Evaluation to Sleeves Used in Granulation Department for the Graduate Programs at Polytechnic University of Puerto Rico

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Abstract *— The DMAIC methodology was applied to analyze a manufacturing system at Johnson & Johnson Pharmaceuticals in Las Piedras, Puerto Rico. The methodology was used to improve the time for changing and washing the sleeves of different machines in the area. Time variables were taken into consideration and based on the results of their analysis, the solution to the problem was identified. In this way, time was minimized and savings achieved in the company.*

Key Terms *— DMAIC, Improvement, Manufacture, Pharmaceutical, Time study.*

INTRODUCTION

The DMAIC methodology can be used in different areas and systems, such as: automobile production systems, Production in medical devices, drug production, among others. In the granulation area of the McNeil, Las Piedras facility, specifically in equipment such as the Charging System, Quick Sieve and the Vertical Granulator VG-2000, reusable bone fabric sleeves are used after their major cleaning, during the evaluation. This process becomes very complex because of having to transport the sleeves to roto granulator area washing machines are located.

The headcount of the area is significantly impacted during the execution of subject process and eliminate the cost related to the utilities requires. After analyzing alternatives, the team reached the conclusion that eliminating this equipment and replacing it with disposable sleeves. The rotor and granulation areas will benefit by having a more agile process while assuring quality and safety standards

LITERATURE REVIEW

DMAIC is a methodology which contains a system of tools that are used to solve problems and make continuous improvements. This methodology is used in existing processes, unlike DMADV which is used in the creation of new projects. The DMAIC methodology can be used in different areas and systems, such as: automobile production systems [1]. Production in medical devices [2], drug production, among others.

DMAIC is divided into five different areas; Define, Measure, Analyze, Improve and Control. The “Define” phase is used to describe and define the place where the data was collected; and problem definition. The client's needs are identified in order to identify and define the problem [1], [2] and [3]. During the “Measure” phase, the data are analyzed with statistical control tools [2], thus facilitating the identification of the system's operation [1]. The analysis phase evaluates the data with quality control tools. During this phase, the probable causes of the problem will be identified and given priority. Improve is the phase in which possible solutions [2] to the problem are exposed, it is important that the engineer be creative and innovative. In the control phase, the new system model must be presented, considering the actions that must be established so that the recommended improvements can be made. During this phase continuous monitoring is implemented.

DMAIC is continuous learning and process improvement model [2]. Various studies have used the DMAIC Methodology to make continuous improvements in the production and pharmaceutical area [3]. In this continuous improvement project,

this methodology will be applied to minimize the cleaning time of the granulation department.

DEFINE PHASE

Johnson & Johnson, McNeil, is located on Highway 183, Las Piedras Puerto Rico 00771. As part of the tools used in this phase, a VOC (Voice of costumer) was carried out to identify the client's needs, in this way to define the problem. It was identified that a significant number of sleeves are being used in different equipment such as Quick Sieve, Charging System and VG 200. This process is taking a long time, since the sleeves have to be removed, transported to the washing area and then washed to be used again. Figure 1 shows a photograph of an example of a sleeve.

After identifying the problem, it is defined. One of the tools used to see the process in a more detailed way is the process flow map. The process begins with equipment disassembly and ends with a cleaning control process in the sleeves before they can be reused. The process is found in Figure 2.

Figure 1
Sleeve Example

MEASURE PHASE

In the measurement phase, statistical measurement tools will be used. With them, the variables of time and distances will be analyzed.

