# *Streamlining Manufacturing Operations Through Lean Six Sigma and Industrial Automation*

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***Abstract*** *— This pharmaceutical packaging design project integrates Lean Six Sigma principles and industrial automation to optimize a manual-intensive process. Focused on loading/unloading, visual inspection, and palletizing, the improvements include automated systems, such as cameras for inspections and robotic lifts for loading and palletizing. The study reveals a substantial reduction in cycle time, from 91 to 72 minutes, showcasing a 20% improvement. Statistical analysis indicates significant results ($p < 0.001$), validating the effectiveness of the enhancements. The streamlined process aligns with Lean principles, emphasizing efficiency, waste reduction, and improved quality control. The project contributes to operational excellence, offering a competitive edge in the pharmaceutical industry.*

***Key Terms*** *— Cycle Time Reduction, Industrial Automation, Lean Six Sigma, Pharmaceutical Packaging.*

## PROBLEM STATEMENT

The Pharmaceutical industry's packaging processes face inefficiencies, including extended lead times, manual interventions, and operational bottlenecks. This design project addresses a specific packaging line grappling with these challenges. Manual loading/unloading, human visual inspection, and lack of synchronization hinder operational efficiency and responsiveness to market demands. The industry's commitment to quality standards and regulatory compliance necessitates a transformative approach. The project aims to integrate Lean Six Sigma and industrial automation to optimize manual interventions, streamline operations, and enhance efficiency. The project seeks to eliminate bottlenecks and reduce cycle times, ultimately solving the inefficiencies in the pharmaceutical packaging process.

Integrating automated loading/unloading and visual inspection systems, the project aims to bring a significant leap in pharmaceutical packaging, enhancing operational efficiency, reducing human errors, and paving the way to a more streamlined and sophisticated process. The infusion of Lean Six Sigma principles reinforces a commitment to continuous improvement and waste reduction, fostering a culture of efficiency within the packaging line.

This design project's holistic contributions, including automation, efficiency enhancements, innovative quality assurance, and user-centric design, collectively provide a significant competitive edge.

## RESEARCH DESCRIPTION

This design project revolves around meticulously examining and redesigning a pharmaceutical packaging process. The specific focus lies on the manual aspects of the process, including the loading and unloading of pallets and bottle boxes, as well as the visual inspection conducted by human operators. The study integrates principles of Lean Six Sigma and Industrial automation to reimagine and optimize these manual interventions, ultimately aiming to enhance the design of the packaging process.

## RESEARCH OBJECTIVES

This research project is designed to address the challenges in pharmaceutical packaging processes by integrating automated systems. The primary objectives include streamlining manual processes such as loading /unloading pallets and visual

inspection through automation. The aim is to achieve a more efficient, error-free process, reducing manual intervention and enhancing overall productivity.

- Integrate automated systems for the loading and unloading pallets and bottle boxes within the pharmaceutical packaging line.
- Design and implement an automated visual inspection system utilizing advanced technologies such as cameras and image recognition.
- Redesign the packaging process to eliminate bottlenecks, reduce cycle times, and improve operational efficiency.
- Develop automation solutions with a user-centric design approach considering ease of use, operator comfort, and minimal training requirements.

## RESEARCH CONTRIBUTIONS

This research project yields substantial contributions to the pharmaceutical packaging domain. Integrating advanced automation technologies, including automated loading/unloading and visual inspection systems, marks a transformative advancement. The resulting impact includes heightened operational efficiency, significantly reduced human errors, and an overall streamlining of the packaging process. Furthermore, the project's emphasis on operational efficiency enhancement through the elimination of bottlenecks and reduction in cycle times reflects a commitment to continuous improvement. By adhering to Lean Six Sigma principles, the project aims to instill a culture of efficiency within the packaging line, fostering adaptability and responsiveness to evolving manufacturing demands. These contributions collectively position the pharmaceutical manufacturer at the forefront of the industry, establishing benchmarks for operational excellence, innovation, and adaptability to dynamic markets.

