

## Abstract

The manufacturing workflow of the Sheath component at Terumo Medical Corporation was identified as a critical area for improvement due to excessive lead time and redundant processing. Using the DMAIC methodology and Value Stream Mapping (VSM), the project focused on consolidating two separate work orders—Tipped Tube and Sheath—into a single streamlined process. Time studies and root cause analysis revealed inventory wait time as the main non-value-added contributor. The implementation eliminated multiple redundant steps, such as reconciliation, kitting, and double handling. Post-implementation results included a 43% lead time reduction, lower work-in-process inventory, improved resource utilization (Expeditor, QA, Warehouse), and enhanced operational efficiency. Financial analysis projected annual savings of approximately \$118,000, reinforcing the sustainability and impact of the improvement. The success of this initiative was driven by cross-functional collaboration and supports Terumo’s commitment to continuous improvement and high-quality manufacturing standards.

## Introduction

Terumo Medical Corporation, a global leader in medical device manufacturing, produces the Angio-Seal® Vascular Closure Device at its facility in Caguas, Puerto Rico. As part of its commitment to continuous improvement, this project focused on optimizing the Sheath manufacturing workflow—identified as a critical area due to extended lead time and inefficiencies. [1] The main issue stemmed from using two separate work orders (Tipped Tube and Sheath), which introduced redundant steps such as intermediate quality reviews, packaging, and material handling.

The project aimed to consolidate both operations into a single work order to reduce lead time and improve efficiency. The DMAIC methodology (Define, Measure, Analyze, Improve, Control) was used to structure the project, identify root causes, and implement sustainable improvements through tools like Value Stream Mapping. [2]

## Problem Statement

The Sheath assembly process—comprising the Tipped Tube and Sheath operations—was identified as the primary bottleneck in the production of the Angio-Seal® Vascular Closure Device. This workflow operated with two separate work orders, introducing redundant steps such as packaging, inventory holding, material handling, and duplicate quality reviews. As a result, the process had an excessive lead time of 7.00 days, negatively impacting throughput and resource utilization.

This project aimed to optimize the Sheath assembly process by consolidating both operations into a single work order. The primary goal was to reduce the lead time by at least one day, while improving operational efficiency, eliminating non-value-added activities, and enhancing the use of personnel and system resources through a structured DMAIC approach.

## Methodology

This project applied the DMAIC methodology—Define, Measure, Analyze, Improve, and Control—to systematically address lead time inefficiencies in the Sheath Manufacturing Workflow of the Angio-Seal® Vascular Closure Device. This structured approach enabled the team to collect and interpret performance data, identify root causes of delays, and establish a sustainable plan for process improvement.

**Define Phase: Problem Identification-** Sheath assembly process as a production bottleneck, with a total lead time of seven days. The project scope was specifically limited to the Sheath accessory workflow, excluding other device components or downstream operations.

**Measure Phase: Data Collection-** In the Measure phase, time studies were conducted across all production shifts to capture real-time performance metrics. Figure 1 demonstrate a current-state flowchart developed to visualize process steps, waiting periods, and flow interruptions, and to classify tasks into value-added and non-value-added activities as demonstrated in Figure 2. Figure 3 illustrates how non-value-added activities process time is distributed across the lean waste categories.

