p*-value obtained was 0.0000, which is less than the significance level of 0.05. Therefore, there is strong evidence to reject the null hypothesis and conclude that the implementation of the optimized electronic system is statistically significant and helps to reduce the deviation rate. In addition, the *F*-statistic of 33.48 supports the conclusion that there was differences in the deviation rated between the data analyzed since in ANOVA, a large *F*-statistics indicated that the variance between group means was greater than the variance within groups [11].

The ANOVA results (Figure 2) indicated that there are significant differences in cycle time between the groups analyzed. The *p*-value obtained for the cycle time of 0.007 was less than 0.05. This indicates that the cycle time between methods differ significantly. In addition, the *F*-statistic of 9.85 was high, which means that the differences between group averages were bigger than the differences within each group [11]. Therefore, the researcher rejects the null hypothesis that all means are equal and concluded that the change from manual to automatic helped to reduce the cycle time and keep it constant.

Method

Null hypothesis	All means are equal
Alternative hypothesis	Not all means are equal
Significance level	α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Factor	2	Old, New

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	1	544.7	544.73	33.48	0.000
Error	14	227.8	16.27		
Total	15	772.5			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
4.03363	70.51%	68.41%	63.54%

Means

Factor	N	Mean	StDev	95% CI
Old	12	16.47	4.37	(13.98, 18.97)
New	4	3.00	2.45	(-1.33, 7.33)

Pooled StDev = 4.03363

Figure 1
One-Way ANOVA for the Deviation Rate: Old, New

Method

Null hypothesis	All means are equal
Alternative hypothesis	Not all means are equal
Significance level	α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Factor	2	Old, New

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	1	0.000054	0.000054	9.85	0.007
Error	14	0.000077	0.000005		
Total	15	0.000130			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.0023393	41.29%	37.10%	29.92%

Means

Factor	N	Mean	StDev	95% CI
Old	12	0.013815	0.002631	(0.012367, 0.015264)
New	4	0.009577	0.000396	(0.007069, 0.012086)

Pooled StDev = 0.00233927

Figure 2
One-way ANOVA for the cycle time: Old, New

CONCLUSIONS

This research project aimed to enhance productivity within a pharmaceutical company by implementing an optimized electronic system, with a focus on keeping the deviation rate in 7% or below and maintaining consistent cycle times. Analysis of data from 2022 revealed fluctuating deviation rates and cycle times, indicating the need for improvement.

After implementing an optimized electronic system that shifted the process from the manual to reduce the deviation rate and the stoppages generated in the process, the results demonstrated that the deviation rate can be kept below 7%, with the highest deviation rate at 5% in December-2023 and January-2024. In terms of cycle time, it was observed that it remained low and much more stable when compared to the 2022 data.

This reduction helps the efficiency of the process by finish on schedule and meeting customer demands.

Comparing data before and after the system was implemented, the researcher can see significant

improvements in both deviation rates and cycle times. However, it is important to remember that the project have a limited timeframe due to holiday shutdowns and the time to collect the data, so the researcher needs more time to keep studying this over a longer time to really understand if the improvement persists. Continuous monitoring of these metrics is crucial for identifying trends that can help to continuously improve the efficiency of the process.

REFERENCES

[1] J. Ni et al., "Obstacles and opportunities in Chinese Pharmaceutical Innovation," *Globalization and Health*, vol. 13, no. 1, 2017. [Online]. Available: doi:10.1186/s12992-017-0244-6. [Accessed: October 20, 2023].

[2] A. Troncoso-Palacio et al., "Using discrete-event-simulation for improving operational efficiency in laboratories: A case study in pharmaceutical industry," Lecture Notes in *Computer Science*, pp. 440–451, 2018. [Online]. Available: doi:10.1007/978-3-319-93818-9_42.

[3] J. Buchholzer and M. Gilbert, "Production Cost Savings Through Managing Process Automation in Manufacturing Companies. Case Study: A Romanian Automotive Airbag Manufacturer," *Review of Management & Economic Engineering*, vol. 21, no. 4, pp. 344-350, 2022. [Online]. Available: https://www.rmee.org/abstracturi/86/09_Articol_652_2nd%20Article%20Marc%20Buchholzer%20revised%20220220927_revizuit_03_10_2022.pdf [Accessed: October 14, 2023].

[4] P. Waurzyniak, "Lean Automation," *Manufacturing Engineering*, vol. 142, no. 2, pp. 65-72, 2009. [Online]. Available: https://www.sme.org/technologies/articles/2009/lean-automation [Accessed October 5, 2023].

[5] Zapier Editorial Team, "Zapier Report: The 2021 State of Business Automation," *Zapier*, 2021. [Online]. Available: https://zapier.com/blog/state-of-business-automation-2021/. [Accessed: October 15, 2023].

[6] T. Vhora and I. Taifa, "Cycle time reduction for productivity improvement in the manufacturing industry," *Journal of Industrial Engineering and Management Studies*, vol. 6, no. 2, pp. 147-164, 2019. [Online]. Available: https://doi.org/10.22116/JIEMS.2019.93495.

[7] R. Pannell, "What is cycle time?," *Leanscape*, November 18, 2022. [Online]. Available: https://leanscape.io/what-is-cycle-time/. [Accessed: April 18, 2024].

[8] B. Ahmed, "Deviations in the Pharmaceutical Industry," *EMMA International*, March 16, 2022. [Online]. Available: https://emmainternational.com/deviations-in-the-pharmaceutical-industry/. [Accessed: April 18, 2024].

[9] A. Lokrantza, E. Gustavssona, and M. Jirstrand, "Root cause analysis of failures and quality deviations in manufacturing using machine learning," *Procedia CIRP*, vol. 72, pp. 1057-1062, 2018. [Online]. Available: https://doi.org/doi.org/10.1016/j.procir.2018.03.229. [Accessed: April 18, 2024].

[10] C. Finch, "What is a Manufacturing Execution System (MES)?," *QAD*, August 24, 2022. [Online]. Available: https://www.qad.com/blog/2022/08/what-is-mes-manufacturing-execution-systems. [Accessed: April 18, 2024].

[11] The Edanz Team, "ANOVA Explained: How to compare differences of means," *Edanz Innovative Scientific Solutions*, May 18, 2023. [Online]. Available: https://www.edanz.com/blog/anova-explained. [Accessed: April 10, 2024].