

Optimizing Efficiency and Employee Satisfaction by Streamlining the Complaint Sample Request SOP of a Manufacturing Company Using Lean Methodology

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Abstract — *In the Complaint department of a Manufacturing Company, the redundancy of documentation within the Standard Operating Procedure (SOP) has emerged as a critical challenge. This redundancy is primarily manifested in the duplication of testing requests, which exist in both electronic (LIMS) and paper format (Logbook). These inefficiencies directly impact employees' ability to accurately track activities in a timely manner and have led to a decline in employee satisfaction. This unnecessary duplication of documentation represents an overprocessing waste by Lean Methodology. It consumes valuable resources, elevates the risk of data entry errors, and introduces delays in carrying out essential tasks. Therefore, addressing this issue is imperative to enhance overall departmental efficiency and boost employee satisfaction.*

Our project aims to eliminate double documentation (overprocessing waste) and, in doing so, eliminate data entry errors. We seek to enhance employee satisfaction by streamlining processes.

Key Terms – *Complaint, Data Integrity, Employee Satisfaction, Lean Methodology, SOP Improvement.*

PROBLEM STATEMENT

The redundancy of documentation within the Standard Operating Procedure (SOP) in the Complaint department of a Manufacturing Company has emerged as a significant challenge in their process. The duplication of testing requests, both in electronic (LIMS) and paper format (Logbook), is generating inefficiencies that directly impact employee's ability to track activities accurately in a timely manner and have negatively impacted employee satisfaction. This unnecessary duplication is an overprocessing waste by Lean Methodology

not only consumes valuable resources but also increases the likelihood of entry errors and delays in carrying out essential tasks. Therefore, it is imperative to address this issue to enhance efficiency and employee satisfaction.

RESEARCH DESCRIPTION

When a complaint is received in the Complaint Department, an investigation must be carried out. For most of the cases, the complainant sent to the Manufacturing Company the complaint sample. When a complaint sample is received, the employee of the complaint department must evaluate and request the test of the complaint sample per their SOP "Complaint Sample Handling Procedure". This current process establishes that the test must be documented in electronic (LIMS) and paper format (Logbook), which is an overprocessing waste by Lean Methodology.

This project aims to apply Lean Methodology to evaluate the overprocessing task of the current SOP "Complaint Sample Handling Procedure" to improve efficiency and reduce waste by eliminating duplicate tasks. Therefore, this project will focus on identifying and eliminating non-value-added activity, standardizing the SOP processes, and enhancing employee satisfaction.

RESEARCH OBJECTIVES

- Conduct a review of the current quality complaint SOP "Complaint Sample Handling Procedure" to eliminate the identified waste and areas for improvement.
- Utilize the Voice of the Customer (VOC) and PDCA (Plan-Do-Check-Act) Lean Methodology tools to measure employee satisfaction and standardize the SOP.

- Measure the effectiveness of the changes implemented in the SOP in terms of waste elimination and employee satisfaction.
- Provide recommendations for further improvements and enhancements to the quality complaint procedures in the Manufacturing Company.

RESEARCH CONTRIBUTIONS

By applying Lean Methodology, with a focus on VOC and PDCA cycle, this project seeks to enhance efficiency by eliminating the overprocessing waste of the current SOP of the Complaint Department. The elimination of the duplicated tasks is expected to streamline the test request process by standardizing the SOP, improving employee satisfaction, and cultivate a culture of continuous improvement. This approach promises both immediate and long-term contributions to the complaint department and the organization, aligning with Lean principles for sustainable efficiency gains.

LITERATURE REVIEW

Several studies have been conducted to explore the importance of effective procedures for handling quality complaints in the manufacturing industry. In the article titled "What's in Your SOP?" [1], the authors emphasize the significance of standard operating procedures (SOPs) in ensuring consistent operations within manufacturing companies. The article highlights the need for well-defined SOPs to address quality complaints and prevent delays in their resolution.