## LITERATURE REVIEW

The foundation of this research delves into integrating Lean Six Sigma principles and industrial automation technologies to streamline manufacturing operations. We explore how this amalgamation of strategies and technologies can lead to efficiency, quality improvements, and cost reductions in the manufacturing sector. In the context of this research, a study taken from the article: "Lean Manufacturing Principles in a Smart Factory" [1] illustrates the application of Lean Manufacturing principles in a smart factory setting. It demonstrates how Lean practices can be harmoniously integrated with industrial automation technologies. The study underscores the potential for waste reduction, process optimization, and enhanced quality control. This research will be instrumental in our quest to understand how Lean principles can synergize with industrial automation.

### Lean Six Sigma Integration in Manufacturing

Lean Six Sigma represents a robust methodology for driving continuous improvement in manufacturing processes. Combining the waste elimination focus of Lean with the data-driven, statistical approach of Six Sigma, organizations can achieve unparalleled levels of efficiency and quality. Research studies, such as those conducted by Antony et al. [2] and Mahdikhani [3], highlight successful Lean Six Sigma implementation in manufacturing contexts, showcasing the benefits of reduced defects, improved cycle times, and enhanced customer satisfaction.

### DMAIC Methodology in Lean Six Sigma

The DMAIC methodology (Define, Measure, Analyze, Improve, Control) is the backbone of Six Sigma. In the context of Lean Six Sigma integration, DMAIC is a structured framework for identifying problem areas, measuring existing processes, analyzing data to identify root causes, implementing improvements, and establishing controls to sustain improvements over time. This section will explore how DMAIC can be applied in

manufacturing, drawing from best practices and case studies.

Our design project adopts a holistic view of Industry 4.0 and its implications for manufacturing processes, with specific attention to AGVs. The article: "Towards Industry 4.0: Smart Manufacturing with AGVs" [4] positions AGVs as vital components in the realization of intelligent manufacturing's efficiency, waste reduction, and enhanced production control. It aligns with our goal of more flexible and agile production systems that readily adapt to evolving market dynamics.

### Lean Automation Plan Implementation

A lean Automation Plan is a strategic roadmap for an organization to integrate lean principles with industrial automation. Drawing inspiration from case studies by Anderson Manufacturing [5] and Smith Industries [6], this section will explore the critical components of a successful Lean Automation Plan, emphasizing the need for clear goals, employee engagement, and continuous improvement.

Integrating lean principles with industry 4.0 technologies, when guided by a Lean Automation Plan, offers a structured and practical approach to streamline manufacturing operations. The operational success of lean automation largely depends on achieving simplicity in processes and ensuring a solid fit between people and technology.

## METHODOLOGY

In streamlining manufacturing operations through Lean Six Sigma and Industrial Automation, the methodology encompasses a structured process that integrates crucial principles and technologies to enhance efficiency and quality in the pharmaceutical packaging process.

- **Lean Six Sigma Integration**: The research will adopt a Lean Six Sigma approach to identify, analyze, and improve critical aspects of the pharmaceutical packaging process. This involves implementing the DMAIC (Define, Measure, Analyze, Implement, Control) methodology to systematically address inefficiencies, reduce cycle times, and enhance overall efficiency.
- **Industrial Automation Integration:** Integrating industrial technologies will be approached through a phased implementation plan. This includes assessing current manual processes and identifying areas suitable for automation. Key technologies such as robotic process automation (RPA), AGVs, and Visual inspection systems will be strategically introduced to optimize specific steps in the packaging process.
- **Quantitative Analysis:** Utilized statistical tools to analyze quantitative cycle time, defect rates, and resource utilization data. Conducted before and after comparisons to quantify the impact of improvements.
- **Qualitative Analysis:** Collected qualitative feedback to assess the human-centric aspects of automation, ensuring alignment with job satisfaction and identifying areas for further enhancement.

## RESULTS AND DISCUSSIONS

This section presents the outcomes of the applied methodology to streamline manufacturing operations in the pharmaceutical packaging process. It also follows the logical order established in the Methodology, highlighting key findings and their implications.

