

DEFINE

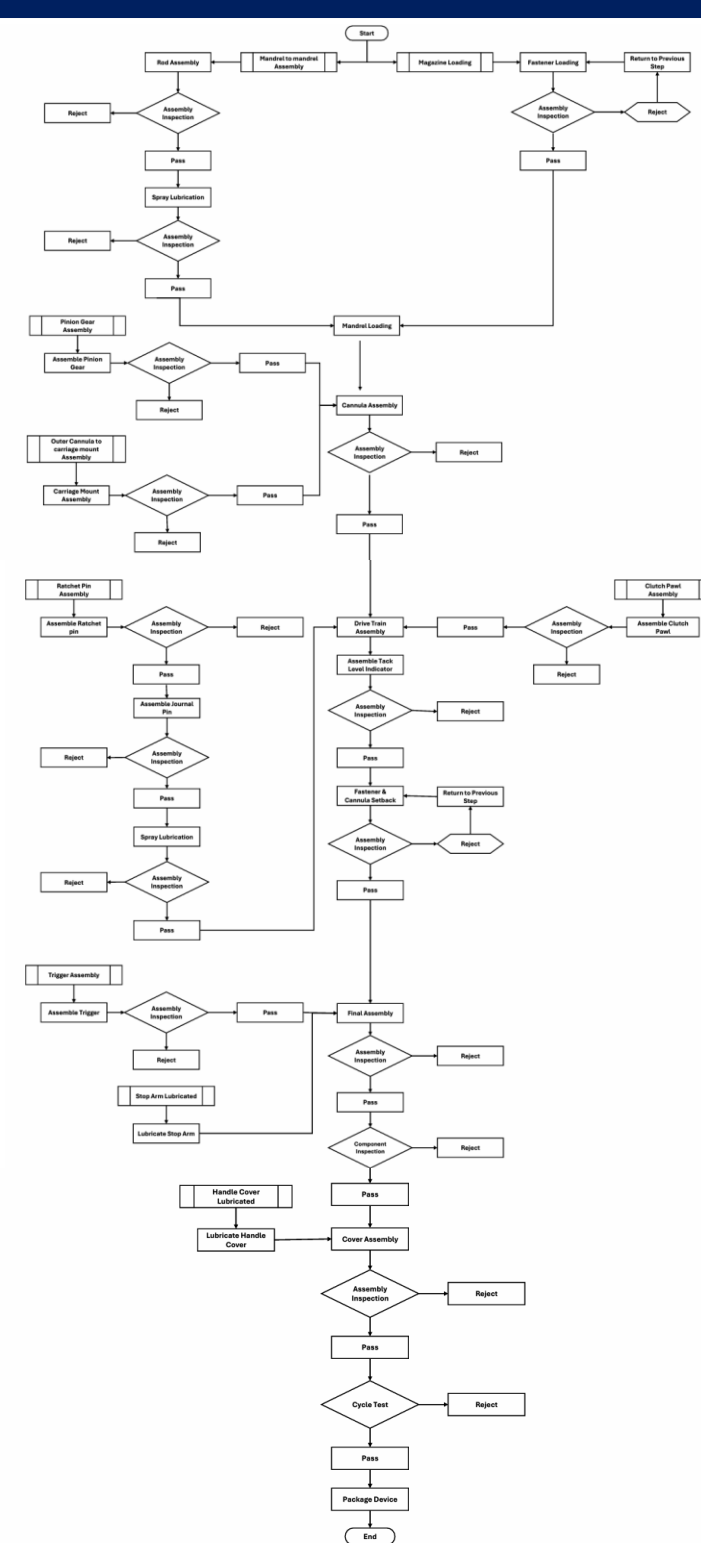
Problem Statement

During fiscal year 2025, a problem has been identified in the CapSure assembly process at BD Humacao. The issue centers on the extended process lead time of approximately 3 days, which has prevented the production line from meeting the increased daily demand of 610 units. Additionally, it has been observed that four (4) sub-assemblies are produced in separate batch processes, creating material flow interruptions, excess handling, and bottlenecks throughout the operation. These conditions have contributed to delays and reduced responsiveness to production requirements.

Voice of Employee (VOE)

A Voice of Employee (VOE) was conducted for the employees working in the CapSure assembly line at BD Humacao. Based on the responses and interviews, several operational issues affecting workflow efficiency were identified. The results showed that bottlenecks and sub-assembly interruptions frequently affect the continuity of the process, while all employees agreed that improving material flow would make the assembly process easier and more efficient.

