



Author: Lyannis M. Garcia Santos

Advisor: Jose A. Morales, Ph.D.

Industrial and Systems Engineering Department

Abstract

The pharmaceutical industry plays a vital role in global health, and to improve people's well being, time delivery is essential. 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.

Introduction

We live in an automatic era, and to stay competitive in the pharmaceutical sector, automation is essential to boost the efficiency of its processes. Transitioning processes from manual to automatic by using automatic systems helps companies to reduce their cycle times and improve efficiency by speeding up the processes. This transition also helps to improve 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. Therefore, automation will be definitely remaining a cornerstone of success for companies that want to continue growing since automation has become an integral part of our lives.

Background

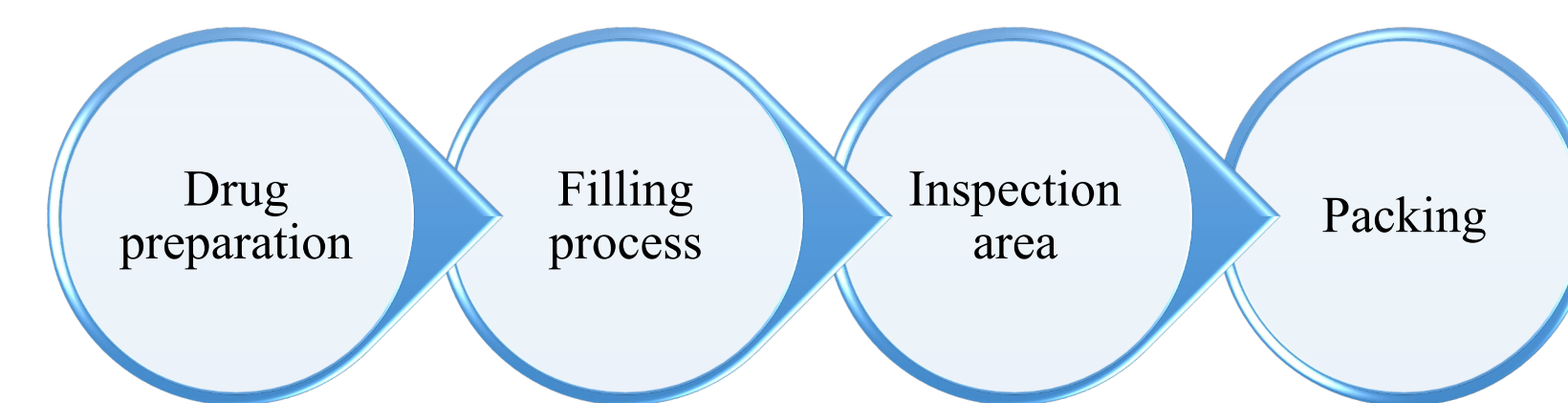
According to an article from the journal Review of Management & Economic Engineering manufacturing companies faces two major challenges:

- fulfill the customers increased demands.
- maintaining competitiveness in the market by improving efficiency and productivity [2]

One way of increasing the level of productivity and efficiency without affecting safety and quality is by optimizing the processes. Transitioning from manual to automatic processes in pharmaceutical industries cuts down cycle time and boost productivity. Manual processes sometimes cause delays and errors due to human interventions. Automation removes these delays and errors by using technology to make things run smoother and with more consistency.

Problem

The overall product flow in the pharmaceutical where I work is the following:



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, usually are cause by human errors. 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 so that it automatically enters the number of units per box into the system and generates labels with the total quantity. This will help to keep the deviation rate in 7% or below and maintaining consistent cycle times.

Methodology

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.

TRAINING

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.

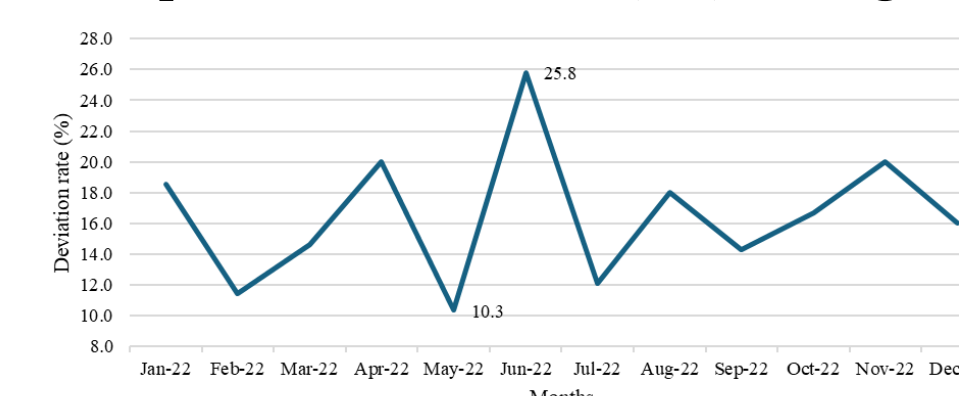
ANALYZE THE DATA

collected before and after the implementation to compare the deviation rate and cycle time.