**Pre-Implementation Assessment:** The baseline data collection revealed critical insights into the existing inefficiencies of the packaging process. Key metrics such as cycle times, defect rates, and resource utilization were identified, providing a comprehensive understanding of the initial state.

**Define Phase:** The project goals, scope, and deliverables were clearly articulated. The primary objective was to address inefficiencies in the pharmaceutical process, specifically focusing on cycle time reduction, improved efficiency, and streamlined operations.

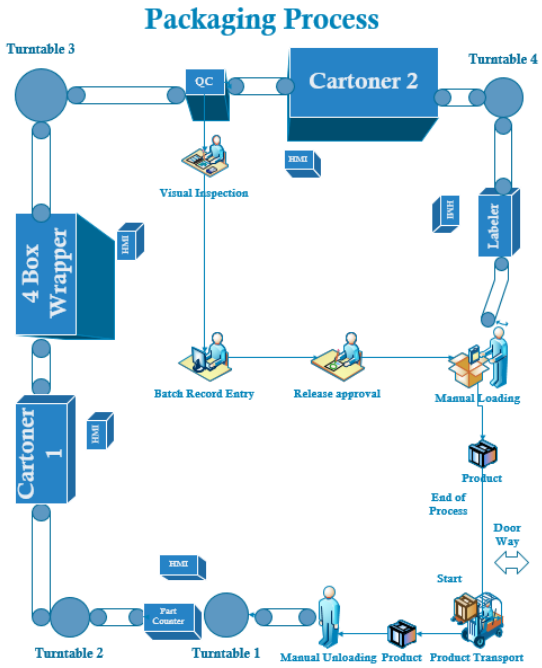


**Figure 1**

**Existing Packaging Process Layout**

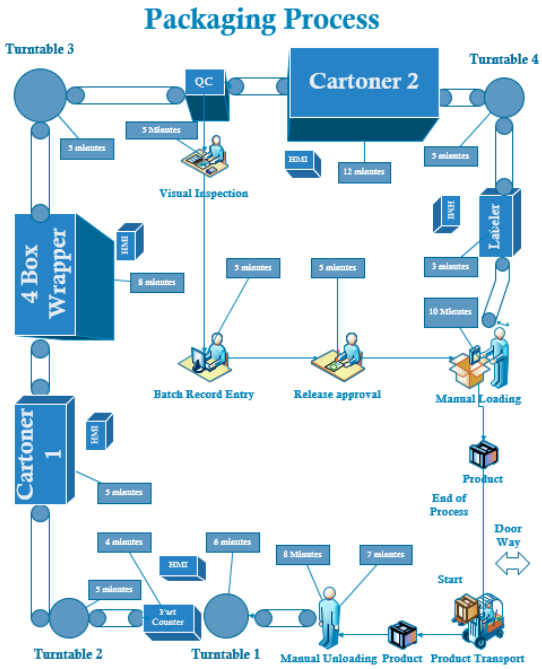


**Figure 2**

**Packaging Process Cycle Time**

**Measure Phase:** Collected and analyzed baseline data such as cycle time and resource utilization in the manual packaging process, identifying key performance indicators (KPIs) for improvement. Establish a baseline for comparison with post-improvement data.

**Table 1**

**Process Cycle Time Study**

| Process Cycle time Study | | |
|---|---|---|
| Task | Action | Time (min) |
| Manual Unloading from Forklift | Forklift unloads 14,000 bottles pallets, divided into cases of 400 bottles | 8 |
| Manual Loading onto Conveyor | Cases are manually placed on a conveyor | 7 |
| Turntable 1 | Cases are push into Turntable 1 | 6 |
| Conveyor Tunnel | Cases pass through a conveyor tunnel with a counting sensor for individual vial accountability | 4 |
| Turntable 2 | Vials are transported to the Cartoner 1 | 5 |
| Cartoner 1 | Automated Process for putting the bottles into boxes | 5 |
| Wrapper | Boxes are wrapped together | 8 |
| Turntable 3 to QC Box | Turntable to QC station | 5 |
| QC Station | Visual inspection done by an operator | 5 |
| Cartoner 2 | Four sets of wrepped boxes are packaged in Cartoner 2 | 12 |
| Turntable 4 to labeler | The truntable takes boxes to the labeler | 5 |
| Labeler | Boxes go through a labeler, an automated process that sticks shipping labels | 3 |
| Batch Record Entry | Batch record data | 5 |
| Release Approval | Verification of data realse batch for shipping | 5 |
| Final Conveyor to Pallet | Boxes are manually loaded onto the final conveyor, which leads to pallet loading | 10 |
| Cycle Time | | 93 |