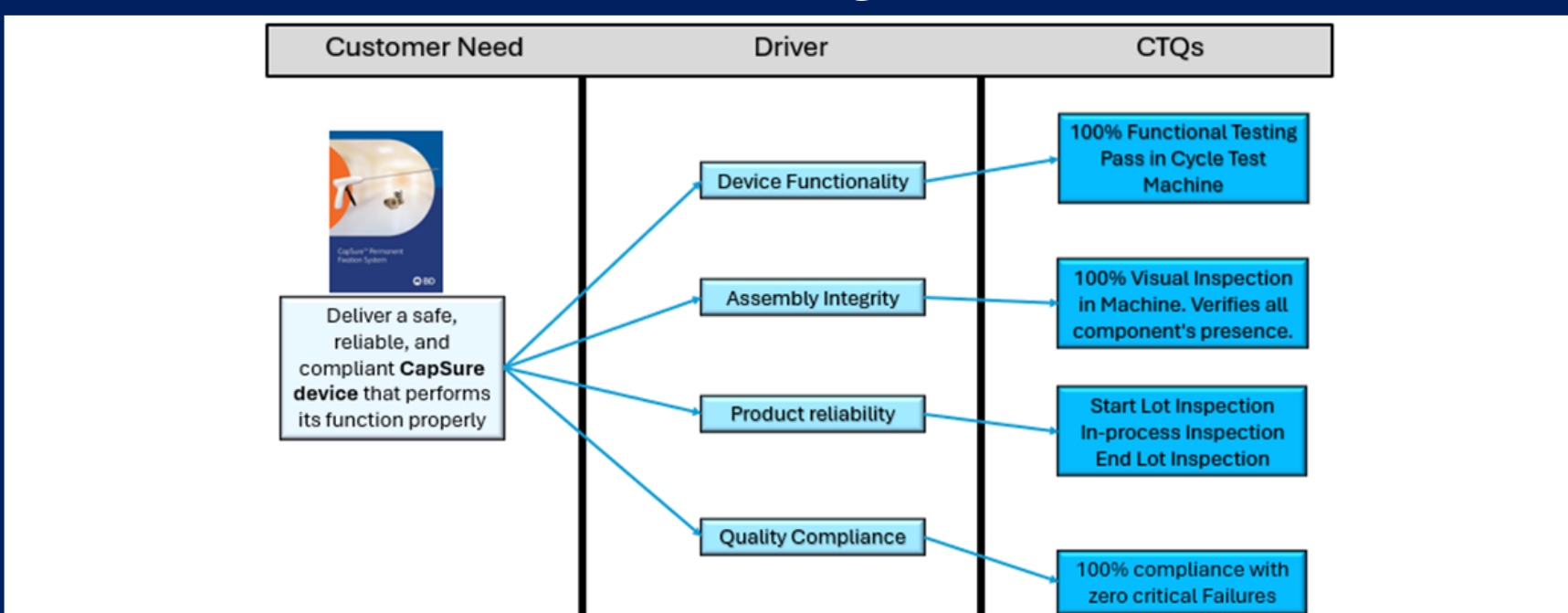
Flowchart



SIPOC Diagram

Suppliers	Inputs	Process	Outputs	Customers
Who provides each input?	What resources are necessary?	What does the process require from each input?	Where does the process start and end?	What does the customer require from each output?
Who are the customers?				
Department of Planning	Production orders and demand signals	The process begins when production orders are released based on customer demand and planning schedules.	Production-ready CapSure devices	Reliable, compliant, on-time product delivery Medical Device Manufacturing Companies
Department of Materials	Raw materials and Components	Materials are received, verified, and staged to support multiple sub-assembly operations throughout the line.	Verified and traceable assembled components	Safe, functional, and traceable devices Hospitals
Department of Operations	Trained Operators	Operators perform sub-assemblies and final assemblies according to standardized work instructions.	Site Flowchart	Fully assembled CapSure device Consistent performance and ease of use Dresses / Sutures
Department of Quality	Inspection Procedures and Quality standards	In-process inspections, component and final inspections are conducted.	Inspected and tested products meeting quality requirements	Safe and effective medical products Patients (end users)
Department of Facilities	Equipment maintenance and technical support	Equipment reliability and regular support ensure continuity of the process and reduce downtime.	Stable and controlled production flow	Complete documentation and compliance Medical Distribution Centers

