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Abstract

A project at Medical Enterprise's Santo Domingo facility aimed to optimize the quality inspection process for Double Pouch Products, a significant part of their annual manufacturing. The focus was on reducing prolonged quality inspection times, with a target of a 20% reduction by the end of Q3 FY24. The solution involved consolidating inspections for inner and outer pouches, resulting in a remarkable 58% increase in monthly output while maintaining product quality. The qualification process confirmed the effectiveness of the refined inspection method. This successful initiative not only addressed extended inspection times but also enhanced operational efficiency and overall output. The project team recommends applying similar optimization strategies organization-wide, emphasizing the role of continuous improvement in sustaining competitiveness.

Introduction

Medical Enterprise, established in 1949 with a mission to sustain lives, operates a significant healthcare manufacturing facility in Santo Domingo, Dominican Republic, employing over 1,000 people and offering a diverse product portfolio. Recent focus on continuous improvement projects centered around Double Pouch Products, which undergo two separate inspections, causing delays in manufacturing. The project aimed to streamline the inspection process, consolidating inner and outer pouch inspections to reduce quality assurance (QA) inspection time by 20% by the end of the third quarter of Fiscal Year 2024 (FY24).



Current state represented a significant time waste for the process since whenever 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.

Literature Review

Productivity management tools enhance manufacturing processes, including cost-effective improvements in product inspection without compromising accuracy [1]. Traditionally, quality management practices like inspection and assurance were seen as non-value-added [2], prompting the industry to utilize productivity tools and statistical models [3]. Basic strategies involve process standardization and motion techniques to reduce unnecessary elements and enhance inspection times [2]. Leadership support is crucial for successful implementation, and recent technological advancements, such as automatic vision inspection systems, offer more reliable alternatives to human-dependent methods [4].

Methodology

The methodology followed to complete the project consisted of evaluating the scope of the project, conduct an analysis of the process to propose a solution implemented through test method qualifications and documentation updates. First, the process was mapped out (See Figure 1) to establish the sequence of the operations:

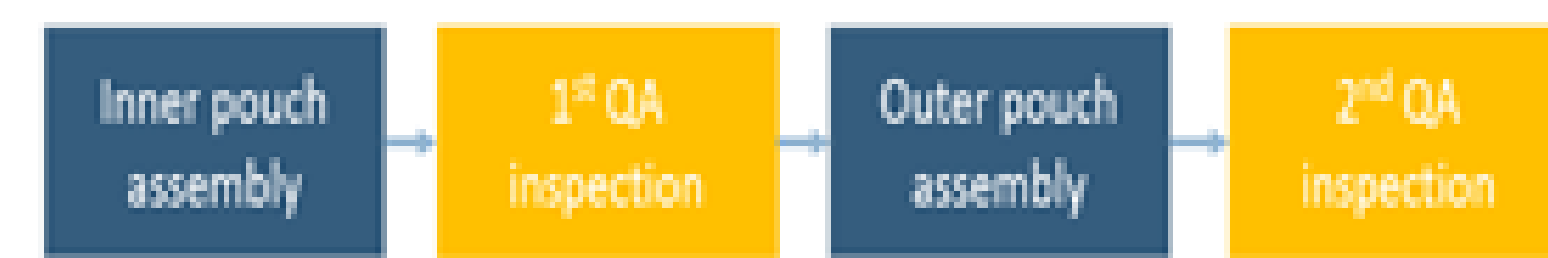


Figure 1. Double pouch products actual process flow

Then, the multidisciplinary team proposed options on how the process could be improved. These proposals were evaluated in terms of inspection time, labor cost and investment. See Table 1

Table 1. Double pouch products inspection process, current method

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

With the proposal selected, the team did the new process analysis to list all the requirements needed to change the manufacturing process, being the Test Method Validation (TMV), the core activity. See Figure 2 and Table 2 for detail