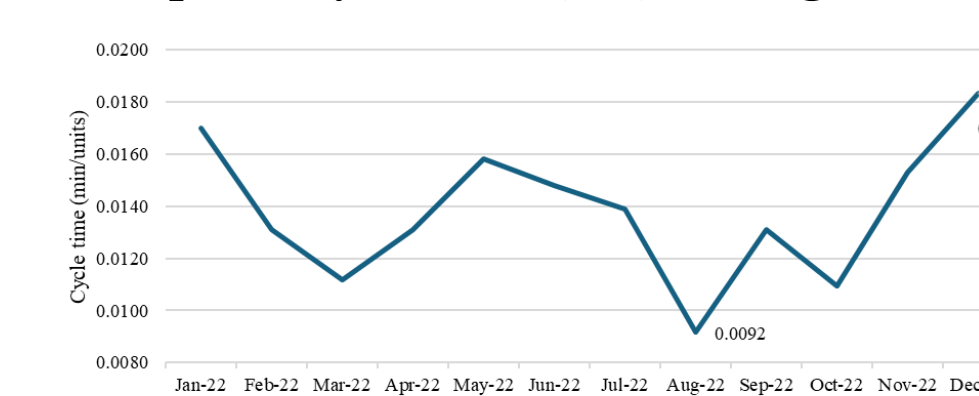
Results and Discussion

We collected and analyzed the data of lots inspected and discrepancies found in units during the year 2022. Then, we implemented the optimized electronic system and collected the same data from December 18, 2023 to March 31, 2024.

Graph 1. Deviation rate (DT) during 2022

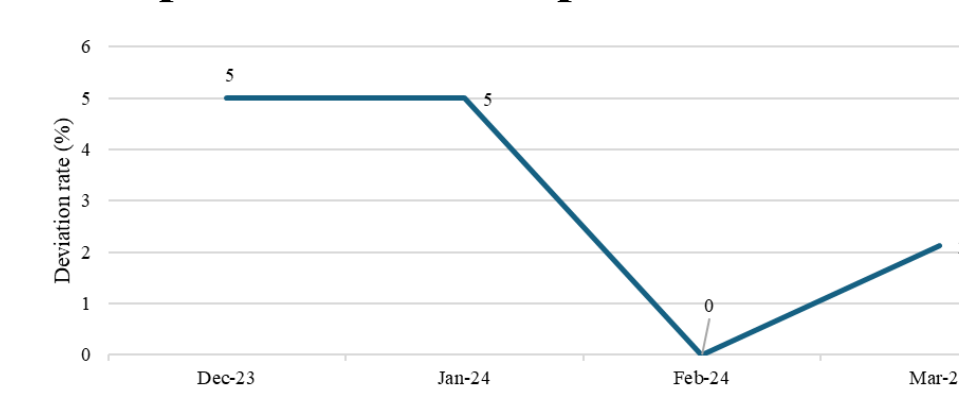


Graph 2. Cycle time (CT) during 2022

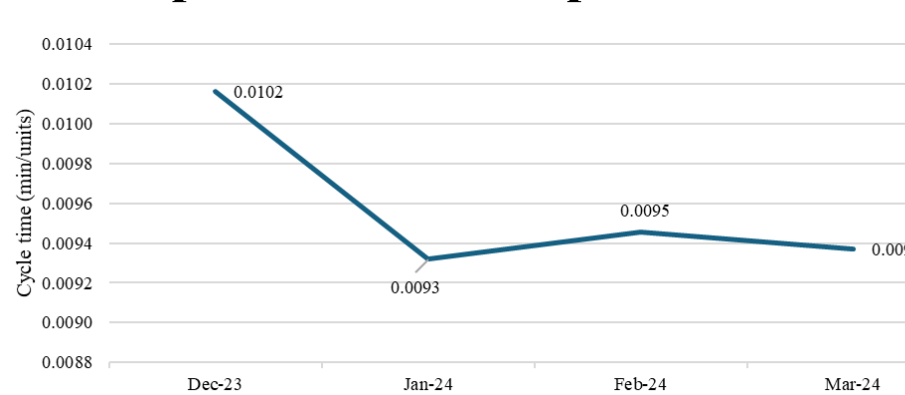


From Graphs 1 and 2, we can conclude that the deviation rate and cycle time were not consistent. During 2022, the deviation rate was high, with the highest at 25.8% and the lowest at 10.3%. Something similar occurred with the cycle time. Since the process was manual, human errors were inevitable, causing 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.

Graph 3. DR after implementation



Graph 4. CT after implementation



In Graph 3 and 4 we can see how the deviation rate and cycle time after the implementation of the optimized electronic system. We can observe that the deviation rate of 7% or less could be maintained, with the highest deviation rate observed in 5%, and the lowest in 0%. In terms of cycle time, we 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, we can observe a 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.

Figure 1. ANOVA for deviation rate

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			

Figure 2. ANOVA for cycle time

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	1	0.000054	0.000054	9.85	0.007
Error	14	0.000077	0.0000055		
Total	15	0.000130			

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.

From this analysis for the deviation rate, we obtained a p-value of 0.0000 and for the cycle time the p-value obtained was 0.007. Both p-values are less than the significance level of 0.05, this indicated that 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 and cycle time.

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. Upon implementing the optimized electronic system, 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 is observed that it remained low and more stable when compared to the 2022 data. This decrease in cycle time reflects an improvement in the efficiency of the process.

Comparing data before and after the system was implemented, we can see significant improvements in both deviation rates and cycle times. However, we need to keep studying this over a longer time to really understand if the improvement persists.

Future Work

Keep monitoring this implementation to have more data to investigate the behaviour of these metrics over time, having the same controls to perform an impartial and precise analysis. Also, monitoring these metrics over time to identify trends that can help to continuous improvement to improve the efficiency and effectiveness of the process.

Acknowledgements

Jose A. Morales, PhD

References

1. 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].
2. 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: Accessed October 14, 2023.
3. 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>.
4. 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.
5. 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.
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. P. Waurzyniak, "Lean Automation," Manufacturing Engineering, vol. 142, no. 2, pp. 65-72, 2009. [Online]. Available: Accessed October 5, 2023.