Optimization in the Account Registration Process in Automated Equipment

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Abstract *— Over the years technology has increased in the manufacturing areas. Companies have moved to obtain automated equipment for the manufacture of their products. In the pharmaceutical industry, this equipment has been implemented to increase production. The equipment is managed by operators, and each operator must have access to them. The pharmaceutical industry in the US is governed by the FDA (Food and Drug Administration), and it has guidelines to ensure the proper use of this equipment and those who use it (21 CFR part 11). During this project, improvements were made to the process of creating accounts for automated teams, where positive results were obtained for the company. Thus, creating a standardized system with quality controls. In addition, the time it took a staff to create an account was reduced from 82 minutes to 51 minutes in this process. For the development of this project, the Six Sigma methodology and its DMAIC tool were used to determine the defects of the process and thus achieve the main objective.*

Key Terms *— Dmaic, FDA, Optimization, Six Sigma.*

INTRODUCTION

The pharmaceutical industry is a highly regulated industry in which each of the activities carried out must follow a "Standard Operating Practices" (SOP) procedure, which states how to carry out a particular job or task. In a pharmaceutical company the "Information Technology" area (IT) oversees managing and supplying all access to the equipment used in the facilities. Before providing these accesses, specific steps must be followed, such as the personnel requesting access being trained on that equipment and their supervisor authorizing it. With all this, a form is filled out and delivered to the IT personnel. During the past months, the department has gone through several events with the control of documentation of the forms used to create accounts. In recent audits, sheets have been found that have been received for several months and have yet to be processed. This, incurring in deviations to "Good Documentation Practice" (GDP) due to lack of realization now and not being current data, means that it was not documented at the moment. The regulatory agency "Food and Drug Administration," known by its acronym FDA, is an agency of the US Department of Health. It seeks to safeguard the quality and protection of biological products and medicines used by human beings. The FDA maintains quality and safety through its guidelines known by its acronym CFR "Code of Federal Regulations." One of the federal regulations is 21 CFR part 11, which establishes the integrity of the data using a registry and electronic signatures so that the data obtained in a process is not eliminated or manipulated [1].

Research Objectives

The main objective of this research is the optimization of team account creation in the IT department. The other purpose of this project is to implement the DMAIC tool, where the defects in the process will be defined, and improvements in the department's performance will be sought. Finally, a record book will be created where the receipt of the forms is documented so that there is a record of the person who delivered and received them. The state will also be modified, and a control number will be changed to register it in the registration book.

Research Contributions

This research aims to develop a strategy that optimizes managing and creating accounts for the different teams in their respective areas. This strategy would create a chain effect that would help the department become more efficient and have the service areas with their operators ready to work. In addition, with the creation of the logbook, there will be a record of the forms that were received and worked on. In addition, there will be an inventory of the accounts and documents made in the IT department.

LITERATURE REVIEW

Companies seek to find efficiency and cost reduction in order to help the success of the business. Previous studies have concluded companies seek to optimize their resources and processes [2] - [13]. Additionally, optimization aims to increase the efficiency of a company through a process and maximize its resources. This topic has been widely studied since techniques are the fundamental basis for greater organizational productivity. Companies select several optimization options according to their needs. When companies optimize a process, they seek to reduce production costs or increase the company's profitability. The research aims to transform an established process into a more efficient one [2], [3], [4], [5]. Every company aims to save time and generate more products.

Research on the optimization of manufacturing processes shows that the implementation of the principles of Lean Six Sigma is possible to observe a company's performance and obtain customer satisfaction [2]. Implementing this methodology has significantly changed the companies that use it, and they have increased their profitability [2]. The study reveals that before the implementation of this methodology, its current production was below the standards and generated more waste than production [2]. In the research methodology, the company conducted a study where it determined that the problem was in the deliveries in real-time, creating dissatisfaction with the client [2]. According to Adeodu, Kanakana-Katumba, and Rendani, "After the implementation of Lean Six Sigma tools for a certain period, many improvements were obtained in the production line in terms of all the parameters" [2]. Implementing this methodology helped optimize the manufacturing process improving production, efficiency, performance, waste reduction, and obtaining customer satisfaction.

