Productivity Increase by Means of Critical Process Automation for Edwards Lifesciences

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Abstract *— Due to the boom in exports of medical devices, the effort to maintain product quality has increased, but productivity has remained unchanged. In the free zone industries, direct labor is one of the variation factors that affect product quality.*

The objective of this project is to understand the effects of automation of a key process in the Dominican Republic's facilities of Edwards Lifesciences, in terms of manufacturing costs and production rates. This body of knowledge will later be applied to a specific manufacturing line which has its demand increased by more than 50%.

Key Terms *— Automation, Efficiency, Process control, Productivity.*

INTRODUCTION

Production systems for the manufacture of medical devices are usually complex systems that contain different quality subsystems.

Assembly operations are the most expensive processes on a production line. This is due [1] to the variability of the assembled parts and the complexity of the tasks to be carried out for the assembly of these, with the problem of fluctuations in demand, both in terms of volume and type of products.

As the business improves, working at a higher rate or over longer periods of time becomes inefficient. This is where the process optimization options and the optimization of flows through the production plant are considered.

When the production rate is high enough, and the production forecast lays the foundation for the above, assembly operations can be automated with machines designed for a process. Thus, designing an assembly line requires deciding how the work will be divided between people and machines for a given sequence.

This decision involves taking into account factors such as [2], the price of labor, the training of labor, the maintenance capacity of the devices, the quality of production, the balancing of the line of production, the limit of discards, the return on investment at the productivity level, the flexibility and the conditions of the operators.

BACKGROUND

Medical Device manufacturing plants in the Dominican Republic, due to their nature of being in free zones, use direct labor in most of their manufacturing processes. In consequence the quality of the product and of the production lines depend on human factors such as training, the fatigue that the work can generate throughout the working day, as well as physical health of the personnel.

These dependencies negatively affect the quality of the product, the productivity of the production line, the production queues, and the inventory in process because of the imbalance between manufacturing operations.

LITERATURE REVIEW

In 2019, the value of exports from the Free Zones sector of the Dominican Republic reached $6,263.50 million dollars, a relative growth of 0.50% compared to the previous year [3].

Exports of Medical and Pharmaceutical Products represented 26.50% of the total exports of the sector [3]. Likewise, the manufacture of medical devices represents 26.20% of the economic activities that concentrate the largest volume of

accumulated investment in the free zones sector, with $ 1,346.40 million dollars.

Automation in manufacturing processes is a strategy that is currently booming in pharmaceutical companies and in medical device manufacturing companies, sectors that are regulated by the Food and Drug Administration (FDA). FDA's current activities reflect that automation has a place in these industries.

The Code of Federal Regulations, Title 21, Volume 8, Section 820, states that [4] when computers or automated data processing systems are used as part of the production or quality system, the manufacturer shall validate the software of the computer for its intended use in accordance with an established protocol. All software changes will be validated prior to approval and issuance. These activities and validation results should be documented.

One definition of automation is [5] the replacement of human activities for activities performed by machines, which [6] emphasizes efficiency, productivity, quality, and reliability, focusing on systems that operate autonomously. under extended periods of time.

In its guide for industries, the FDA proposes that [7] manufacturers should understand the sources of variation, detect the presence and degree of variation, understand the impact of process variation on the product, and control such variation in a consensus manner with the risk that represents the process and the product.

Likewise, it suggests that advanced strategies such as Process Analytical Technology (PAT) be used so that the outputs of the processes remain constant.

The PAT is defined [7] as a system to design, analyze and control manufacturing processes through measurements of critical process parameters that affect the critical qualities for product quality.

The purpose is [7] reduction in cycle times, reduction of discards, reduction in human error, and increase in the productivity and efficiency of a production line.

PROBLEM STATEMENT

Currently, Edwards Lifesciences' assembly operations in the Dominican Republic site, have a low level of automation.

This is because, fundamentally, direct labor manufacturing operations are usually cheaper than their automated counterpart.

However, at sub-assembly levels, one manufacturing line has increased its demand by more than 50% in the past six months. After implementing a 3rd shift to cover 33% of the demand surplus, one question arose: Which process can benefit from automation to meet the remaining demand level?