Furthermore, Vuk examines the management of complaints and product recall in the article "Management of Complaints and Product Recall" published in the ISBT Science Series [2]. The author emphasizes the impact of efficient complaint management systems on customer satisfaction and the overall reputation of manufacturing companies. The article highlights the importance of timely response, effective communication, and appropriate corrective actions in handling quality complaints.

In the realm of process improvement within manufacturing, Charyaa [3] discusses the utilization of Lean Manufacturing principles for material handling and process improvement. In the article "Material Handling and Process Improvement Using Lean Manufacturing Principles" published in the International Journal of Industrial Engineering [3], the author explores how Lean principles can contribute to enhancing the efficiency and effectiveness of quality complaint procedures. The study emphasizes waste reduction, streamlined processes, and continuous improvement as essential aspects of managing quality complaints in manufacturing.

By incorporating findings from these three articles, this literature review highlights the significance of well-defined SOPs, efficient complaint management systems, and the application of Lean Manufacturing principles in handling quality complaints within the manufacturing industry. These studies underscore the need to reduce delays, improve customer satisfaction, and identify opportunities for enhancing product quality through effective quality complaint procedures.

METHODOLOGY

VOC and PDCA are essential tools of continuous improvement by Lean Methodology. VOC is the process of collecting and analyzing feedback, comments, suggestions, and opinions from customers regarding a product, service, or brand.

The goal of capturing the "voice of the customer" is to gain a deeper understanding of customer needs, preferences, and expectations [4]. In this project, VOC survey was used to measure employee satisfaction with the current and new SOP processes.

PDCA is a problem-solving and continuous improvement methodology commonly used in various fields, including business, manufacturing, healthcare, and project management [5]. The PDCA cycle is a very useful tool for carrying out continuous improvements in processes, including Standard

Operating Procedures (SOPs), and will be explained in the next paragraph.

1. Plan:

- Identify the problem: Here we recognize the presence of duplicated tasks in the current SOP and their negative impact on efficiency and employee satisfaction.
- Identify objective: Here we identified the main objectives such as optimizing the SOP.
- Gather Data and Analyzed: Here we collect data on current SOP process times and employee satisfaction levels.

2. Do:

- Implement Lean Methodology: Execute the improvement strategies identified in the "Plan" phase.
- Train and Communicate: Here we ensure that employees are trained in the new process changes.

3. Check:

- Monitor results: Continuously monitor the impact of the changes on efficiency, entry error reduction, and employee satisfaction.
- Compare with objectives: Evaluate whether the objectives set in the "Plan" phase are being achieved. Assess whether the elimination of duplicated tasks has improved the SOP.

4. Act:

- Adjust and Standardize: Based on the monitoring and evaluation in the "Check" phase, make further adjustments to the SOP as necessary.
- Continue Monitoring: The PDCA cycle is iterative. Continue to periodically review the SOP and make improvements as needed to maintain efficiency and effectiveness.

RESULTS AND DISCUSSION

The PDCA cycle was employed to apply Lean Methodology in optimizing the quality complaint sample testing process. This approach follows a

systematic path towards ongoing process improvement, encompassing SOP.

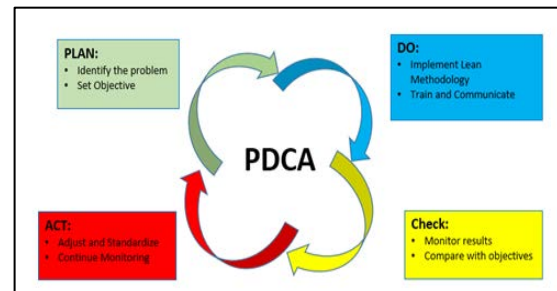


Figure 1
PDCA Lean Tool

1. Plan:

- Identified the Problem: Duplication of tasks for complaint sample testing requests, both in electronic (LIMS) and paper format (Logbook). This results in a loss of time, and resources, employee dissatisfaction, and potential data entry errors.
- Objectives: The main objective is to optimize and enhance the SOP by effectively eliminating duplicated tasks. This will be achieved through:
 - Identification of duplicated tasks within the existing SOP.
 - Evaluation of the necessity and purpose of each duplicated task.
 - Removal of unnecessary duplicated tasks while maintaining effectiveness and regulatory compliance.
 - Documentation and communication of SOP revisions to all employees.
 - Measurement and tracking of efficiency after the implementation of the changes.
- Gather Data and Analyze: Current complaint sample testing process flow SOP:

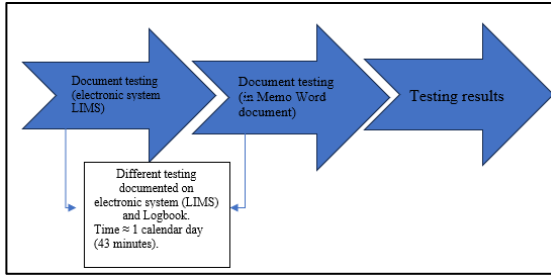


Figure 2
Current Process Flow

Table 1
Sample Testing Request Current Process Flow

No.	Time	No.	Time
1	44	11	41
2	41	12	45
3	43	13	47
4	44	14	39
5	43	15	44
6	41	16	40
7	45	17	47
8	42	18	45
9	43	19	41
10	41	20	44
		Average	43

The data collected covers complaints with samples received from January 01, 2022, to June 26, 2023. During that period, a total of twenty-nine (29) complaints with samples were received, with fourteen (14) of them having entry errors in the logbook.

It was noticed that 11 complaints had a timeline extension due to delays in testing results. Testing results delays and investigation timeline extension are not part of our main objective, but it was included in the data analyzed to see if it was caused by the overprocessing waste task.

Documentation of testing in LIMS and Logbook was measured from May 11, 2023, to June 26, 2023, it takes an average of forty-three (43) minutes to do both tasks (refer to Table 1). This double documentation is a non-added value activity and can be classified as a waste of overprocessing by Lean Methodology. Additionally, a VOC satisfaction survey was conducted on all the employees of the complaint department, to measure the level of satisfaction with the current SOP (refer to Figures 3, 4, and 5).

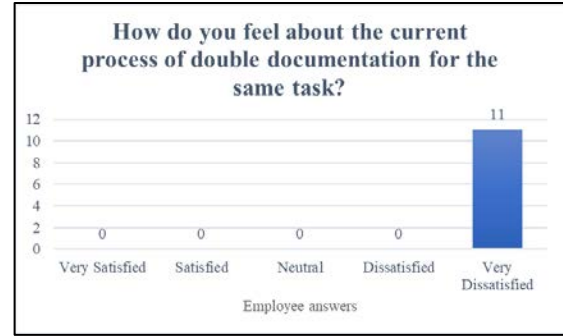


Figure 3
Employee Satisfaction Survey of the Current Process No.1

The survey results show a 100% for very dissatisfied with the current process of double documentation for the same task. These results strongly suggest that there is a need for change in the current process to address the concerns and dissatisfaction related to double documentation.

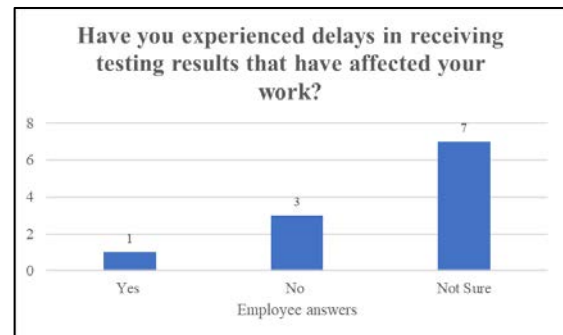


Figure 4
Employee Satisfaction Survey of the Current Process No.2

The survey results reveal that seven (7) out of eleven (11) employees are not sure if they experienced delays in receiving testing results that have had an impact on their work. However, the data collected show that eleven (11) complaints timelines were extended due to a delay in the testing results.