Various studies indicate that optimization is the discipline that adapts processes to improve parameters without breaking their limits [2], [4] - [7]. The use and implementation of methodologies such as Six Sigma are to increase the efficiency of a department by improving processes that create better use of resources. This is worked through process management strategies. This is worked through process management strategies. The researchers indicate that to optimize a process, the main objective is to eliminate those added values that consume time, resources, money, and more. Optimizing a department makes it profitable for the company. Thus, an analysis must be carried out where the necessary changes are identified to add efficiency to the process; then, implementation is carried out to have continuity in the tasks and finally create a follow-up to obtain the expected results. These tools will turn an already established process into a more efficient and profitable one. Developing an optimized strategy in a company requires a structure or a system.

By implementing a methodology such as Six Sigma, the problem will be quickly defined, or the situation needs to be corrected. Measurement is one of the most important objectives of this methodology to obtain a faster way to identify the problem and optimize the process. This system is vital for any company looking to improve a department or a manufacturing process. Optimization can be applied in any situation where one seeks to get the most out of that process. Previous studies in optimizing processes using Six Sigma found that using tools of this methodology,

such as 5s, Dmaic, Kaizen, and Pareto Charts, helps improve a process [6] – [8].

On the other hand, studies have also found that implementing this methodology significantly increases the productivity and efficiency of a company. Studies carried out in different manufacturing companies determined that implementing a methodology to optimize a process improves efficiency, reduces costs, and increases the value of these companies [5], [7] – [8]. In addition, optimizing the process enhances the efficiency of employees in the impacted areas. By obtaining a more efficient process, the delivery of products was also improved, and therefore customer satisfaction improved. The techniques used by the researchers were based on examining the operation in real-time where the manufacturing production process was studied, including the personnel work [2], [8]. Using Six Sigma, and its tool DMAIC, the observations were documented, and measurements were made and analyzed [9] – [10]. Then the researchers to investigate changes were established for continuous improvements to increase the productivity of the companies where these investigations were carried out [5], [7] – [8]. These studies mentioned above found the need to optimize a process to eliminate waste that causes loss of time and money to companies and thus increase the efficiency of the impacted area.

METHODOLOGY

For this project, the Six Sigma and Lean manufacturing methodologies will be used. The Six Sigma methodology is a technique based on the analysis of information from a constant department or company process. The main objective of this methodology is to reduce waste through statistics and to increase the performance of a process. With the combined use of Six Sigma and Lean, this study aims to get better results. This study seeks to improve processes to increase productivity and performance by merging its tools to eliminate waste. One of the tools used for implementing Lean Six Sigma is DMAIC.

According to M. Dziak, the DMAIC is a tool whose main objective is to eliminate the changes in the processes that cause defects in the product [11]. Many companies use this tool. This process is described in 5 phases defined by its acronym (Define, Measure, Analyze, Improve, and Control). The DMAIC works cyclically with a beginning and an end. If this cycle is not completed, it must be repeated until the result is obtained. This tool can be implemented in any situation to obtain maximum efficiency in the process. Figure 1 represents the cycle phases.

Figure 1
DMAIC Methodology

The first phase of the DMAIC tool is to Define the problem. During this phase, the objectives of the problem that will be evaluated and how the different areas will be dealt with will be defined. The second phase is known as Measure; a study will be carried out to measure the defects found. The data obtained in the measurement phase will be evaluated in the Analyze phase. The reasons why these defects were obtained will be established, and thus the changes to be made will be considered. The Improvement phase continues, and solutions and ideas will be implemented to eliminate the defects obtained in the first Analysis phase. Finally, the Control phase will monitor the implementations that were made. In addition, measures will be taken to guarantee that it is implemented correctly.

The Lean Six Sigma methodology was reinforced to implement the improvements, implementing the DMAIC tool using its five phases in the project. DMAIC is determined to reduce and optimize account creation time. The first phase, which is Define, is secured SIPOC. Figure 1 includes the steps of the process, such as the inputs, the suppliers that complement the information in the process, and the result. At the end of the first phase, the problems will be confirmed, and the magnitude of the impact of this project will be obtained.