Table 1 identifies the manual processes currently in place at Edwards Lifesciences' Dominican Republic Site.

Table 1
Manual Assembly Processes in Medical Device Manufacturing

Process	Can the unit be reworked?
Threading	Yes
Solvent Bonding	No
Adhesive Bonding	No
Tube Coiling	Yes

The main objectives of implementing this project are:

- Increase the capacity of the manufacturing line by 20%.
- Maintain current manufacturing costs.

METHODOLOGY

The objectives will be achieved by:

- Observing the current process flow
- Determining the process bottleneck
- Challenging the baseline process against a proposed process
- Redesigning the baseline manufacturing layout based on results
- Calculating general savings of the proposal

STUDY RESULTS

Baseline Process Flow

Currently, the process flow consists of nine (9) different steps or processes, shown on Table 2.

Table 2
Cycle Time (in seconds) of Baseline Process Flow

Process	Cycle Time (s)
Cap & Plunger Assembly	4.7
Piston Assembly	6.7
Seal Assembly	7.4
Seal Siliconization	6.5
Body Assembly	7.6
Adhesive Bonding	8.5
Rework Station (pre-curing)	9.6
Visual Inspection (post curing)	7.0
Functional Tests	7.5

The adhesive bonding process was determined to be the bottleneck. Currently, this process is duplicated to keep up with the current demand. The systems used for this process use a timed pressure setting to dispense the adhesive. This has the disadvantage [8] that the dispensed volume is dependent on fluid viscosity, which can change based on local environmental conditions. Additionally, the system must be constantly purged to eliminate trapped air bubbles.

Proposed System vs. Baseline System

A volumetric dispensing system was proposed. Here, the dispensed volume is independent of fluid viscosity. The SOP of the adhesive bonding process specifies an adhesive shot size between 0.0103 and 0.0200 grams.

Thirty (30) samples were taken from three separate runs and were compared against the general specifications.

Figure 1 shows that the current adhesive bonding process system is not capable of achieving the expected results. This is the reason why the rework station is currently implemented.

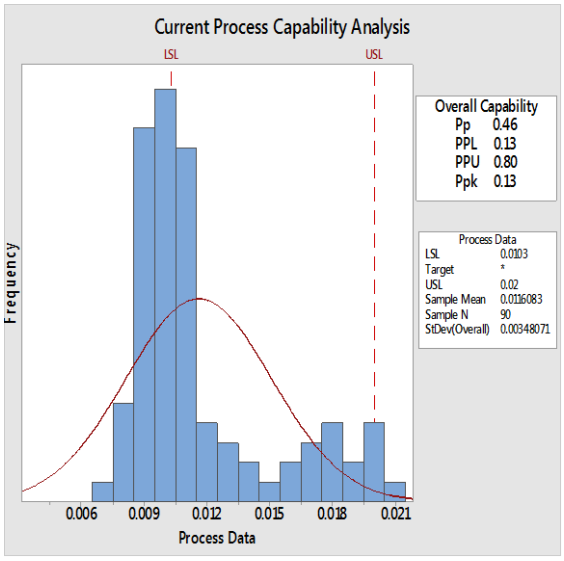

Figure 1
Capability Report of Baseline Adhesive Bonding Process

The proposed system variability fits ten times inside the general specifications range. Reported process capability is 4.60. Figure 2 shows the data frequency distribution of the proposed system.