Figure 2. Double pouch products selected proposal for process flow

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

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

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 3

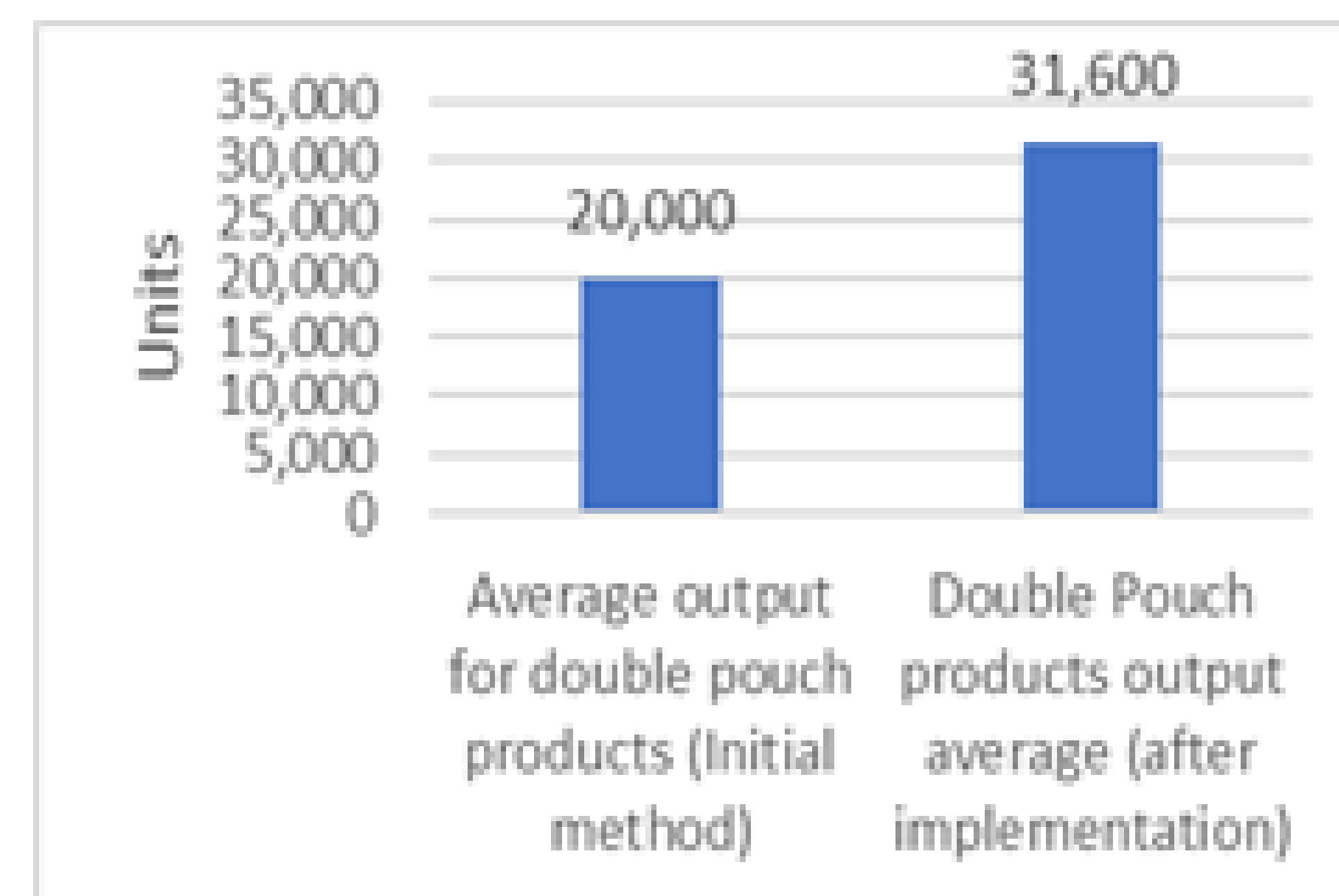


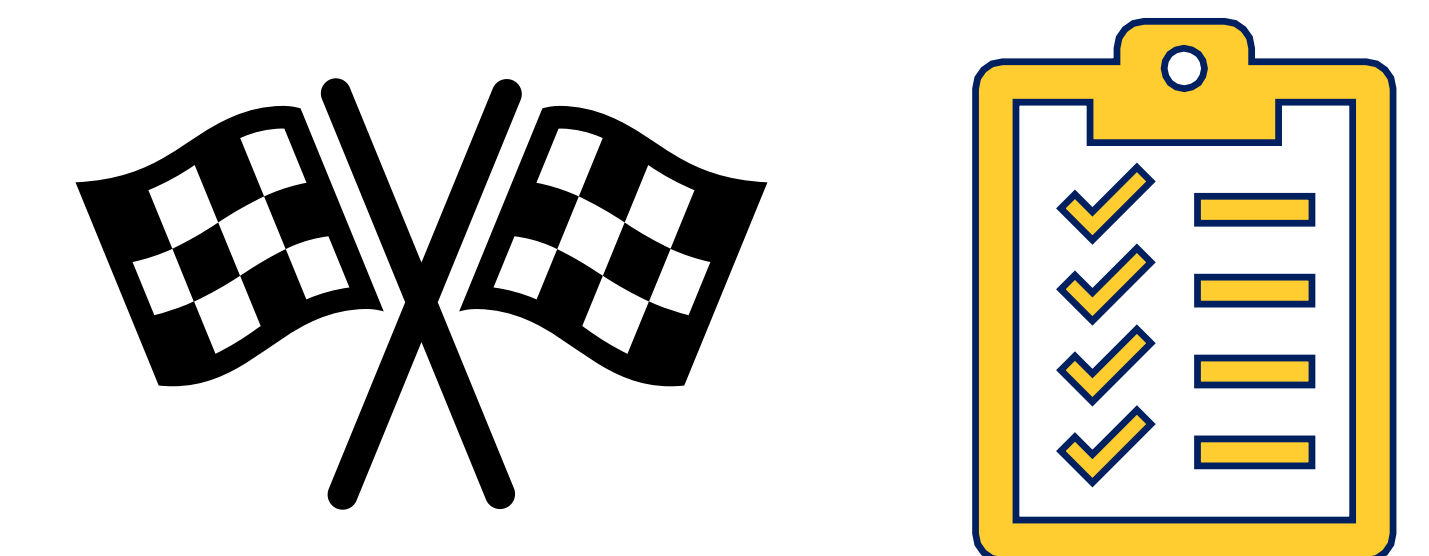
Figure 3. Double pouch products monthly output comparison, Initial versus implemented method

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.

Conclusions

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.



References

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