The next phase is Measure, where the cause of the delay in reviewing the forms and their creation will be identified. A pilot plan will be implemented in a specific department for 3 months, and it will be shown through a chapter project. The new form will be used with your control number on this plan. The standard that will be used for the creation of accounts in the teams will also be tested. In this way, the deviations in the process will be obtained. In addition, I-MR graphs will be used to monitor the mean and the variation of continuous data. This graph will be used to monitor the time of the process to correct its deficiencies.

In the analysis phase, the data of the pilot plan that was used in the chosen department will be obtained. This tool will give this study the impact of defects in the process. Additionally, this will assist in identifying which steps aid the process and which create waste. Finally, the data obtained in this phase indicates the situations that generate difficulty in the process.

In the improvement phase, when obtaining the data from the previous phases, the possible implementations begin to be analyzed. These implementations should be aimed at the details obtained in the measurement and analysis stage. Upon completing the pilot plan, the quality department will work to review and approve the documents that will be used. A complete verification must also be made of the process obtained up to this phase to determine if this project is implemented or if the investigation must be restarted.

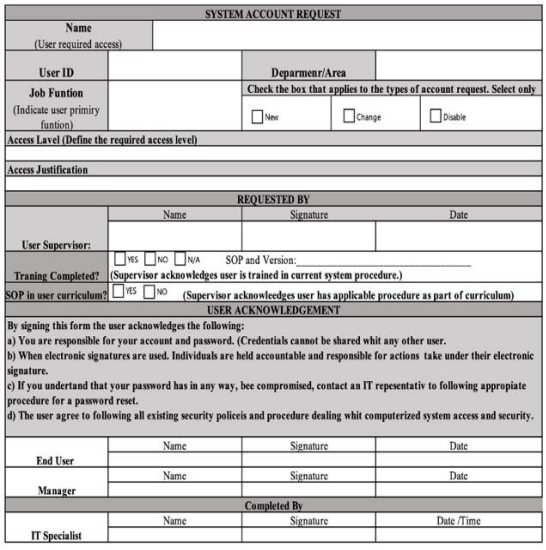
The process will be standardized in the Control phase using a Flow chart. After standardizing the process, it will describe how to perform the task in a straightforward way. The main objective of the Flow chart is to describe the correct way to perform the job and ensure that there are no deviations to the process. By having the entire process completed and guaranteeing it, an SOP will be created. This will give validity and security when carrying out the process.

RESULTS AND DISCUSSION

The objectives were met during the project's development, and an impact was created in the IT department. The project's purpose was to implement a standardized system where the time to develop equipment accounts is reduced. Using the Six Sigma Dmaic tool, it was possible to define the problem and optimize the process of creating accounts in automated equipment. The SIPOC tool was used to establish the areas that are impacted.

Suppliers	Inputs	Processes	Outputs	Customers
QA Area	Training Report	Account Creation	Operator with Access to Equipment	Manufacturing Area
Manufacturing Area	Supervisor Approve			Packaging Area
Packaging Area	Manager Approve			

Figure 2
SIPOC



SYSTEM ACCOUNT REQUEST			
Name (User required access)			
User ID		**Deparmenr/Area**	
Job Funtion (Indicate user primiry funtion)		**Check the box that applies to the types of account request. Select only**	☐ New ☐ Change ☐ Disable
Access Lavel (Define the required access level)			
Access Justification			
REQUESTED BY			
	Name	Signature	Date
User Supervisor:			
Traning Completed?	☐ YES ☐ NO ☐ N/A SOP and Version:_____ (Supervisor acknowledges user is trained in current system procedure.)		
SOP in user curriculum?	☐ YES ☐ NO (Supervisor acknowledges user has applicable procedure as part of curriculum)		
USER ACKNOWLEDGEMENT			
By signing this form the user acknowledges the following: **a) You are responsible for your account and password. (Credentials cannot be shared whit any other user.** **b) When electronic signatures are used. Individuals are held accountable and responsible for actions take under their electronic signature.** **c) If you undertand that your password has in any way, bee compromised, contact an IT repesentativ to following appropiate procedure for a password reset.** **d) The user agree to following all existing security policeis and procedure dealing whit computerized system access and security.**			
	Name	Signature	Date
End User			
	Name	Signature	Date
Manager			
Completed By			
	Name	Signature	Date /Time
IT Specialist			

Figure 3
Form "System Account Request"

Using the SIPOC tool, the process of creating an account for teams was identified. By making the SIPOC Diagram (Figure 2), they can identify the areas related to creating an account. Currently, the process to create an account for automated equipment is through a form that requires information about the applicant, information about the training taken, and signatures to authorize their approval (Figure 3).