CTQ



MEASURE

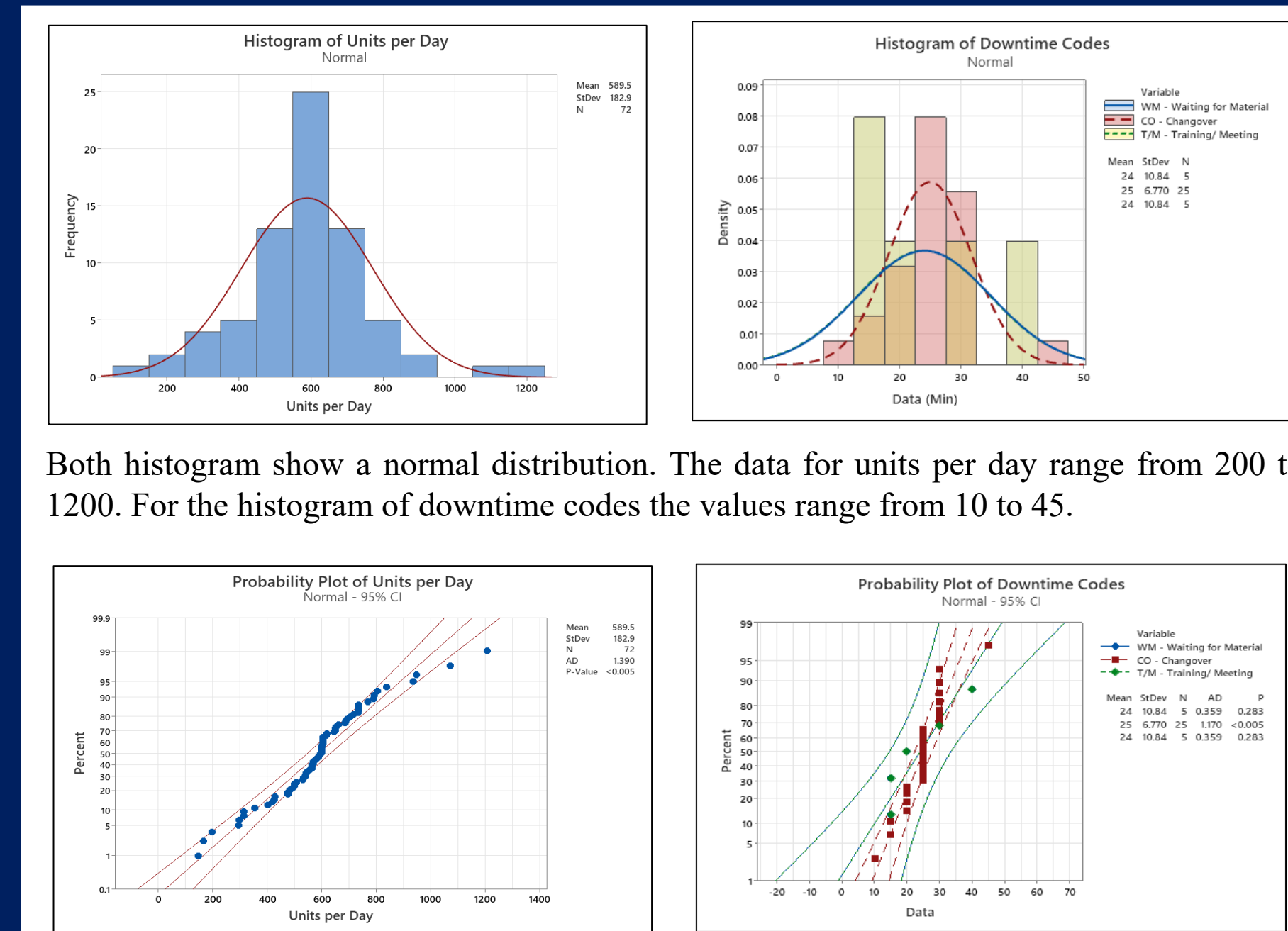
Descriptive Statistics

Variable	Total Count	Mean	StDev	Variance	CoeffVar	Median	Range
Units per day	72	589.5	182.9	33448.5	31.02	597.0	1092.0