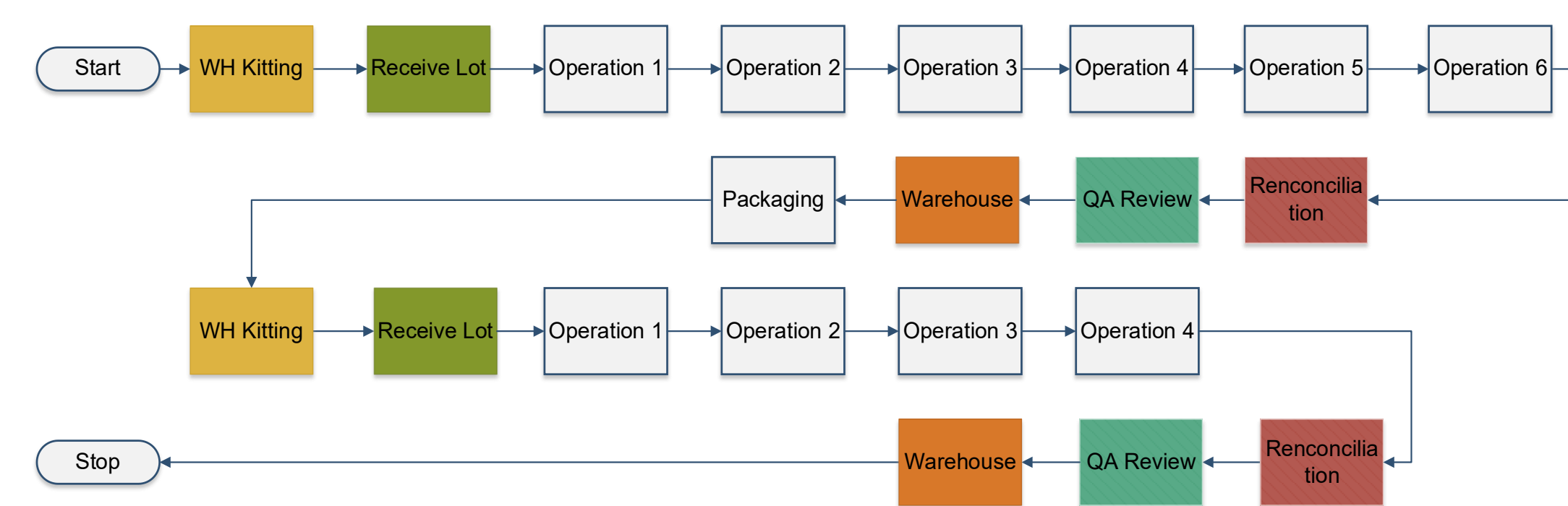


Figure 1

Current State Flowchart

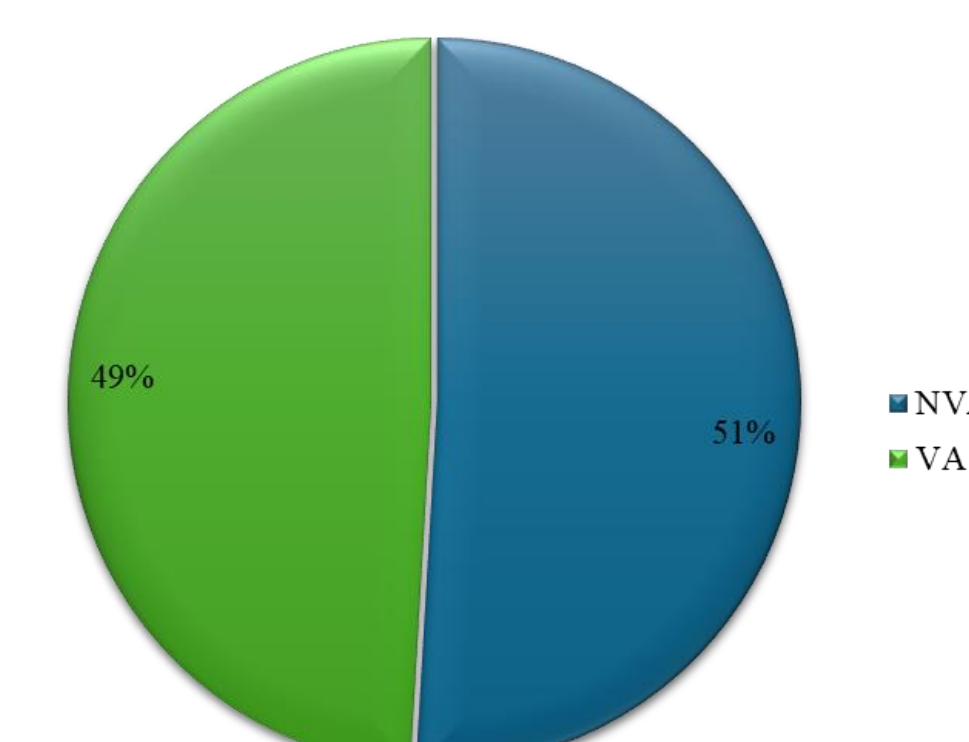


Figure 2

Proportion of Value-Added activities vs Non-Value-Added Activities

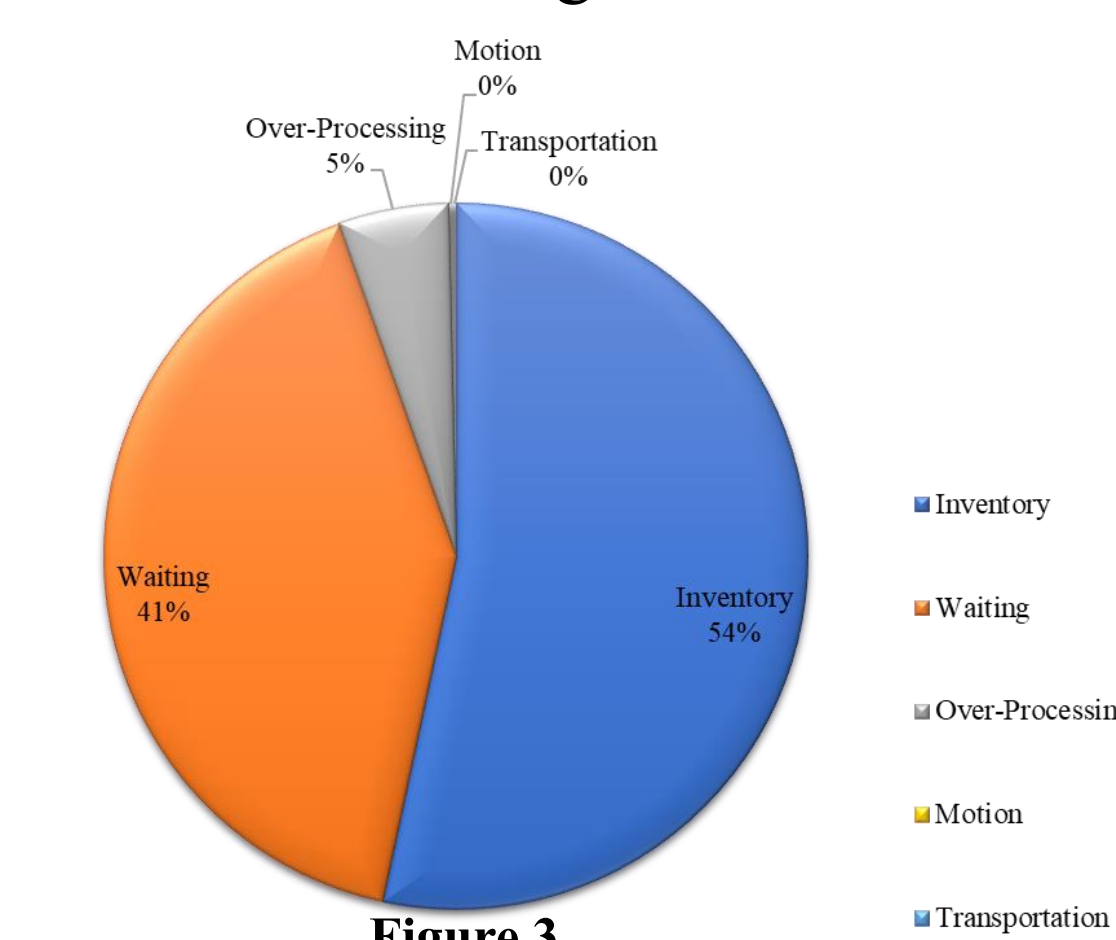


Figure 3

Proportions of process activities waste types

**Analyze Phase: Root Cause Identification and Improvement Proposal-** Using value stream mapping and time analysis, the primary contributor to the extended lead time in the Sheath manufacturing workflow was identified as inventory time—specifically the delay introduced between the completion of the *Tipped Tube* subassembly and the initiation of the *Sheath* assembly. As a result of this analysis, the team proposed a key improvement: consolidating the Tipped Tube and Sheath manufacturing into a single work order. This approach eliminates the non-value-added steps listed above and creates a more continuous and efficient flow.

**Improve Phase: Solution Development and Execution-** The Improve phase has focused on executing the proposed solution to consolidate the Sheath manufacturing process into a single work order. A total of 58 documents were identified as impacted, including 20 BOMs, 15 Terumo Manufacturing Documents, and 23 internal documents. On the shop floor, implementation activities included 5S improvements, updated production scheduling, material buildup, and operator training to ensure a smooth transition to the new process.

**Control Phase: Standardization and Sustainability-** The Control phase focused on sustaining the process changes and ensuring consistent performance.