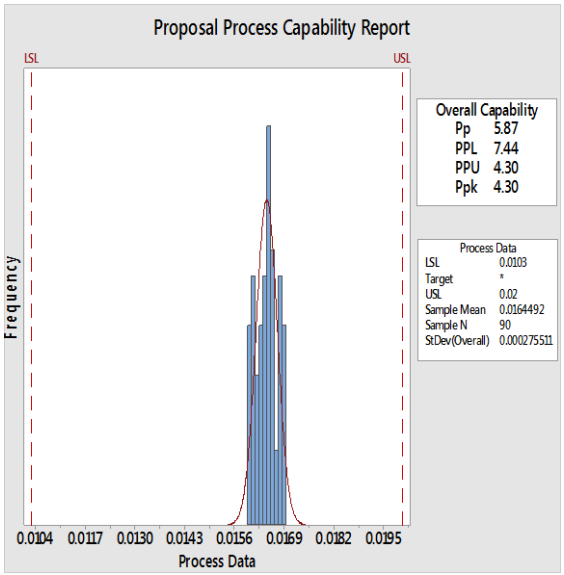

Figure 2
Capability Report of Proposed Adhesive Bonding Process

The current systems were validated with a movement rate of 15 mm/sec. For a 3-unit batch process, with 5 dispensing points on each unit, the

total cycle time of each machine is around 51 seconds.

The proposed system can complete the cycle run of a 3-unit batch in around 7.3 seconds.

Layout Redesign Based on Preliminary Results

Based on the preliminary results, the following changes are proposed:

1. Elimination of redundant adhesive bonding station. The proposed process' throughput with a single machine is higher than the baseline adhesive bonding process.
2. Elimination of rework station. The purpose of this station is to inspect the five dispensing zones and add adhesive if needed.

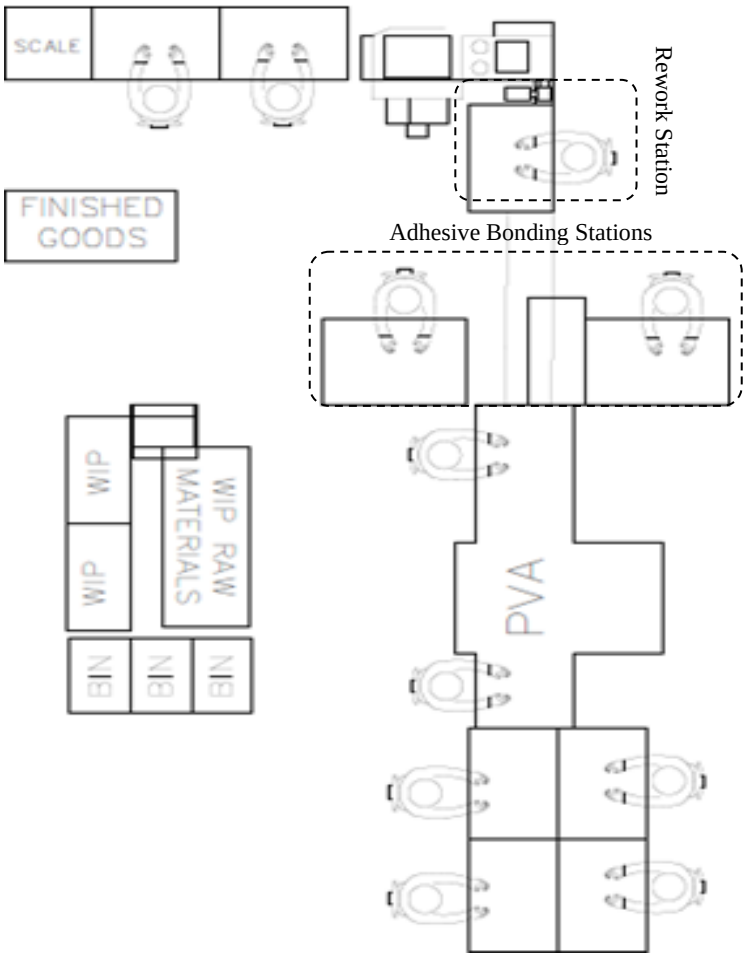

Figure 3
Current Manufacturing Layout

With this approach, manufacturing headcount is reduced by 18%. Figure 4 shows the proposed manufacturing layout.

A productivity increase of 21% is expected with this implementation. The production bottleneck will no longer be the adhesive bonding rework process. Instead, it will be the body assembly process, as demonstrated by the comparison in Table 3.

Estimated Savings

With a headcount reduction of two operators per shift, a productivity increase of 21% against baseline and a defect elimination of excess and lack of adhesive, the estimated savings of the implementation can reach $35.5k USD Year Over Year against baseline.

