Quality Inspection Time Reduction for Double Pouch Products

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Abstract *— Improvements on inspection times are a common subject of analysis for continuous improvements projects, because of the imperative need of reducing time for non-value-added processes. This project, undertaken at Medical Enterprise's Santo Domingo facility, targeted the optimization of quality inspection processes for Double Pouch Products, a substantial portion of the annual manufacturing output. The primary focus was on alleviating prolonged quality assurance (QA) inspection times, with a goal of achieving a 20% reduction by the end of Q3 FY24. To address this challenge, a strategic solution was implemented by consolidating inspections for inner and outer pouches, resulting in a notable 58% increase in monthly output without compromising product quality. The qualification process, incorporating a Test Method Validation, unequivocally validated the efficacy of the refined inspection method. This successful initiative not only directly addressed the initial issue of extended inspection times but also contributed significantly to heightened operational efficiency and increased overall output. Project team's recommendations emphasize extending similar optimization strategies across the organization, highlighting the pivotal role of continuous improvement in sustaining competitiveness and fostering innovation.*

Key Terms *— Continuous improvement, Quality Inspection, Manufacturing, Test Method Validation*

INTRODUCTION

Medical Enterprise is a leading healthcare company with presence all over the world and recognized as a world leader in technology innovations and medical devices manufacturing. It was founded in 1949, with the mission of "Sustaining lives" which is still embraced today.

Medical Enterprise facility at Santo Domingo, Dominican Republic is one of the key manufacturing sites on the east region, with more than 1,000 employees with a portfolio of over 2,000 products, serving as subject for several continuous improvement project's implementations.

Double pouch products are defined as packaged products that by specification (Drawings, Bill of Materials, etc.) are packaged using two pouches (One Inner pouch and one Outer pouch). Prior project's implementation of Double Pouch Products validated state was such that inner pouch's content and sealing was inspected by the quality inspector (QA) and then the product was returned to the manufacturing process. Afterwards, the manufacturing process was completed by assembling the outer pouch and introducing the inner pouch. Finally, the product was inspected by QA for outer pouch content and sealing. This double inspection process represented a significant time waste for the process since whenever the inner pouch was being inspected, the manufacturing process was stopped until all units were fully inspected and returned to the manufacturing line to perform the remaining steps of the packaging process before the second quality inspection process.

The project consisted of updating the QA inspection process on the packaging area, to unify the inspection process for products with both inner and outer pouches for all applicable codes to reduce inspection time. Therefore, the project objective was defined as:

- Reduce the QA inspection time of Double Pouch products by at least 20% by end of third quarter (Q3) of Fiscal Year 2024 (FY24).

LITERATURE REVIEW

Productivity management tools are used for the improvement of all kinds of manufacturing processes, including product inspection. The implementation of these tools decreases cost without reducing inspection accuracy.

Through the evolution of the manufacturing industry both product quality and cost reduction are two key pillars for the success of a company. However, in occasions these two elements have seen as counterparts and inversely proportional since a big segment of the product quality management is related to product inspection and quality assurance [1], which are processes that do not add value to the product and lead to time and resource investment, that are translated to costs.

Therefore, the industry has look up into ways of gaining advantage of productivity management and statistical tools to improve the inspection process while maintaining quality levels. One of the most basic ways to improve inspection times are the use of process standardization and motion techniques to eliminate unnecessary movement and elements that do not collaborate to the purpose of the task being performed [2]. Also, a common and low-cost method of reducing inspection time is by developing methods which are capable of detecting non-conformances even if they reduce the frequency of inspection, normally these methods are based on statistical models that provide objective evidence and high confidence level, an example of these are AQL inspections or skip lot monitoring [3].

A crucial point into the improvement of quality inspections within a company while applying simple methods and low-cost alternatives is the support of the management and leadership roles since these improvements or changes are people-driven [1] and require the comprise of the personnel to be achieved.

In the last decades new technology aided methods have come into play, as most of the inspection methods are visually performed, a large amount of the new technologies efforts has focused on creating resources as automatic vision inspection systems, scale weighted systems and cam-inspection systems aided with motion and detection sensors. These advancements in the inspection technologies have gained popularity in the industry since they provided more reliability and confidence that their human dependable counterpart methods [4].

METHODOLOGY

Product scope and impacted processes

Medical Enterprise at its Santo Domingo site manufactures three product families in the Packaging area, which are:

- Single pouch products
- Double pouch products
- Polybag products

Double Pouch Products represented 40% of the annual product manufactured at the Packaging lines, as described on Figure 1.

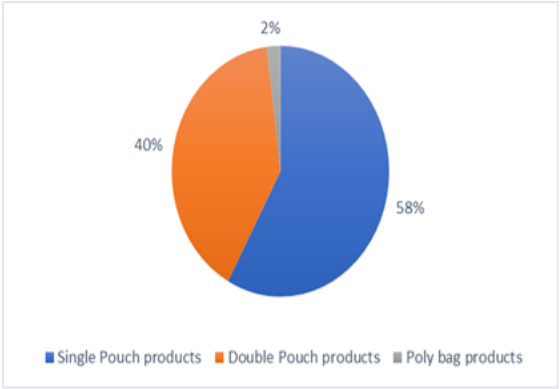

Figure 1
Volume distribution for Packaging lines

Process assessments

The initial assessment consisted of performing a process map of the established process as shown in Figure 2, to compare with the alternatives proposed.