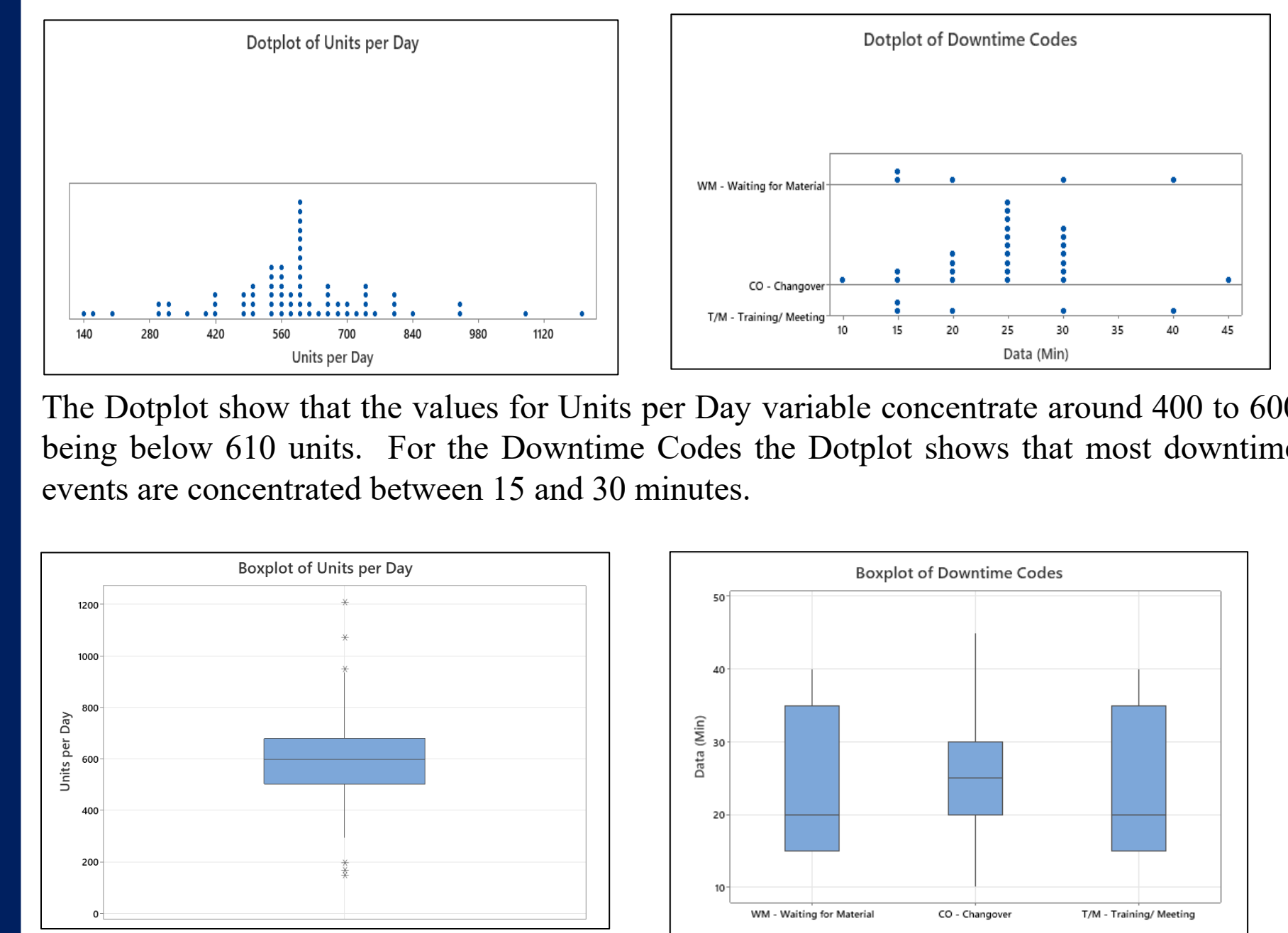
Variable	Total Count	Mean	StDev	Variance	CoeffVar	Median	Range
WM - Waiting for Material	5	24.00	10.84	117.50	45.17	20.00	25.00
CO - Changeover	25	25.00	6.77	45.80	27.08	25.00	35.00
T/M - Training/Meeting	5	24.00	10.84	117.50	45.17	20.00	25.00

The variable of units per day has a mean of 589.6 being below than the demand of 610 units per day. For the variables of downtime code changeover (CO) presented the highest frequency with 25 occurrences and lower variability, while Waiting for Material (WM) and Training/Meeting (T/M) showed higher coefficients of variation at 45.17%.