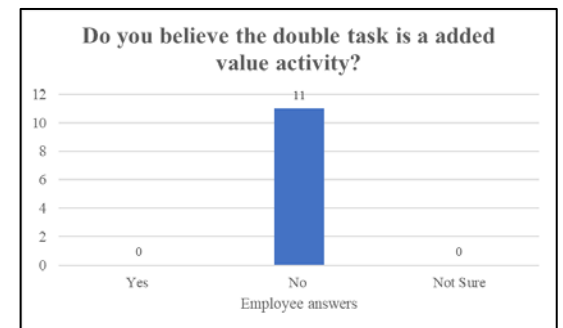


Figure 5
Employee Satisfaction Survey of the Current Process No.3

All employees believe the current process of double task is not an added-value activity. This highlights the importance of addressing the current process to improve overall workflow and efficiency in the organization.

2. Do:

- **Implement Lean Methodology:** Revision of the SOP started on May 11, 2023. In this revision, it was collectively decided to retain the LIMS system as the preferred method, opting against the use of Logbook (paper format). LIMS is a validated electronic system that empowers us to maintain a comprehensive chain of custody, diligently tracking the sample's whereabouts and status throughout its journey.
- **Train and Communicate:** Since the employees were already trained in documenting the testing requirements in LIMS, training was unnecessary, and all employees participated in the decision to eliminate the Logbook and keep LIMS. SOP revision became effective on June 27, 2023.

3. Check:

- After the SOP revision became effective on June 27, 2023, the process flow of sample testing requests was measured, and a second VOC satisfaction survey was conducted on all the employees of the complaint department to measure their satisfaction with the changes implemented.

New complaint sample testing process flow SOP:

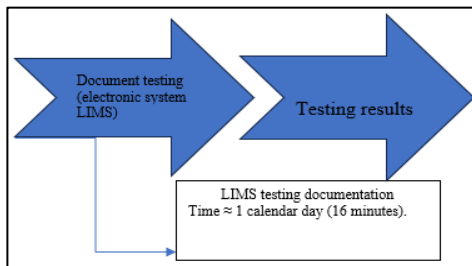


Figure 6
Improved Process Flow

Table 2
Sample Testing Request Improve Process Flow

No.	Time
1	15
2	17
3	17
4	16
5	16
AVG	16

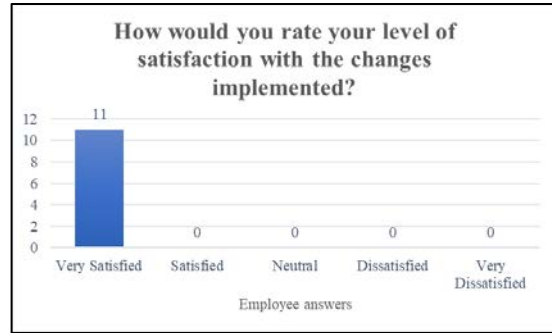


Figure 7
Employee Satisfaction Survey of the Improved Process No. 4

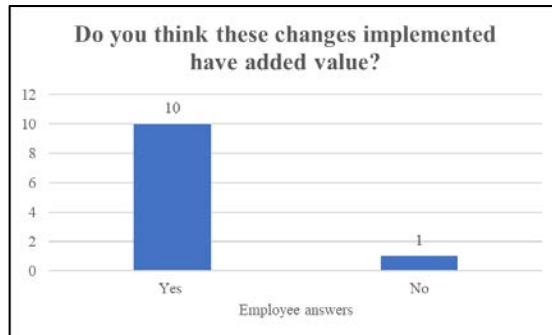


Figure 8
Employee Satisfaction Survey of the Improved Process No. 5

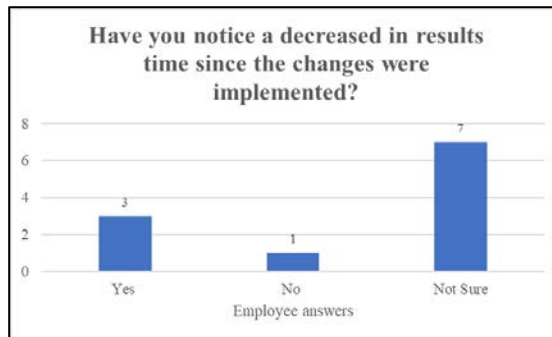


Figure 9
Employee Satisfaction Survey of the Improved Process No. 6

Measure Results

New data, collected after the implementation of the SOP change, covers the period from June 27, 2023, to August 31, 2023. During this period a total