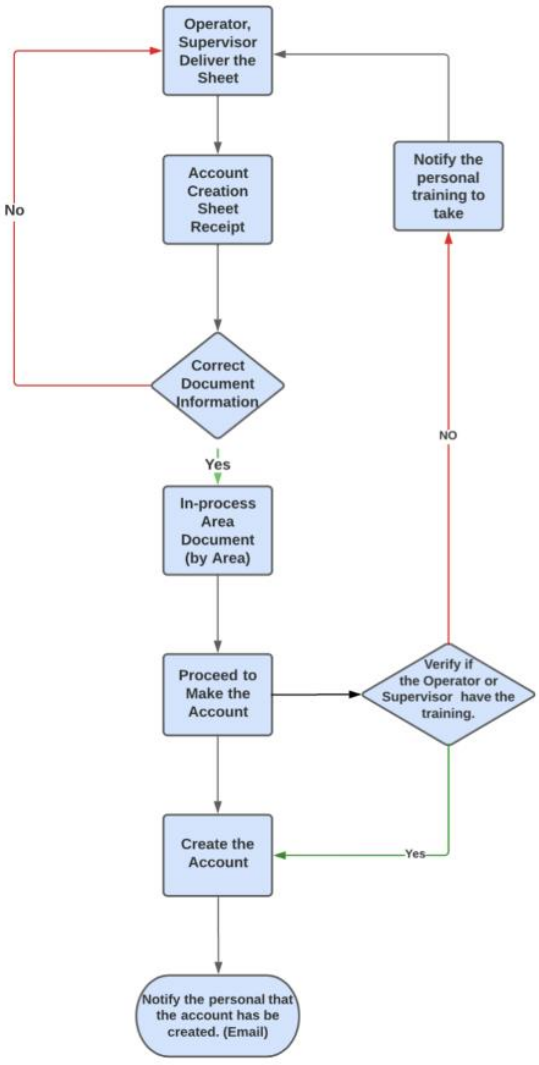


Figure 4
Process Flowchart (Actual)

During the measurement phase (DMAIC), the problems were: the staff needed to comply with the training required to operate the equipment and the lack of signatures from the managers of the areas. This training was necessary for the accounts to be executed. In the active part, it was observed that the technicians needed to track the sheets that were delivered to them, and they needed to be dedicated by area. In addition, there was a time difference between when the sheet was delivered and when the staff completed it. With these results, it was possible to identify the deficiencies in the process. The defects delay the process; an employee must be authorized to use equipment to complete his functions. In addition, it was found that the technicians needed a defined time to work on the requests. These requests, upon being received by the IT department staff, are archived. This causes recommendations to accumulate and creates a delay when working on them. After obtaining all the data in this phase, a flowchart (Figure 4) of the entire current process was made.

To identify the defects in creating an account for equipment, the IT department was asked for the sheets made three months before the optimization of the process. Sixty-eight sheets were obtained during the three months before implementation (Table 1). However, 30 of the 68 sheets that had been generated in the past three months before implementation were evaluated and collected upon receiving. From those 30 sheets obtained, a technician's time (minutes) to verify the entire document, verify if the employee has the equipment training, and finally create the account was obtained. These data are shown in Table 2.

Table 1
Sheets Created Before Optimization

Month	Sheets created before optimization
1	25
2	20
3	23

Additionally, during the three months of optimization in the account creation, changes were made in how the account sheets are worked, where the technicians were assigned a specific area and will be taking charge of it. During the three months of implementing a new system, 110 sheets were completed (Table 3) compared to the previous three

months when only 68 sheets were completed (Table 1). After completing the three months of the pilot plan, improvements in account creation times were seen. Thirty created account sheets were chosen, and the time it took from receipt to completion was verified (Table 4) to obtain the data.