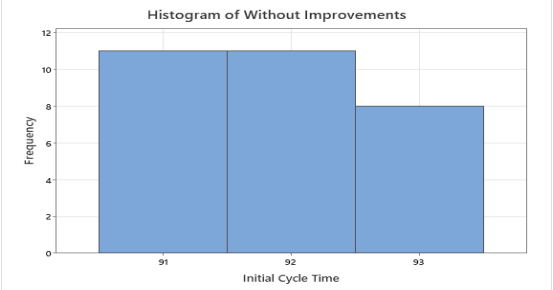


**Figure 3**

**Packaging Process without Improvements Histogram**

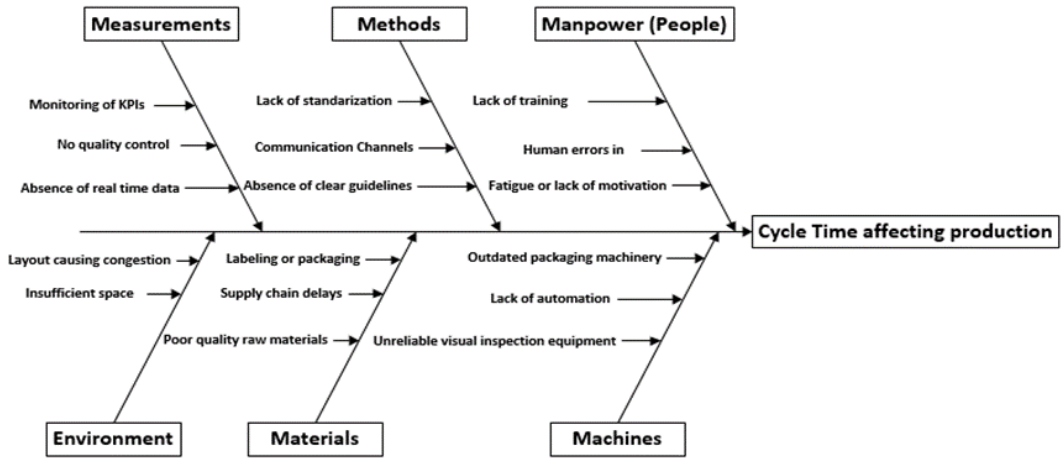


**Figure 4**
**Packaging Process Cause and Effect Diagram**

- **Analyze Phase:** Employed Lean Six Sigma tools to identify the root cause of inefficiencies, pinpointing areas for improvement.

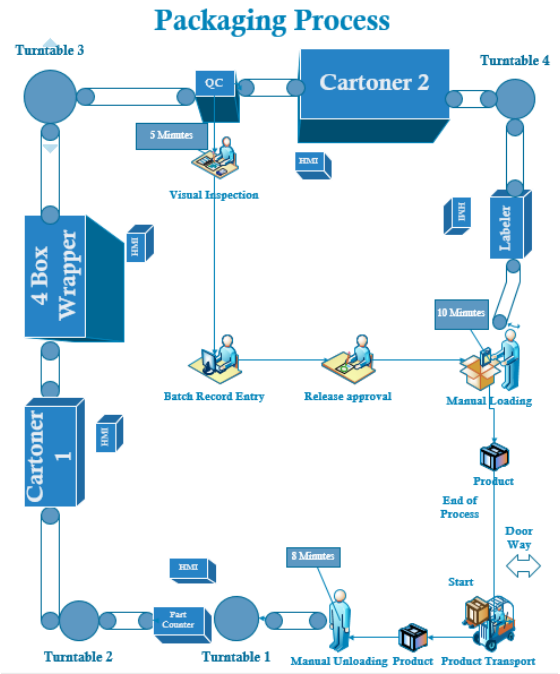


**Figure 5**
**Packaging Process Kaizen**

- **Improve Phase:** Implemented Lean Six Sigma principles to streamline processes, reduce cycle time, and enhance efficiency. Ensure that user-centric principles are considered in the implementation of solutions.