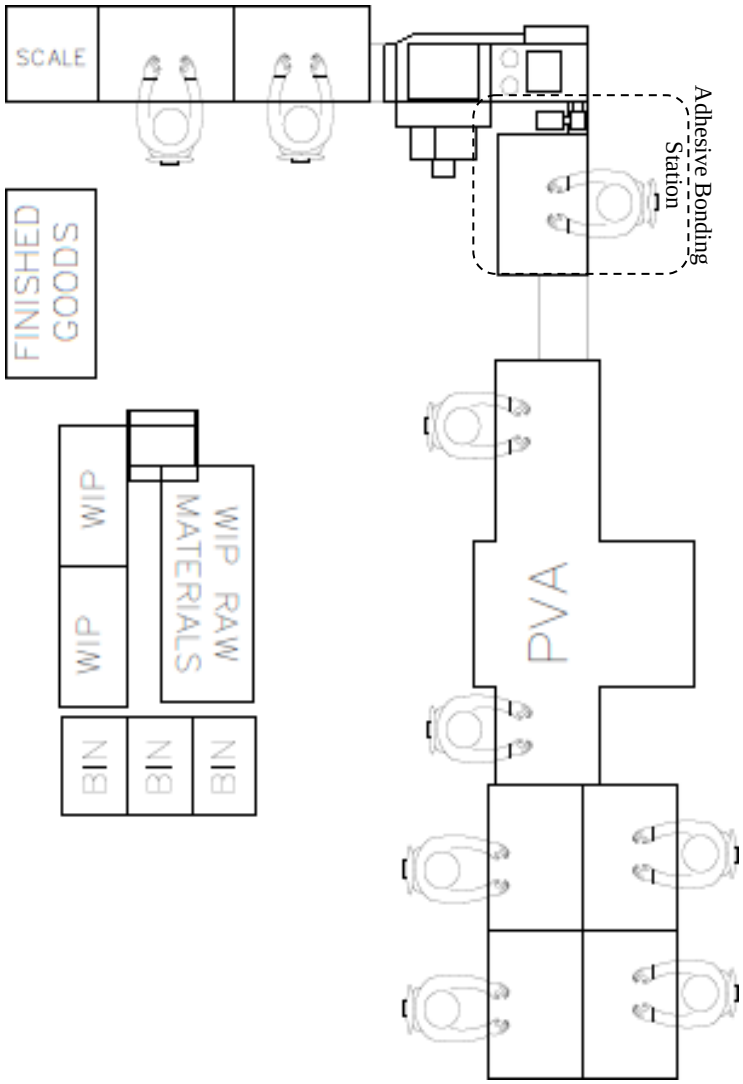

Figure 4
Proposed Manufacturing Layout

Table 3
Cycle Time (in seconds) Comparison

Process	Baseline	Proposal
Cap & Plunger Assembly	4.7	4.7
Piston Assembly	6.7	6.7
Seal Assembly	7.4	7.4
Seal Siliconization	6.5	6.5
Body Assembly	7.6	**7.6**
Adhesive Dispensing	8.5	7.3
Rework Station	**9.6**	N/A
Visual Inspection	7.0	7.0
Functional Tests	7.5	7.5

Table 4
Summary of Changes

Criteria	Baseline	Proposal
Mfg. Output per Shift	2,700	3,260
Manufacturing Headcount	11	9
Capacity Increase	N/A	21%
Cost Savings	N/A	35.5k USD

CONCLUSIONS AND FUTURE WORK

While the output is expected to be 21% after the implementation, further optimizations and work rebalancing can be implemented in the manufacturing line, should demand increase.

As defined by the regulations, the system must be validated, i.e. Software Validation, Installation Qualification, and Operational Qualification must be previously exhausted before its implementation.

Additionally, as the line layout and its throughput will change, a Performance Qualification must be executed to objectively determine that the manufacturing line meets the stablished objectives.

Finally, as compliance and change control, Standard Operating Procedures and ancillary documents should be updated to reflect the new assembly process. Applicable personnel should be trained in the new document revision.

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