Descriptive Graphs

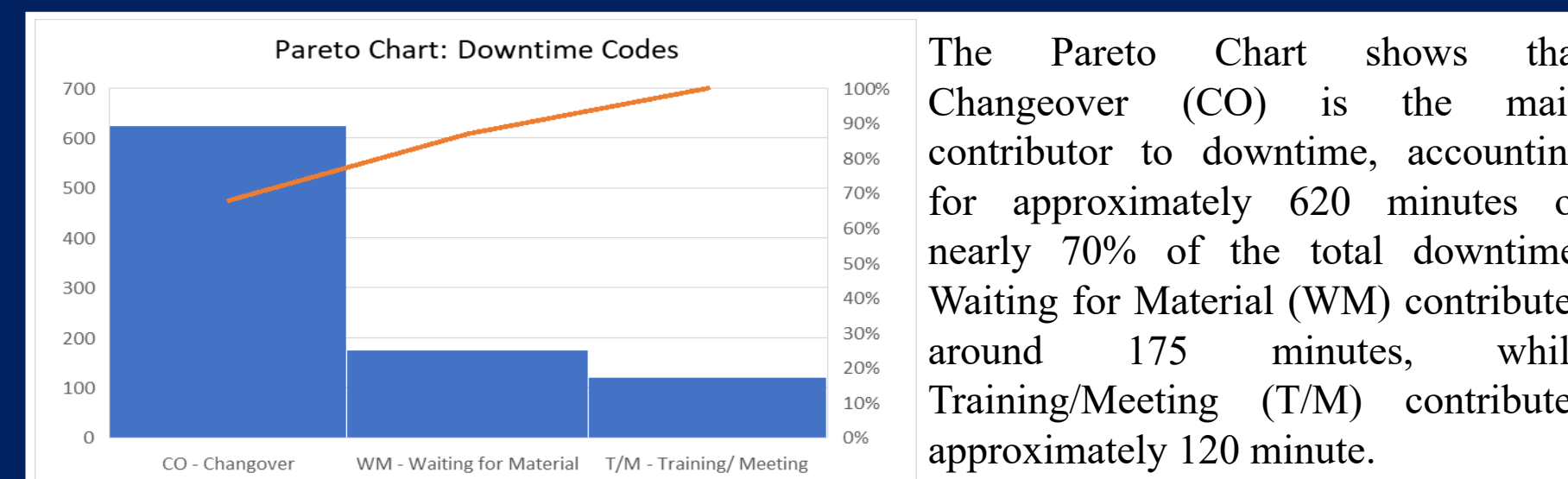


Both histogram show a normal distribution. The data for units per day range from 200 to 1200. For the histogram of downtime codes the values range from 10 to 45.



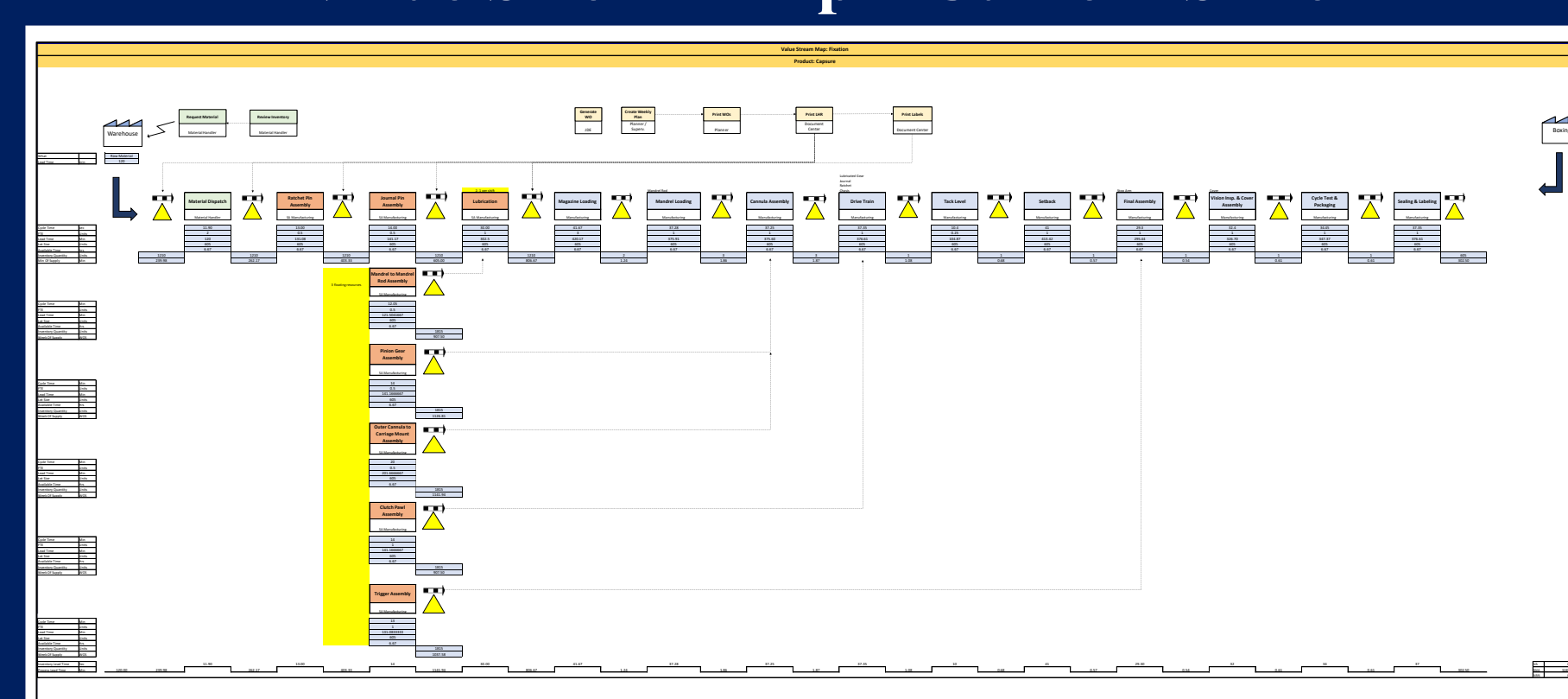
The Dotplot show that the values for Units per Day variable concentrate around 400 to 600 being below 610 units. For the Downtime Codes the Dotplot shows that most downtime events are concentrated between 15 and 30 minutes.