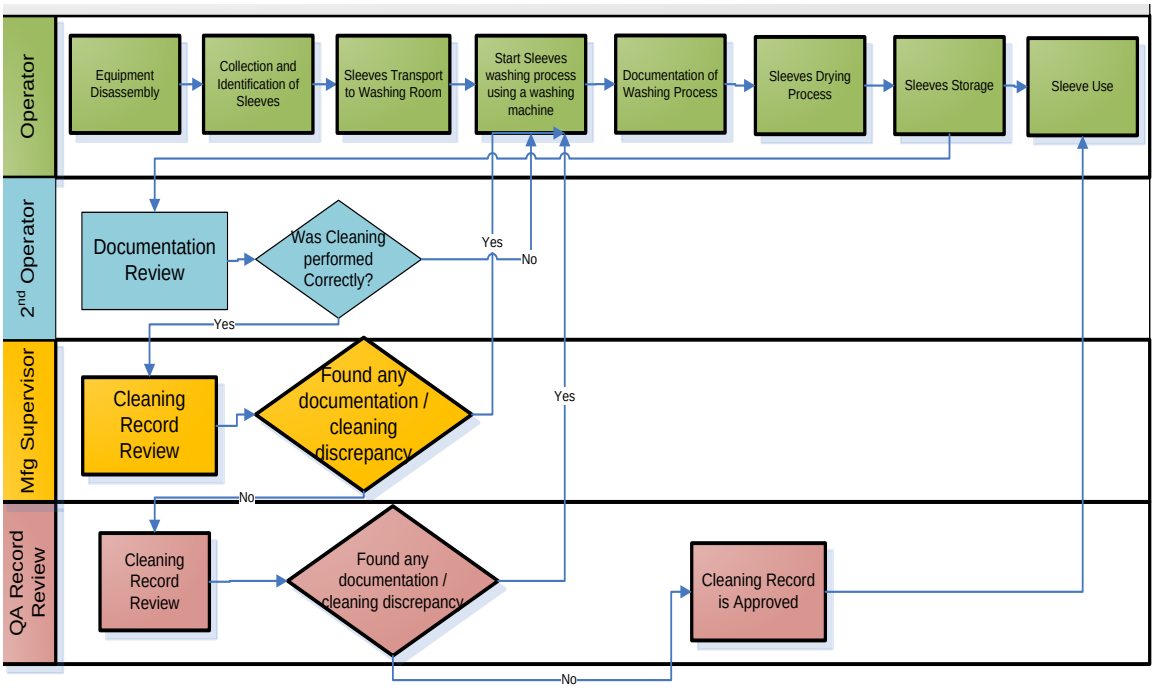


Figure 2
Sleeves' Process Flow Map

In Figure 3 we can see a control chart with which it indicates that the average washing time is 15 hrs. With a maximum expected time of 43 hrs. This is the time 2 operators will spent in the washing room plus the time operations batch record review takes to evaluate the batch record.

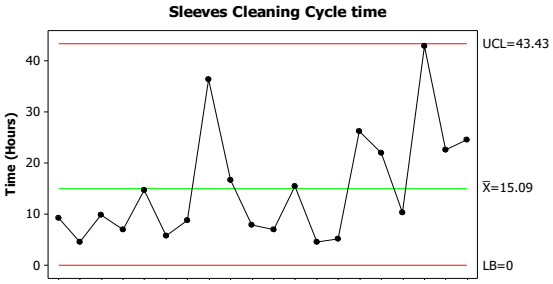


Figure 3
Control Chart

Another tool used in this phase is the spaghetti diagram. With it, the distance and time traveled during the process was calculated. Sleeve transportation was evaluated using Spaghetti Diagram, as shown in Figure 4. The transportation complexity and total steps were evaluated.

The results of the phase show that the areas of opportunity on this process are reduction of man-hours and the reduction complexity including transportation time of the sleeves and documentation.

During the analysis phase, several tools were used to further identify the reason why the problem exists, so a cause and effect diagram was used.

Figure 5 shows the four main points to evaluate in the problem: men, machine, product, method.