Standard operating procedures (SOPs), work instructions, Manufacturing execution System and quality documentation were updated to reflect the new single-work-order process.

## Results

The implementation of the optimized Sheath Manufacturing Workflow was completed following the recommendations developed during the Analyze and Improve phases. The core improvement—consolidating the Tipped Tube and Sheath work orders—successfully removed non-value-added steps, improving the overall flow and efficiency of the production line as demonstrate pos implementation flowchart on Figure 4. The initial value stream map revealed that the total lead time for the Sheath process was approximately 7 days, largely due to inventory hold times and redundant handling between disconnected operations. The mapping also showed significant waste in the form of waiting between quality reviews, warehouse transfers, and documentation processes.

**Post- Implementation Results and Activity Classification-**Following the process consolidation and implementation of change orders, MES/SAP system updates, and production floor training, the total lead time was reduced from **7 days to 4 days**, achieving a **43% improvement**. Value-added tasks now make up 78% of the total process time, as demonstrate on Figure 5, and support resource utilization has improved across QA, Planning, and Materials Handling teams.

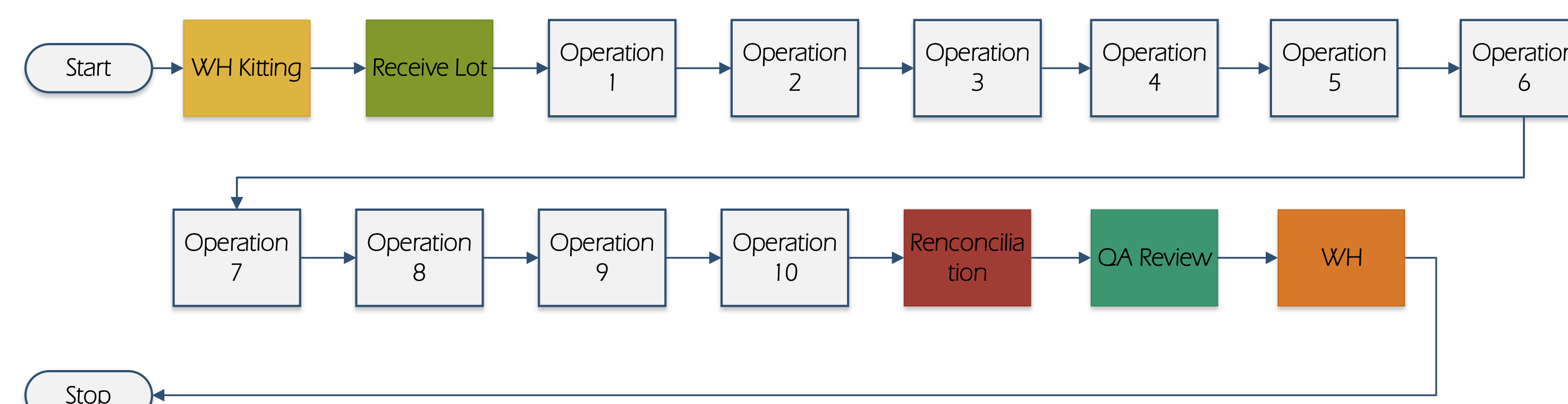


Figure 4

Post Implementation Flowchart

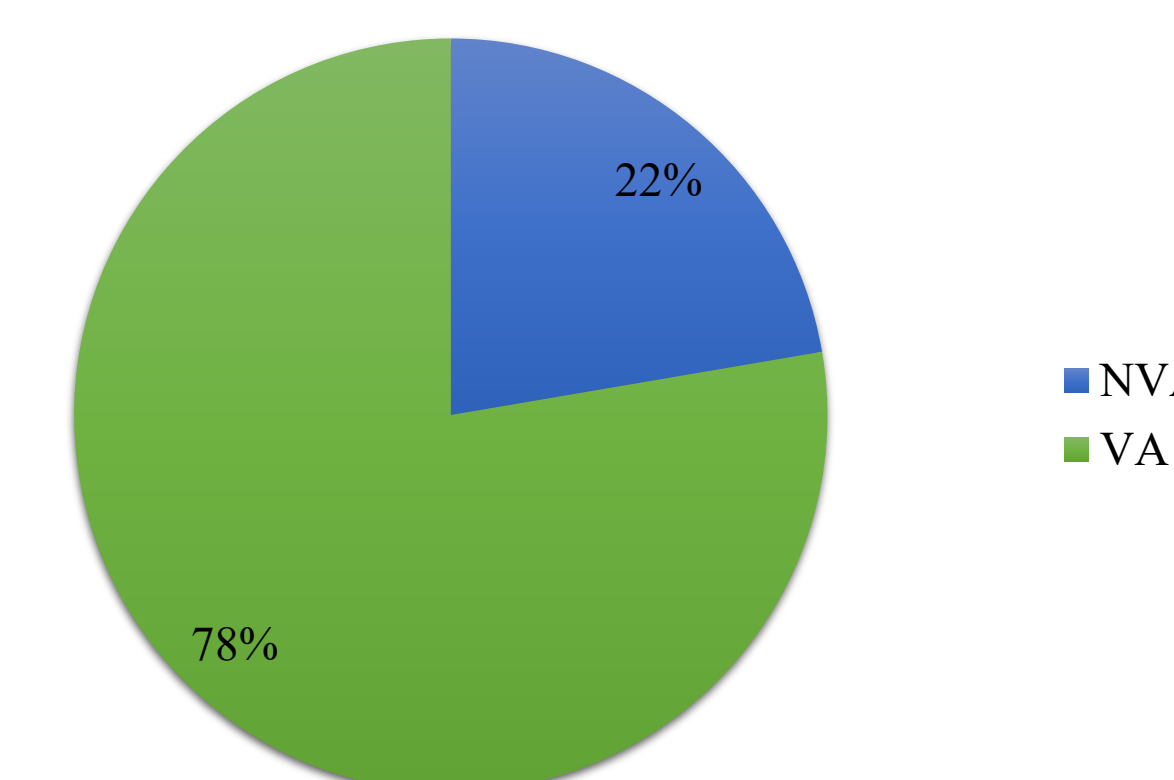


Figure 5

Proportion of Value-Added activities vs Non-Value-Added Activities

## Financial Impact

The financial analysis confirms the annual savings attributed to the streamlined workflow from QA review time reduction, fewer transaction tasks, from reduced kitting, BOM improvements, sampling reduction and warehouse handling. This results in a total projected cost saving of **\$118,000** per year. These savings reflect not only reduced labor time but also more efficient resource utilization and increased production capacity.