**Table 2**
**Cycle Time with Improvements**

| Improvements Implementation | |
|---|---|
| **Task Improved** | **Time (min)** |
| Automated Unloading from Forklift | 3 |
| Automated Loading onto conveyor | 2 |
| Turntable 1 (No change) | 6 |
| Conveyor Tunnel (No change) | 4 |
| Turntable 2 (No change) | 5 |
| Cartoner 1 (No Change) | 5 |
| Wrapper (No change) | 8 |
| Turntable 3 to QC Box (No change) | 5 |
| Visual Inspection Station | 1 |
| Cartoner 2 (No change) | 12 |
| Turntable 4 to labeler (No Change) | 5 |
| Labeler (No change) | 3 |
| Automated Palletizing | 5 |
| Electronic Batch Record Entry | 4 |
| Electronic Release Approval | 4 |
| **Cycle Time** | **72** |

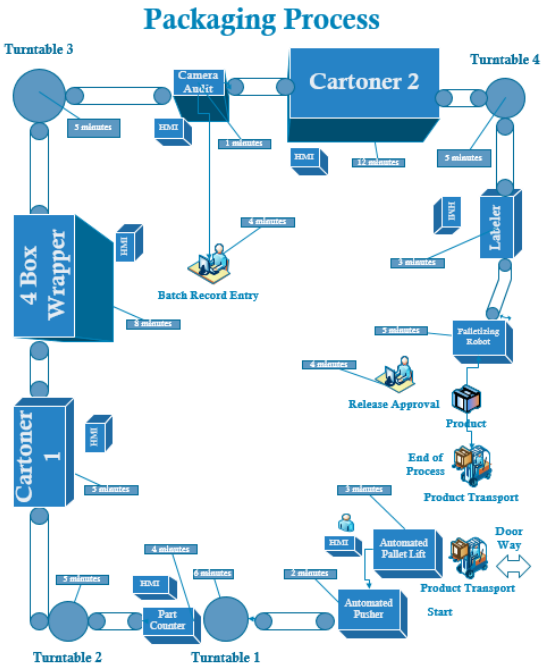


**Figure 6**

**Packaging Process with Improvements**

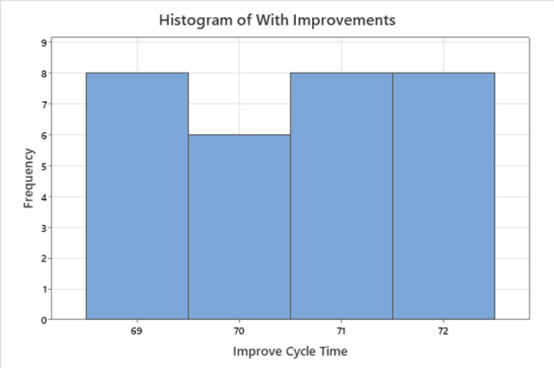


**Figure 7**

**Packaging Process with Improvements Histogram**

- **Control Phase:** Establish a control mechanism to sustain improvements over time, incorporating continuous monitoring and feedback loops. Conduct training for operators on the new processes and technologies.

### Industrial Automation Integration

- **Assessment:** Identified manual processes prone to inefficiencies, focusing on loading/unloading visual inspection and palletizing
- **Technology Selection:** Evaluated and selected suitable automation technologies based on ROI, feasibility, and compatibility with Lean Six Sigma objectives.
- **Implementation:** Introduces automation technologies in a phased manner, focusing on loading/unloading, visual inspection, and palletizing processes.
- **Testing:** I conducted rigorous testing to ensure seamless integration, alignment with Lean Six Sigma goals, and compliance with quality standards.