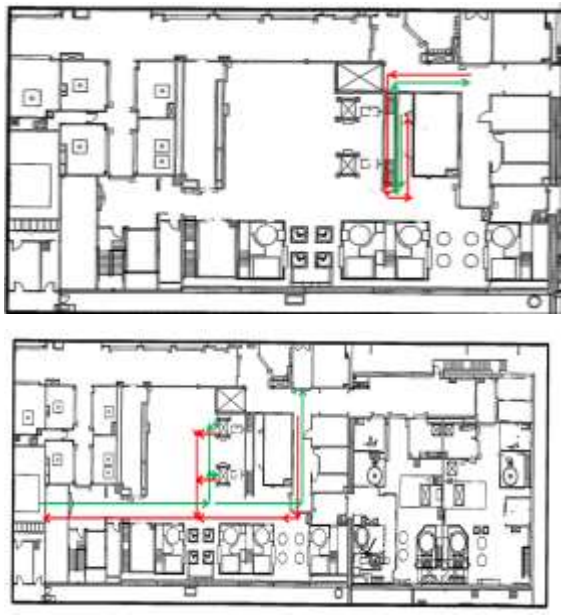


Figure 4
Spaghetti Diagram

The Cause and Effect diagram was used to identify the main causes of the complexity. In addition, the Prioritization Matrix tool is used, see Figure 6.

During this phase 4 options was identified to improve the complexity of the sleeve handling system. To select one alternative a prioritization matrix tool was used (see Figure 6). Other alternative identified was the relocalization of the washing machine. Even though this is a second alternative it could be also considered in case the use of disposable sleeves is not implemented or implemented as an alternative to the current system.

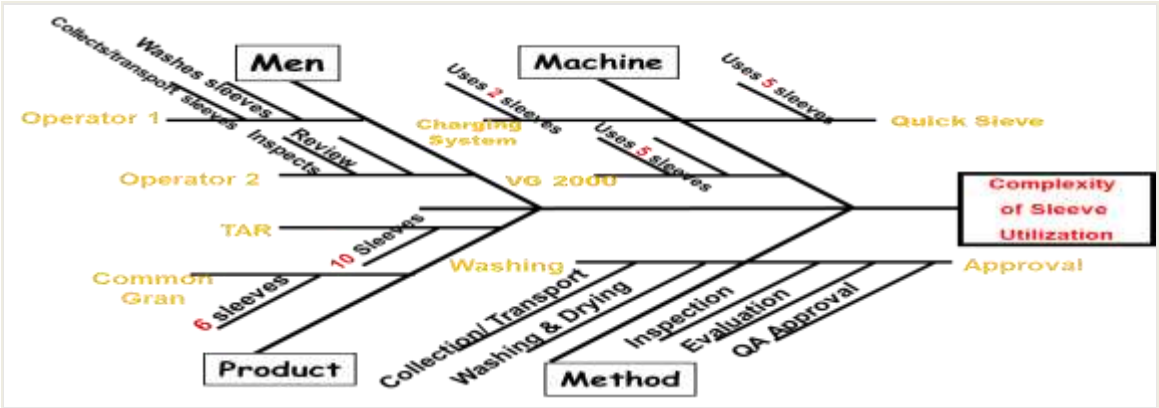
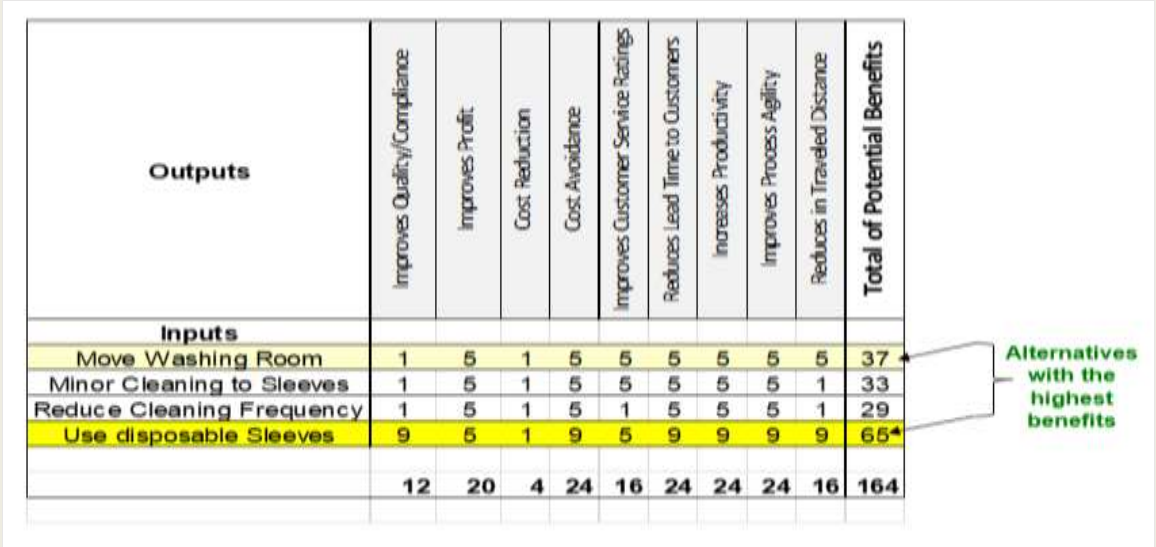