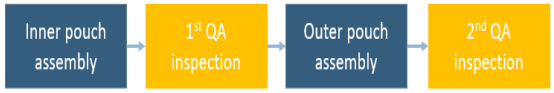

Figure 2
Double pouch products actual process flow

Once current method was mapped, the multidisciplinary team conducted brainstorming sessions to determine possible solutions to reduce time inspection, the resulting proposals were:

- Combining inner and outer pouch inspection (Proposal 1).
- Adding a second operator to increase output (Proposal 2).

Proposals were compared to the current method in terms of inspection time, cost and initial investment, as shown in Table 1. As per the comparison made, the team selected the option of combining the inspections (Proposal 1) since the cost per hour or labor cost and the initial investment were significantly lower than Proposal 2, even though Proposal 2 had a lower inspection time. Refer to Figure 3 for details on the selected proposal. Compared to the current method, Proposal 1 meant a significant reduction of the inspection time, as shown in Figure 4.

Table 1
Double pouch products inspection process, current method versus proposals

Metric	Current method	Proposal 1	Proposal 2
Operator quantity	1	1	2
Inspection time (min/un)	6	3.5	3
Cost per hour (labor)	US$1.18	US$1.18	US$2.36
Investment (US$)	-	<US$5k	>US$10k

Figure 3
Double pouch products selected proposal for process flow

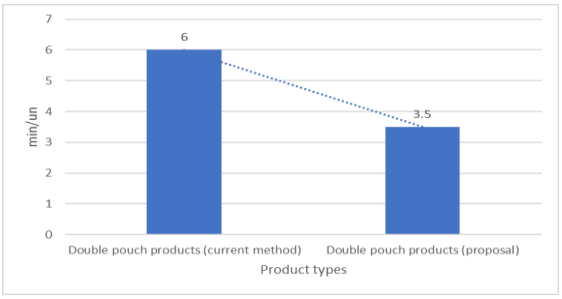

Figure 4
Double pouch products inspection methods time comparison, current method versus Proposal 1

Risk assessment and requirements for implementation

After the team selected the proposed method to be implemented, a risk assessment was conducted to address and list all the requirements for the implementation. These requirements are listed on Table 2.

Table 2
Project requirements based on risk assessment

Requirement #	Activity description
1	Change Control opening
2	Master Validation Plan
3	Test Method Validation (TMV)
4	TMV execution
5	TMV report
6	Master Validation Report
7	Procedures updates
8	Standard work package update
9	Change Control closure

RESULTS

Inspection time and efficiency improvement

After all project activities were completed, the manufacturing line performance was monitored to collect data over the improvements implemented. It was observed that the average Double Pouch Product's unit output increased from 20,000 monthly units to 31,600 after the implementation of

the new inspection method. Refer to Figure 5 for further detail.

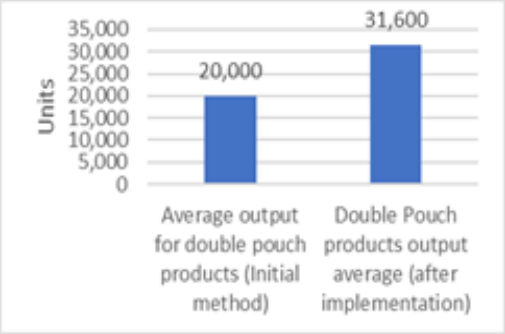

Figure 5
Double pouch products monthly output comparison, Initial versus implemented method

The reduction in the time inspection meant an increase of 58% percent in the monthly output of units for Double Pouch Products. Also, no non-conformances related to Double Pouch Products inspection processes were detected in the Packaging manufacturing lines during the data collection period.

Qualification results

The qualification process for the Test Method Validation for the inspection unification was conducted through an Attribute Agreement Analysis.

The Attribute Agreement Analysis displays the results on four different assessments of agreement evaluated through a Kappa Test. The four-agreement analysis evaluated were the following: Within Appraiser, Each Appraiser vs. Standard, Between Appraiser, and All Appraiser vs. Standard. The requirement to accept this test was that each agreement should obtain a Kappa > 0.70 to be considered as a favorable inspection method as per procedure requirements. The Attribute Agreement Analysis consisted in verifying if the new inspection method was reliable, for this each person that worked as subject for the study (appraiser) was challenged to inspect prepared defective and acceptable sample units to verify if any defects or non-conformances could be properly detected. Appraisers were evaluated in four different scenarios presented in Table 3 with satisfactory results since all categories were passed with over the minimum of 70%.

Table 3
TMV results

Agreement	Results
Within appraiser	Appraiser 1: 100% Appraiser 2: 96% Appraiser 3: 100%
Each appraiser versus Standard	Appraiser 1: 100% Appraiser 2: 93% Appraiser 3: 100%
Between appraisers	96%
All appraisers vs Standard	97%

Based on the results obtained for this qualification, all the agreement analysis assessments obtained a Kappa value >70% which is considered an effective inspection method.

CONCLUSIONS

Summary of achievements

In conclusion, the following milestones were reached out during this project's implementation:

- Successful unification of Double Pouch Product inspection through qualification.
- Fifty-eight (58%) of inspection time reduction for Double Pouch products without increasing long term costs.
- Monthly output increase of approx. 12,000 units of Double Pouch products.
- Project activities completion on schedule.

Future recommendations

The multidisciplinary team recommends extending inspection time reduction projects through the organization since it was demonstrated that these projects can lead to cost reduction improvements without compromising product quality.

Also, the multidisciplinary team encourages to invest in continuous improvement since it is essential for organizations aiming to remain

competitive, efficient, and responsive to both internal and external factors. It promotes a proactive mindset, a commitment to quality, and a culture of ongoing learning and innovation.

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