Table 2
Sheets vs Time (min) Before Optimization

Before Optimization	
Sheets	Time (minute)
1	75
2	90
3	95
4	90
5	75
6	80
7	85
8	85
9	75
10	75
11	90
12	90
13	83
14	78
15	79
16	75
17	85
18	83
19	80
20	84
21	87
22	82
23	76
24	90
25	84
26	70
27	76
28	84
29	80
30	84

Table 3
Sheets Created After Optimization

Month	Sheets created after optimization
1	40
2	35
3	35

Table 4
Sheets vs Time (min) After Optimization

After Optimization	
Sheets	Time (minute)
1	50
2	55
3	57
4	60
5	65
6	48
7	47
8	53
9	50
10	50
11	45
12	46
13	47
14	45
15	53
16	52
17	47
18	45
19	45
20	45
21	43
22	50
23	52
24	54
25	47
26	56
27	64
28	62
29	47
30	48

After optimizing the process, the IT department technicians increased the number of accounts created per month. Based on the time variance before optimization, the average was 82 minutes. On the other hand, based on the time variance after process optimization, the average time to create an account was 51 minutes. I-MR graphs shown in Figures 5 and 6 were used to obtain the data to evaluate the time to create an account before and after optimization. According to the information obtained, a reduction in the average time of around 31 minutes was seen.

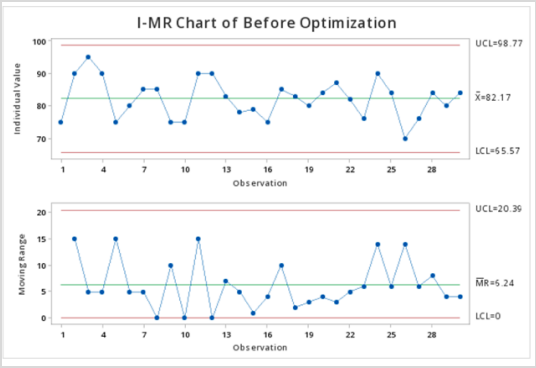


Figure 5
Time Variation Before Optimization

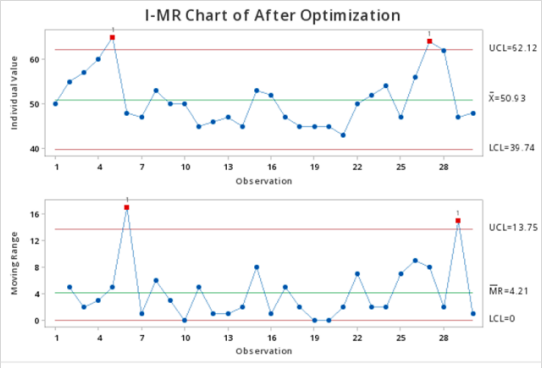


Figure 6
Time Variation After Optimization

During the measurement phase, it was observed that the system accounts were not created on time due to different interruptions. They were analyzed, and a new method of working with them was established. One of the changes implemented was that when the account sheet was delivered, it had the training certification taken. Thus, the technician can check in the system if the requested personnel have or need the training to complete the sheet. With the segregation of areas, an increase has been observed in the number of sheets made in the months that the standardization of the process was carried out (Table 3). There is an increase in 3 months of a total of 42 sheets completed. This shows that the root cause of the delay in the accounts is the need for more information on the sheets and the need to have the areas assigned to the technicians. On the other hand, the time to create an account decreased after the process standardization.