Figure 5
Causes and Effects Diagram



Outputs	Improves Quality/Compliance	Improves Profit	Cost Reduction	Cost Avoidance	Improves Customer Service Ratings	Reduces Lead Time to Customers	Increases Productivity	Improves Process Agility	Reduces in Traveled Distance	Total of Potential Benefits
Inputs										
Move Washing Room	1	5	1	5	5	5	5	5	5	37
Minor Cleaning to Sleeves	1	5	1	5	5	5	5	5	1	33
Reduce Cleaning Frequency	1	5	1	5	1	5	5	5	1	29
Use disposable Sleeves	9	5	1	9	5	9	9	9	9	65
	12	20	4	24	16	24	24	24	16	164

Figure 6
Prioritization Matrix

IMPROVE PHASE

During the improve phase, Figures 7 and 8 are shown, they will help us to understand a little better, through a Process Flow Map, the changes to be made in the process; while Figure 8 will help us to see what are the activities that must be done to implement the new changes and what areas and roles it involves.

The important recommendations and advice in this phase are:

- Tyvek Sleeve is a disposable item classified as a Consumable Level 2.
- This item is intended to be in contact with product or product contact equipment surface.
- The assessment conducted in Part C of the QRM form did not identify any high risk scenarios. Particulates may possibly be introduced into the process, but the likelihood of occurrence was determined to be low.
- The conclusion of this assessment is that the risk associated to the use of disposable Tyvek Transfer sleeves in the Granulation area is acceptable.
- It is recommended to initiate the inclusion of this item as a Consumable Level 2 following Consumables Procedure 99-OP-GP-010.
- Tyvek Sleeve is a disposable item classified as a Consumable Level 2.

CONTROL PHASE

During the control phase it is important to bear in mind that the improvements are continuous, the fact that the improvements made to the System to save time and money does not mean that we should not continue to collect data from the process. We must remember that there are more opportunities to continue improving the process. Table 1 shows us the before and after implementing the improvements to the process.

The success of this project is based on the fact that the voice of the customer was heard and completely fulfilled. Project accomplishments could be attributed to the fact that team was willing to challenge the status quo. Key stakeholder, Operators, Technical Operation, External suppliers, Business Improvement Team and Management were engaged. Knowledge from team was the most important asset. Ideas and alternatives were captured and assessed using the correct tools, which assured that the best options were identified, properly handled and that related risks were considered.