### Data Analysis

- **Quantitative Analysis:** Utilized statistical tools to analyze quantitative data on cycle time, defect rates, and resource utilization. Conducted before and after comparisons to quantify the impact of improvements.

***Initial Cycle Time:*** *93 minutes per cycle*

***Improved Cycle Time****: 72 minutes per cycle*

$$\left(\frac{Initial\ Value - Final\ Value}{Initial\ Value}\right) \times 100\% \quad (1)$$

$$\text{Improvement Percentage} = \left(\frac{93-72}{93}\right) \times 100 \quad (1)$$

$$\text{Improvement Percentage} = \left(\frac{21}{93}\right) \times 100 \quad (1)$$

$$Improvement\ Percentage = 22\%$$

The results from the process testing revealed a notable reduction in cycle times with implementing Lean Six Sigma and industrial automation. The average cycle time decreased from 93 to 72 minutes, with statistical significance confirmed. The standard deviation, median cycle time, and other metrics also demonstrated positive trends. The percentage improvement of 22% underscores the effectiveness of the proposed enhancements. These findings suggest that the integrated approach significantly streamlines the manufacturing process.

The results include statistical metrics for the scenario without improvements and the scenario with enhancements.

### Mean Average

- Without Improvements: 93 min
- With Improvements: 72 min

The mean represents the average value of the data. In this context, it signifies the average cycle time for the packaging process. The improvement from 91.90 to 70.533 indicates a significant reduction in the average cycle time after implementing the upgrades.

### Standard Error of the Mean (SE Mean):

- Without Improvements: 0.0147 min
- With Improvements: 0.0213 min

The Standard error of the mean measures the variability of sample means. It estimates how much the sample mean will likely vary from the actual population mean. The slight increase in SE Mean with improvements suggests a slightly higher variability in the sample means after the changes.

### Standard Deviation (StDev)

- Without Improvements: 0.803
- With Improvements: 1.167

Standard Deviation measures the variation or dispersion in a set of values. The increase in standard deviation with improvements indicates more variability in the cycle times. This could be due to various factors, including introducing new processes and technologies.

Descriptive Statistics: Without Improvements, With Improvements

Statistics

| Variable | N | N* | Mean | SE Mean | StDev | Minimum | Q1 | Median | Q3 |
|---|---|---|---|---|---|---|---|---|---|
| Without Improvements | 30 | 0 | 91.900 | 0.147 | 0.803 | 91.000 | 91.000 | 92.000 | 93.000 |
| With Improvements | 30 | 0 | 70.533 | 0.213 | 1.167 | 69.000 | 69.000 | 71.000 | 72.000 |

| Variable | Maximum |
|---|---|
| Without Improvements | 93.000 |
| With Improvements | 72.000 |

**Figure 8**
**Packaging Process Descriptive Statistics**

### Interpretation

- The substantial reduction in the mean average cycle time from 91.90 to 70.533 suggests that the improvements have effectively reduced the time required for the packaging process.
- The SE Mean and standard deviation increase may indicate more variability in cycle times with improvements. This could result from the system adapting to new processes of technologies, leading to slightly more fluctuation in individual cycle times.
- Overall, the mean reduction is a positive outcome, signifying the success of implementing the improvements in streamlining the manufacturing process.

### Hypothesis Test

In the rigorous assessment of process improvements, a hypothesis test was conducted to validate the efficacy of the implemented changes in the manufacturing process. The objective was to ascertain whether the introduced improvements had a statistically significant impact on the mean cycle time, thereby substantiating the enhancements made to the process.