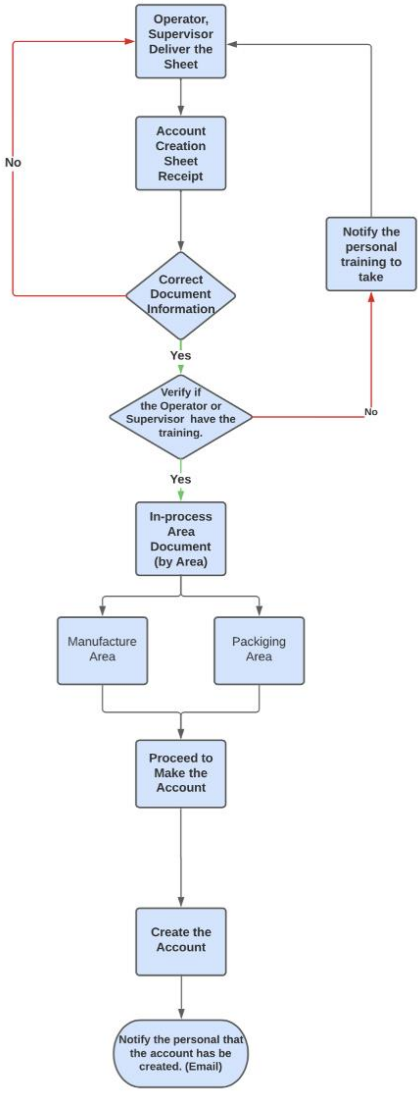


Figure 7
New Process Flowchart

For the continuous improvement phase, the optimized account creation process was reorganized. This was done by updating the flowchart (Figure 4) with the already optimized process (Figure 7). A monthly inventory verification system is also being established to determine how the equipment accounts are working and how many are being made per month. This work will be carried out by the supervisor of the technicians or a person designated by the supervisor to have control outside of the technicians who work on these sheets. With this system, the efficiency of

each employee will be measured when creating the accounts.

Form Tracking Log				
Control #	Area	Receive Performing by/date	Complete Perfomed by/ date	Comment
1				
2				
3				
4				
5				
6				

Figure 8
Form Tracking Log

SYSTEM ACCOUNT REQUEST			
Name (User required access)		Log Control #:	
User ID		Deparmenr/Area	
Job Funtion (Indicate user primiry funtion)		Check the box that applies to the types of account request. Select only one.	
		☐ New	☐ Change ☐ Disable
Access Lavel (Define the required access level)			
Access Justification			
REQUESTED BY			
	Name	Signature	Date
User Supervisor:			
Traning Completed?	☐ YES ☐ NO ☐ N/A SOP and Version:_____ (Supervisor acknowledges user is trained in current system procedure.)		
SOP in user curriculum?	☐ YES ☐ NO (Supervisor acknowledges user has applicable procedure as part of curriculum)		
USER ACKNOWLEDGEMENT			
By signing this form the user acknowledges the following: a) You are responsible for your account and password. (Credentials cannot be shared whit any other user. b) When electronic signatures are used. Individuals are held accountable and responsible for actions take under their electronic signature. c) If you undertand that your password has in any way, bee compromised, contact an IT representativ to following appropiate procedure for a password reset. d) The user agree to following all existing security policeis and procedure dealing whit computerized system access and security.			
	Name	Signature	Date
End User			
Manager	Name	Signature	Date
Received By			
	Name	Signature	Date / Time
IT Specialist			
Completed By			
	Name	Signature	Date / Time
IT Specialist			

Figure 9
New Form " System Account Request"

The purpose of the control phase was to ensure that the implemented improvements would continue to be met and that the process would continue effectively. This project implemented changes in how the accounts are executed and the worksheets are worked. A control logbook was implemented to provide a number attached to the sheet (Figure 8). Changes were also made to the account request form, where the signature of the technician who received the sheet was included since he will have to fill out the logbook and add the control number found in the logbook to the form (Figure 9). This logbook can be filled out by any technician who receives the sheet. This technician will be in charge of delivering the sheet to the corresponding place. This will help keep track of the forms that arrive at the department, who receives them, and who completes them. The employees assigned to creating accounts must follow the flowchart (Figure 7) to guarantee the effectiveness of the process, "First In, First Out" will also be used so as not to accumulate forms; they will be carried out subsequently as they are received.

CONCLUSIONS

Through this project, it was possible to meet the main objectives: to optimize the process of creating accounts in the IT department to comply with the federal statute 21 CFR part 11. This was carried out using the Six Sigma methodology and its Dmaic tool. The causes of the loss of time when creating an account were identified, and a system was implemented to mitigate these causes. The account creation process was standardized in automated equipment reducing time and increasing the efficiency of the process. In addition, the number of forms that are processed has increased significantly.

A new system was implemented where the forms are received by a technician when they arrive at the department and are segregated by areas to be more efficient when working on them. This change made it possible to distribute the workload to the employees equitably, and their performance was increased. This project showed that optimizing a process would be reflected not only in the area that is worked on but also in all departments. The benefits of optimizing a process are minimizing human errors, eliminating waste of time, and getting the most productivity out of the impacted area. This project demonstrated that the loss of time in a process or an area would affect the final product in a chained way.