of five (5) complaints with samples were received. The average documentation of the test request had decreased from forty-three (43) minutes to sixteen (16) minutes, as shown in Table 2, and zero (0) data entry errors. Even though only five (5) complaints have been received since the revision of the SOP, this reflects a positive impact of efficiency improvements, as evidenced by the elimination of overprocessing waste of the SOP process and the elimination of data entry errors. Furthermore, with the elimination of the Logbook, we don't only comply with Data Integrity (DI), with this, we save time on Logbook generation and employee Logbook revision. This suggests that the implemented changes have led to a more efficient and effective process.

Only one (1) complaint investigation required an extension to the investigation timeline due to awaiting complaint results. This extension was due to the complaint sample arriving late at the Manufacturing site and, therefore, is not related to the testing result delay due to overprocessing waste (double documentation). However, it is important to note that further data and analysis are required before definitively attributing the delay in results to the duplicated documentation task.

Regarding the employee satisfaction employee survey, Figure 7 shows that all employees expressed evident satisfaction with the implemented changes. In Figure 8, all employees indicated that they feel the implemented changes have added value to reducing waste and streamlining the SOP process. Figure 9, a clear majority of employees (7 out of 11) noticed a decrease in results time since the changes were implemented, a smaller number of employees (2 out of 11) did not notice a decrease, and a minority of employees (2 out of 11) were unsure or did not provide a definite response. The statistical analysis suggests that there is a notable association between the changes implemented and the employee's perception of a decrease in result time. Notably, this change implemented in the SOP resulted in 100% levels of employee satisfaction as previously discussed in Figure 7.

Compare to Objectives

The data collected, and the analysis conducted align with the objectives of improving efficiency, the double documentation (overprocessing waste) was eliminated, data entry errors were completely eradicated, which is a positive impact on DI, and enhanced employee satisfaction was achieved, as outlined in the project's goals.

4. Act:

- **Adjust and Standardize:** SOP revision became effective on June 27, 2023. Based on the results and analysis comparison, the objectives have been effectively addressed:
 - **Improving Efficiency:** Eliminating the overprocessing waste of the double documentation of sample testing requests is a significant improvement in efficiency, as it saves both time and resources.
 - **Reducing Sample Testing Delays:** By eliminating the overprocessing waste of the double documentation, data entry errors were eradicated. The fact that entry errors were eliminated is a strong indicator of improved efficiency in this regard and has a meaningful impact on DI, as this is one of the aspects Regulatory Agencies evaluate in their inspection.
 - **Increasing Employee satisfaction:** The implemented change in the SOP achieved and enhanced a positive impact on employee satisfaction by 100%.
- **Continue Monitoring:** The process will be monitored until June 30, 2024, to ensure that the changes are sustained and remain effective over time.

Overall, the data and analysis align well with the project's objectives, indicating that significant improvements have been made. The elimination of double documentation (overprocessing waste), the absence of data entry errors, and enhanced employee

satisfaction are all positive outcomes that contribute to the project's success.

CONCLUSION

Through this project, several significant findings have come to light. Foremost among them is the successful achievement of our project objectives. The elimination of double documentation (overprocessing waste) marked a reduction in testing results delays, the total absence of data entry errors, and the evident boost in employee satisfaction all underscore the profound impact of our efforts. However, it's essential to acknowledge certain limitations. Our project, while comprehensive, focused on a specific timeframe and may benefit from further long-term monitoring to validate the sustained effectiveness of the changes.

By implementing Lean Methodology, we have demonstrated the practical benefits of Lean principles. Additionally, the inclusion of employee feedback mechanisms underscores the importance of human factors in process optimization.

Future research presents promising opportunities across various domains. Firstly, a longitudinal study will establish the enduring impact of our implemented changes. Furthermore, research into advanced Lean techniques and applying Lean Methodology offers various possible ways to enhance efficiency, particularly in terms of reducing complaint investigation timelines.

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