Descriptive Statistics

| Sample | N | Mean | StDev | SE Mean |
|---|---|---|---|---|
| Without Improvements | 30 | 92.167 | 0.747 | 0.14 |
| With Improvements | 30 | 70.733 | 0.907 | 0.17 |

**Figure 9**
**Hypothesis Test Descriptive Statistics**

Test

Null hypothesis $H_0: \mu_1 - \mu_2 = 0$
Alternative hypothesis $H_1: \mu_1 - \mu_2 \neq 0$

| T-Value | DF | P-Value |
|---|---|---|
| 99.92 | 55 | 0.000 |

**Figure 10**
**Hypothesis Test Results**

The null hypothesis (H0) posited no discernible difference in the mean cycle time between the process with and without improvements, while the alternative hypothesis (H1) postulated a significant disparity. The test statistic (T-value) of 99.92, calculated with 55 degrees of freedom, provided a robust measure of the extent of deviation from the

null hypothesis. The resulting P-value, an infinitesimal 0.000, emphatically rejects the null hypothesis at a conventional significance level of 0.05. This implies that the observed mean difference of 21.433 minutes is unlikely to have occurred by random chance alone. Consequently, with a high degree of confidence, we can assert that the improvements made to the process have led to a substantial reduction in the mean cycle time.

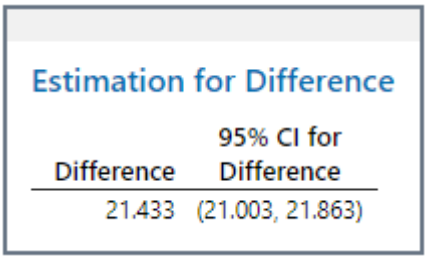


**Figure 11**
**Hypothesis Test Difference**

The 95% confidence interval (CI) for the difference in means, ranging from 21.003 to 21.863 minutes, further fortifies this conclusion. This interval signifies the plausible range, reinforcing the conviction that the process improvements have yielded a noteworthy reduction in cycle time.

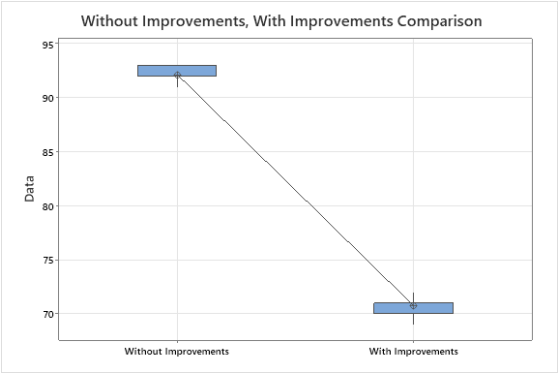


**Figure 12.**
**Boxplot of Without Improvements, With Improvements**

In summary, the hypothesis test results unequivocally affirm the success of the implemented process improvements. The statistically significant reduction in mean cycle time, supported by a narrow confidence interval, underscores the effectiveness of the enhancements in streamlining and optimizing the manufacturing process. This validation credence the strategic decision to embrace and implement changes to improve operational efficiency and overall process performance.

### Most Important Findings

- **Lean Six Sigma Integration:** Implementing Lean Six Sigma principles has systematically identified, analyzed, and improved critical aspects of the pharmaceutical packaging process. The pre-implementation assessment unveiled inefficiencies, and the implementation phases, from Define to Control, effectively streamlined processes, reduced cycle times, and established control mechanisms.
- **Industrial Automation Integration:** Integrating industrial automation technologies addressed manual inefficiencies, focusing on loading/unloading, visual inspection, and palletizing processes. The phased approach, from assessment to testing, ensured seamless integration, alignment with Lean Six Sigma goals, and compliance with quality standards.
- **Limitations:** Despite the notable successes, it's crucial to acknowledge limitations. Implementing new technologies and processes may initially introduce variability, as indicated by a slight increase in the Standard Error of the Mean and standard deviation. These fluctuations are expected during the adaptation phase.

### Future Research

As with any transformative project, avenues for future research emerge. Subsequent studies could further refine automation technologies, continuous improvement methodologies, and integration of emerging Industry 4.0 technologies.

## CONCLUSION

The culmination of this design project signifies a significant stride in addressing the pressing challenges faced by the pharmaceutical industry in optimizing its packaging processes. The research was driven by meticulous examination and redesign

of the manual aspects of the pharmaceutical packaging process, incorporating Lean Six Sigma principles and industrial automation technologies.

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