During this project, a series of ideas were presented that can help in future research and would help develop a more robust account creation system. One of the ideas is to use a virtual system in which sheets of paper are eliminated, and tickets are created with the information of the requesting employees. Thus, reducing the use of paper and using technology in our favor. Also, create a union of the training system with the system to create an

account to speed up the process; when the staff takes the training, a ticket or work request is generated to create the account at the moment, reducing the time to develop a sheet and deliver it personally.

REFERENCES

[1] FDA. (2017, January,03) *21 CFR Part 11 Subpart C* Retrieved August 08, 2022, from: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11/subpart-C.

[2] A. Adeodu, M. G. Kanakana-Katumba & M. Rendani, "Implementation of Lean Six Sigma for Production Process Optimization in a Paper Production Company," *Journal of Industrial Engineering & Management*, 14(3), 661–680, 2021, https://ezproxy.pupr.edu:2093/10.3926/jiem.3479.

[3] V. A. Hauder, A. Beham, S. Wagner, K. F. Doerner, & M. Affenzeller, "Dynamic online optimization in the context of smart manufacturing: an overview," *Procedia Computer Science*, 180, 988 995, 2021. Available: https://ezproxy.pupr.edu:2093/10.1016/j.procs.2021.01.356

[4] J. L. Meng, "Demand Prediction and Allocation Optimization of Manufacturing Resources," *International Journal of Simulation Modelling (IJSIMM*), 20(4), 790–801, 2021. Available: https://doi.org/10.2507/IJSIMM20-4-CO20.

[5] V. R. R. Pinninti & V. B. Krovvidi, "Six Sigma Optimization of Process Costs and Chemicals Consumption in Demin Water Plants," *IUP Journal of Operations Management*, 20(3), 39–51, 2021.

[6] J. Chávez Medina, L. N. A. Santiesteban, F. O. González Manzanilla, M. C. Fierro-Xochitototl, & V. G. Luna Fernández, "Optimización Del Proceso De Barrenado Para El Incremento De Productividad Y Reducción De Rechazos a Través De La Metodología Dmaic: Caso Empresa Del Sector Automotriz," *Estudios de Administración*, 29(1), 142–164, 2022. Available: https://ezproxy.pupr.edu:2093/10.5354/0719-0816.2022.66714.

[7] M. Marrero Vázquez, "Optimization of pharmaceutical product production lots at the granulation manufacturing stage," *Puerto Rico Cloud Repository*, COBIMET, 2018, Available: https://prcrepository.org/xmlui/handle/20.500.12475/207.

[8] D. Rivera, "Optimización del Proceso de Revisión de los Registros de Manufactura," *Puerto Rico Cloud Repository*, COBIMET, 2018, Retrieved January 22, 2023, from: https://prcrepository.org/xmlui/handle/20.500.12475/216.

[9] M. H. Sajjad, K. Naeem, M. Zubair, Q. M. Usman Jan, S. B. Khattak, M. Omair, & R. Nawaz, "Waste reduction of polypropylene bag manufacturing process using Six Sigma DMAIC approach: A case study, *Cogent Engineering*, 8(1), 1–22", 2021. Available: https://doi.org/10.1080/23311916. 2021.1896419.

[10] Seyed Mohsen Hosseini, & Angelika Peer. "Wood Products Manufacturing Optimization: A Survey," *IEEE Access*, 10, 121653–121683, 2022. Available: https://doi.org/10.1109/ACCESS.2022.3223053.

[11] M. Dziak, "DMAIC (Define, Measure, Analyze, Improve and Control)," *Salem Press Encyclopedia*, 2020.

[12] C. Liu, Y. Liu, & J. Wang, "A revised imperialist competition algorithm for cellular manufacturing optimization based on product line design," *Journal of Industrial & Management Optimization*, 19(1), 69–104, 2023. Available: https://doi.org/10.3934/jimo.2021175.

[13] J. Phillips, & L. Simmonds, "Using fishbone analysis to investigate problems," *Nursing Times*, 109(15), 18-20, 2013.