Pareto Chart



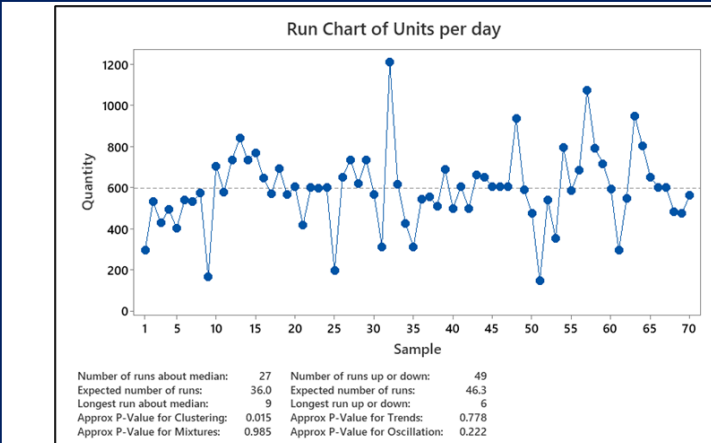
The Pareto Chart shows that Changeover (CO) is the main contributor to downtime, accounting for approximately 620 minutes or nearly 70% of the total downtime. Waiting for Material (WM) contributes around 175 minutes, while Training/Meeting (T/M) contributes approximately 120 minutes.