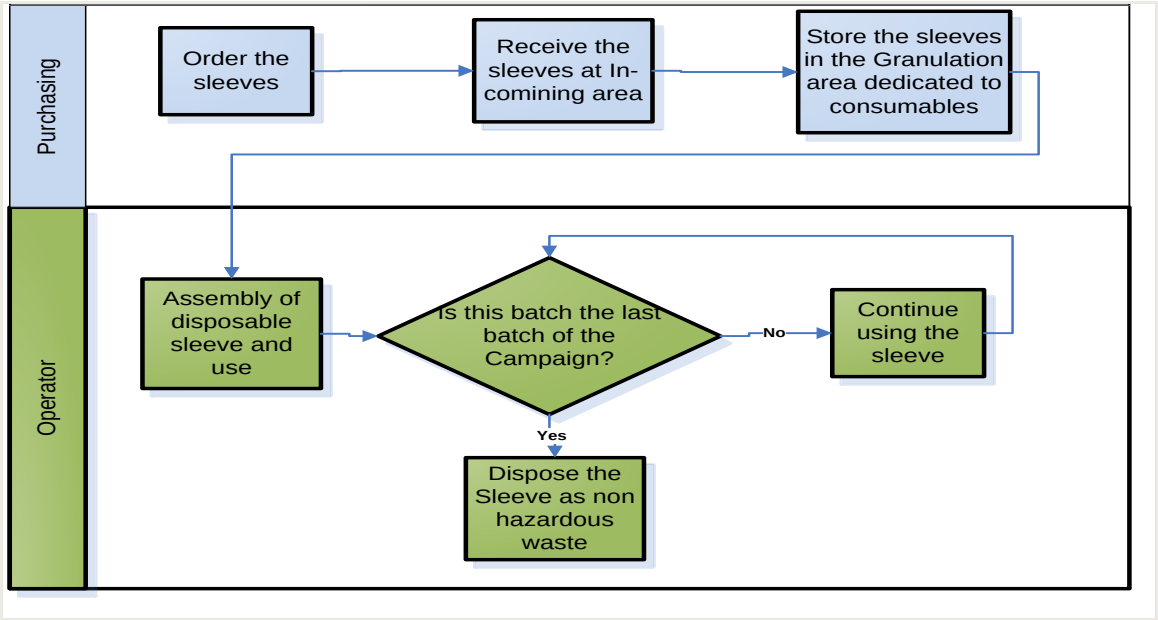


Figure 7
New Process Flow Map

This project confirms that there are opportunities ready to be identified, need to assure that this level of team performance is maintained and utilized as an asset to the success of our company.

Table 1
Before and After Changes

Changes	Before	After
Sleeves were changed from re-usable to disposable.	Granulation area sleeves were washed and dried after the campaign is completed to be re-used	Granulation area sleeves will be disposed after the campaign is completed
Sleeves Transportation was eliminated	After use, sleeves are transported from the Granulation area to the washing room 365 steps are required. After cleaning, sleeves are transported back to the Granulation area	Sleeves are disposed, no transportation to washing room is required
Cleaning Record generation is eliminated	During the cleaning process, 2 operators generate a record as part of the cleaning requirements	Since sleeves are disposed no cleaning documentation is required
Cleaning Record is reviewed by Operations and QA is eliminated	Operations personnel and batch record review review/revise the cleaning records for approval	Since sleeves are disposed no cleaning documentation is required

CONCLUSION

During the Project, several tools were used to analyze the process and identify the improvements that should be made. When analyzing the time, it was found that during the cleaning process in a total of 20 washes a total of 15 average hours was obtained, giving a total cost of $11,700.00. Based on that, it was thought that other alternative identified was the relocation of the washing machine.

As we see in Table 2, the areas affected by the process are electrical energy, water, carryout, and detergent. The total cost of expenses, before the suggested changes is $90,937.00.

Table 2
Cost and Savings

Monetary Areas	Cost Before Changes	Saving	Cost After Changes
Electrical Energy	$58,700.00	$10,600.00	$48,100.00
Water	$20,000.00	$8,556.00	$11,444.00
Carryout	$11,700.00	$11,700.00	$0
Detergent	$537.00	$537.00	$0
Total	$90,000.00	$31,393.00	$59,544.00