## Conclusion

The optimization of the Sheath manufacturing workflow at Terumo Medical Corporation successfully demonstrated how Lean Six Sigma tools such as DMAIC and Value Stream Mapping can be applied to reduce lead time, eliminate waste, and enhance operational efficiency in a regulated manufacturing environment. By consolidating two separate work orders (Tipped Tube and Sheath) into a single integrated order, the project eliminated redundant processes—including reconciliation, packaging, and inventory transfers—resulting in a more streamlined production flow.

The analysis revealed that inventory time was the major contributor to inefficiency. The improvement phase addressed this through data-driven decision-making, cross-functional collaboration, and system updates. As a result, the project **surpassed its objective**, achieving a total **lead time reduction of 3 days**, exceeding the initial 1-day goal. These included a significant reduction in inventory days, increased resource utilization, and an estimated annual cost savings of over **\$118,000**.

This initiative aligns with Terumo’s broader goals of continuous improvement and customer-focused innovation, setting a precedent for similar future improvements across other manufacturing processes within the organization.

## References

- [1] Terumo Medical Corporation. (2024, February 14). *Terumo Medical Corporation Breaks Ground on New Manufacturing Facility in Caguas, Puerto Rico*. Retrieved from <https://www.terumomedical.com/news-and-events/news/tpr-expansion-press-release.html>
- [2] American Society for Quality (ASQ). (n.d.). *The Define Measure Analyze Improve Control (DMAIC) Process*. Retrieved from <https://asq.org/quality-resources/dmaic>
- [3] Patil, A. S., Pisal, M. V., & Suryavanshi, C. T. (2021). *Application of value stream mapping to enhance productivity by reducing manufacturing lead time in a manufacturing company: A case study*. *Journal of Applied Research and Technology*, 19(1), 11–22. Retrieved from [https://www.scielo.org.mx/scielo.php?pid=S1665-64232021000100011&script=sci\\_arttext](https://www.scielo.org.mx/scielo.php?pid=S1665-64232021000100011&script=sci_arttext)