Value Stream Map - Current State



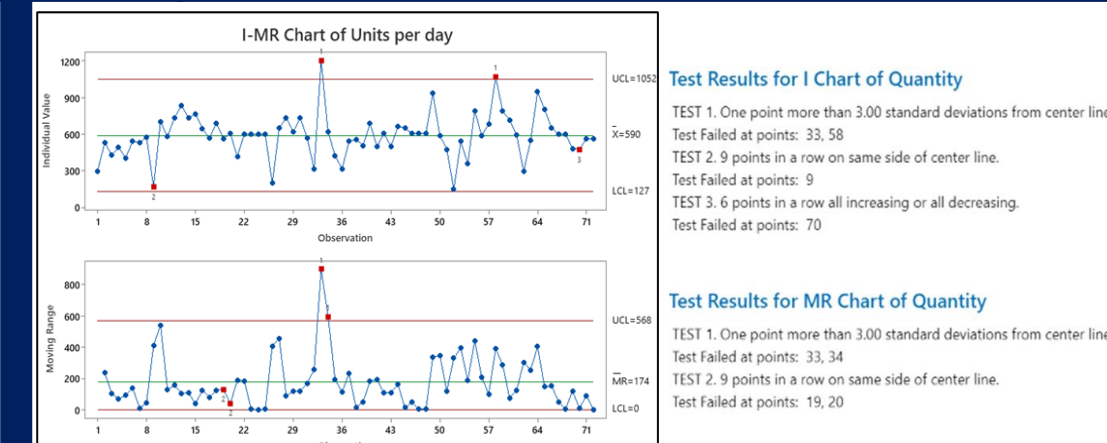
ANALYZE

Run Chart



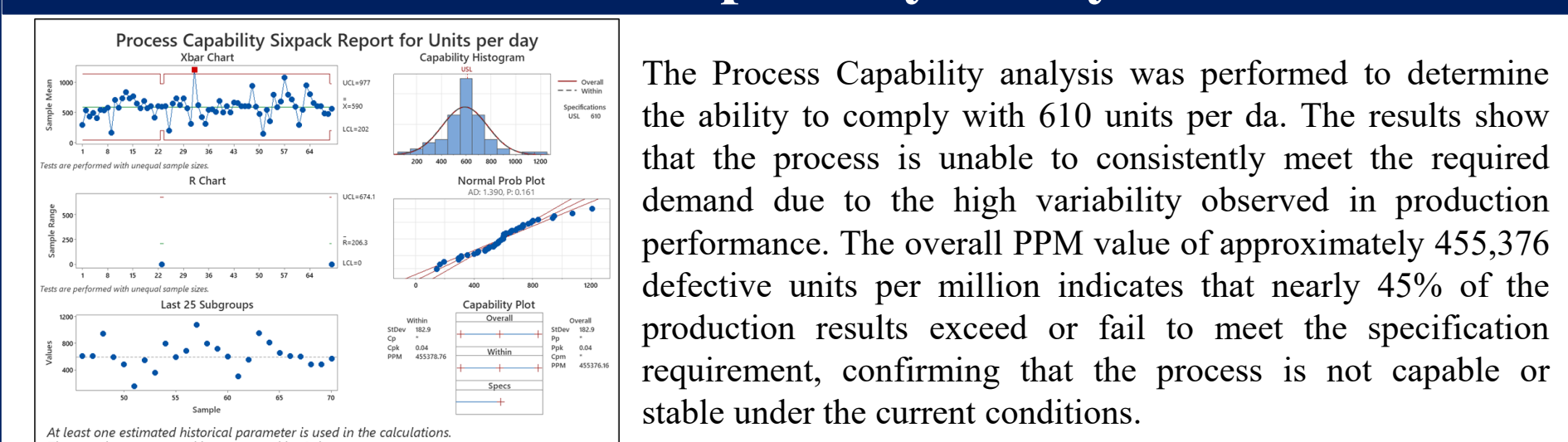
The run chart for Units per Day shows that the p-values for trends, clustering, and oscillation are all greater than 0.05, suggesting that the variation appears random and that no strong non-random patterns are present in the process.

I-MR Chart



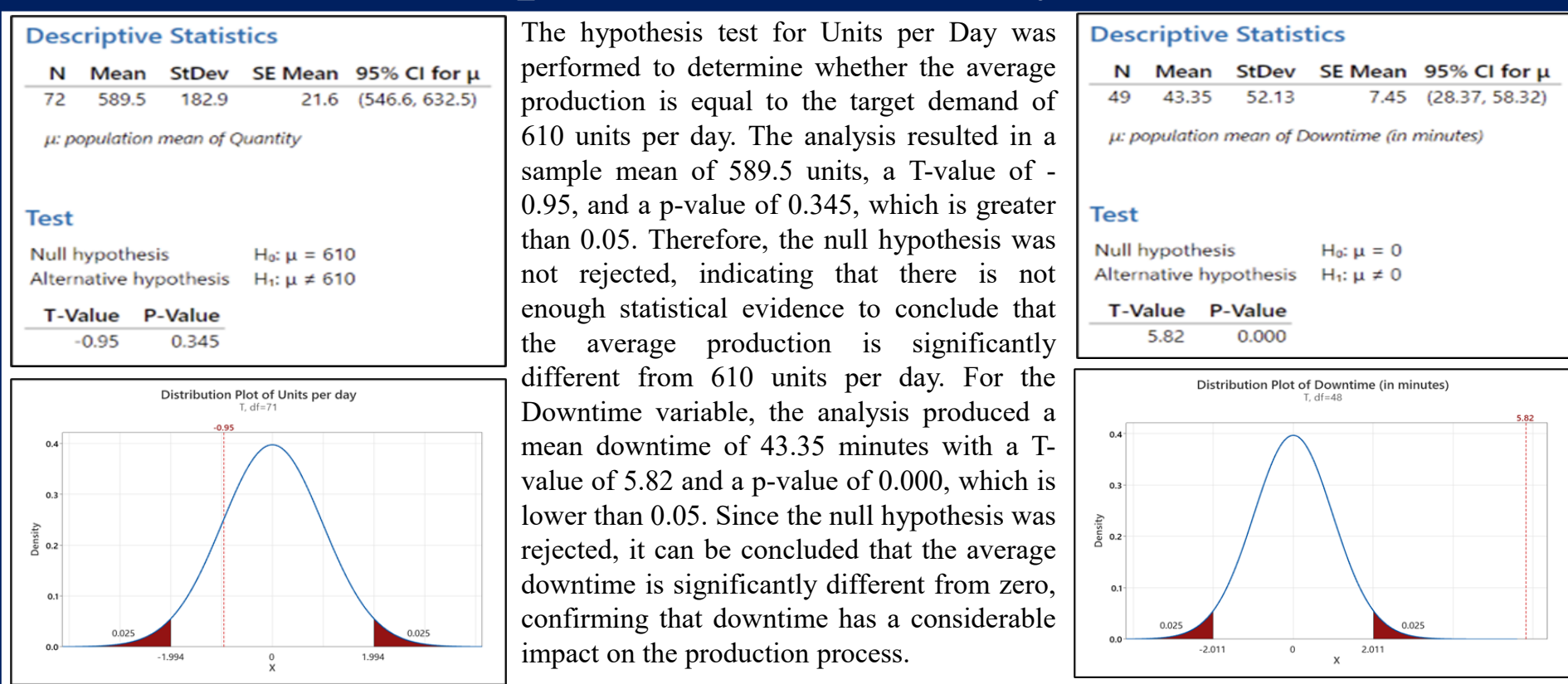
The I-MR chart for Units per Day shows a process average of approximately 590 units, with several points outside the control limits, indicating process instability and special-cause variation. The Individual (I) chart identified unusual production values at observations 33 and 58, while the Moving Range (MR) chart showed significant variation between observations 33 and 34, confirming significant fluctuations in production.

