

Chapter I

Executive Summary

This capstone project was developed at Becton, Dickinson and Company (BD) Humacao, Puerto Rico, focusing on the CapSure Permanent Fixation System assembly line. The project was conducted using the DMAIC (Define, Measure, Analyze, Improve, Control) methodology with the objective of reducing the excessive manufacturing lead time of approximately three days and improving the line's ability to consistently meet the required daily demand of 610 units. The analysis identified that multiple sub-assemblies were being produced separately through batch processing, creating interruptions in material flow, excessive work-in-process (WIP), transportation waste, operator waiting time, and bottlenecks across the production system.

During the Define and Measure phases, several Lean and Six Sigma tools were utilized, including SIPOC, CTQ analysis, Voice of the Employee (VOE), Value Stream Mapping (VSM), descriptive statistics, Pareto analysis, probability plots, histograms, and control charts. Data collected from 72 production days revealed an average daily output of 589.5 units with high variability and inconsistent performance. Additionally, VOE results confirmed significant operational issues such as material shortages, excessive operator movement, workstation bottlenecks, and delays caused by disconnected sub-assembly operations.

The Analyze phase confirmed that the primary root cause was the separation of sub-assemblies from the continuous manufacturing flow. Tools such as takt time analysis, line balancing, Connect Activity Analysis, spaghetti diagrams, and Ishikawa diagrams demonstrated that the process contained excessive transportation, waiting, and motion waste. The current state spaghetti diagram showed operators traveling approximately 2,364 feet per lot, while the Value Stream Map revealed that only 0.21% of total production time was value-added. Several end-item assembly operators were also operating above the takt time of approximately 40 seconds per unit, creating bottlenecks that prevented stable throughput performance.

To address these issues, the Improve phase focused on integrating sub-assemblies directly into the continuous flow assembly line and redesigning the manufacturing layout based on Lean Manufacturing principles. Improvements included line balancing, implementation of a pull-based material replenishment system, workstation reorganization, reduction of WIP inventory, and the development of a Karakuri material management system to support high cycle-time operations. The future-state analyses demonstrated significant operational improvements, including a reduction in operator travel distance from approximately 2,364 feet to only 106 feet and a reduction in travel time from 19.6 minutes to approximately 50 seconds per lot. Future-state VSM also reduced non-value-added activities while improving production synchronization and workflow continuity.

Finally, the Control phase established sustainability measures to maintain the implemented improvements over time. Standard work procedures, SPC control charts, layered process audits, visual management systems, KPI dashboards, and pull-system controls were implemented to continuously monitor production performance and process stability. The redesigned continuous flow layout successfully reduced transportation, waiting, excess inventory, and unnecessary handling while improving ergonomics and material accessibility. As a result, the manufacturing process became capable of supporting the required daily demand with an estimated lead time reduction from approximately three days to one day. Additionally, the project generated substantial operational and financial benefits, with projected annual savings exceeding \$928,000 through inventory reduction, labor optimization, improved space utilization, and productivity gains. Overall, this project successfully demonstrated how Lean Manufacturing and continuous improvement principles can transform a disconnected batch-production system into a more efficient, balanced, and sustainable continuous flow manufacturing operation.