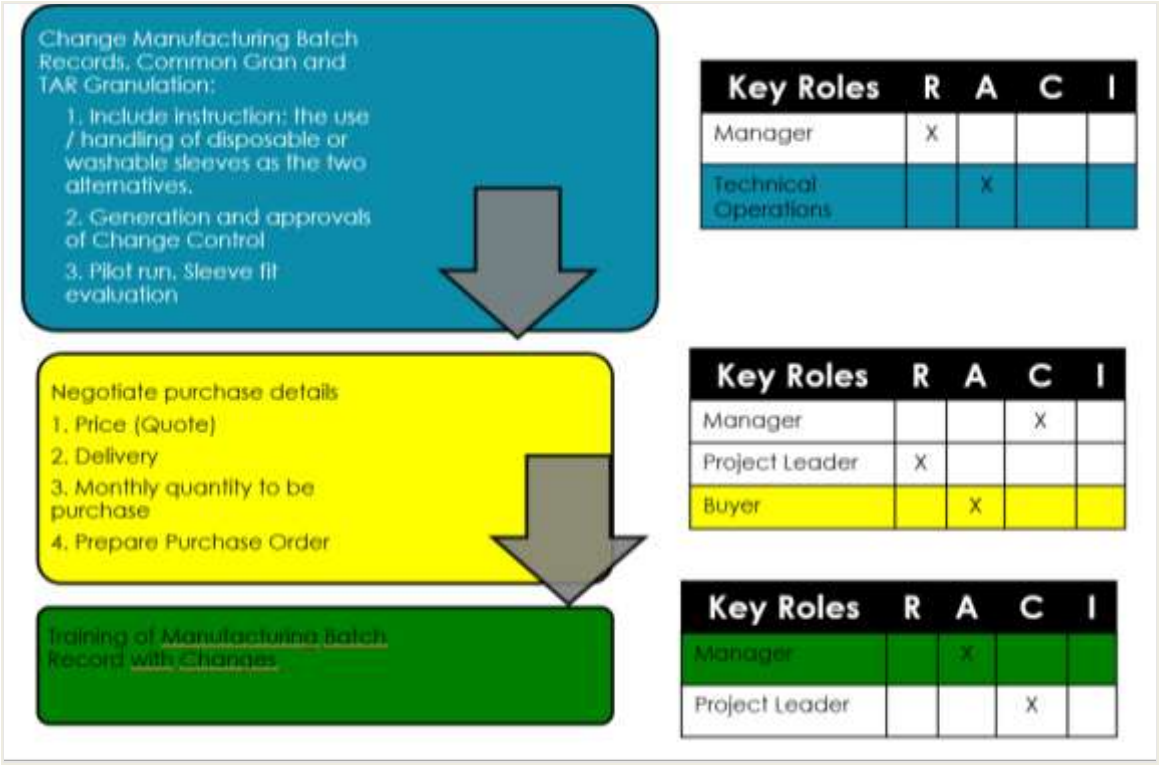


Figure 8
Activities Required to Implement New System

The savings produced after the improvements are: In monetarily measurable terms it can be stated that said project saved in the cost of electrical energy in the amount of $10,600.00. Water savings for an amount of $8,556.00, savings in the hours that were used to carry out the task by the operators for an amount of $11,700 and, detergent for an amount of $537.00. This means that before the improvements the process has a cost of $90,937.00 and after the improvements it would be $59,544.00.

REFERENCES

[1] H. Rifqi, A. Zamma, S. B. Souda, and M. Hansali, " Lean manufacturing implementation through DMAIC Approach: A case study in the automotive industry," *Quality Innovation Prosperity*, vol. 25, no. 2, pp. 54-77, 2021. [Online]. Available: 10.12776/QIP.V25I2.1576

[2] P. Jirasukprasert, J. A. Garza-Reyes, H. Soriano-Meier and L. Rocha-Lona, "A case study of defects reduction in a rubber gloves manufacturing process by applying Six Sigma principles and DMAIC problem solving methodology," Proceedings of the 2012 International Conference on Industrial Engineering & Operations Management, 2012, pp. 472-481.

[3] P. Sharma, A. Gupta, S. C. Malik, and P. C. Jha, "Quality Improvement in Manufacturing Process through Six Sigma: A case study of Indian MSME firm," *Yugoslav Journal of Operations Research*, vol. 29, no. 4, pp. 519-537, 2019.