Process Capability Analysis



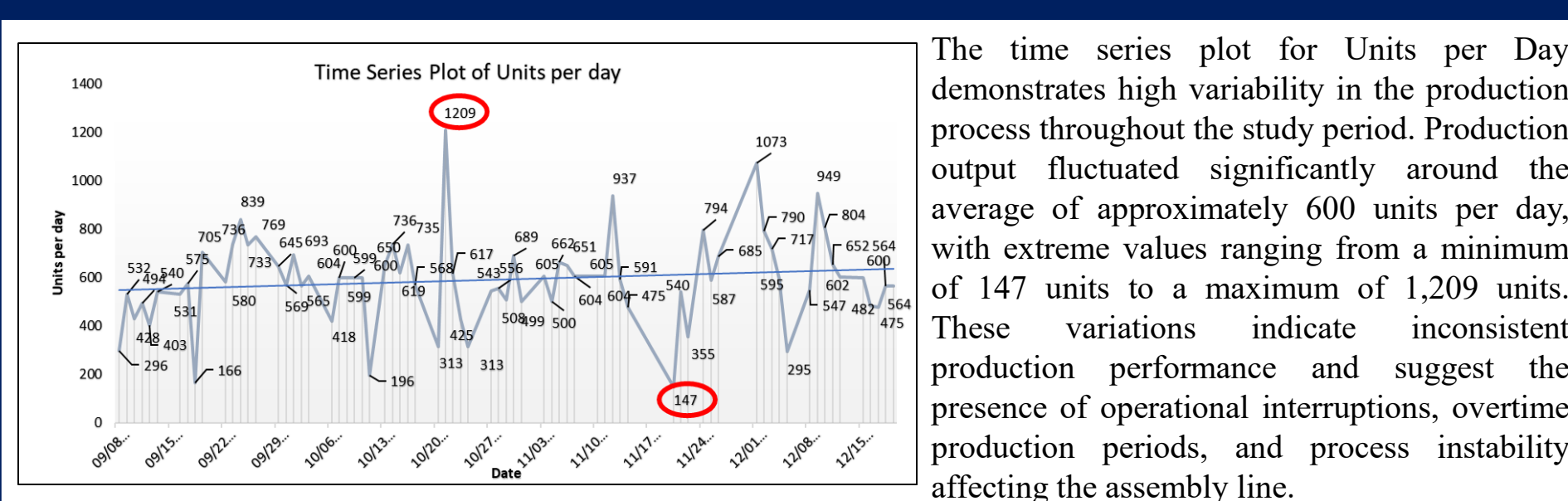
The Process Capability analysis was performed to determine the ability to comply with 610 units per day. The results show that the process is unable to consistently meet the required demand due to the high variability observed in production performance. The overall PPM value of approximately 455,376 defective units per million indicates that nearly 45% of the production results exceed or fail to meet the specification requirement, confirming that the process is not capable or stable under the current conditions.

Population Test Analysis



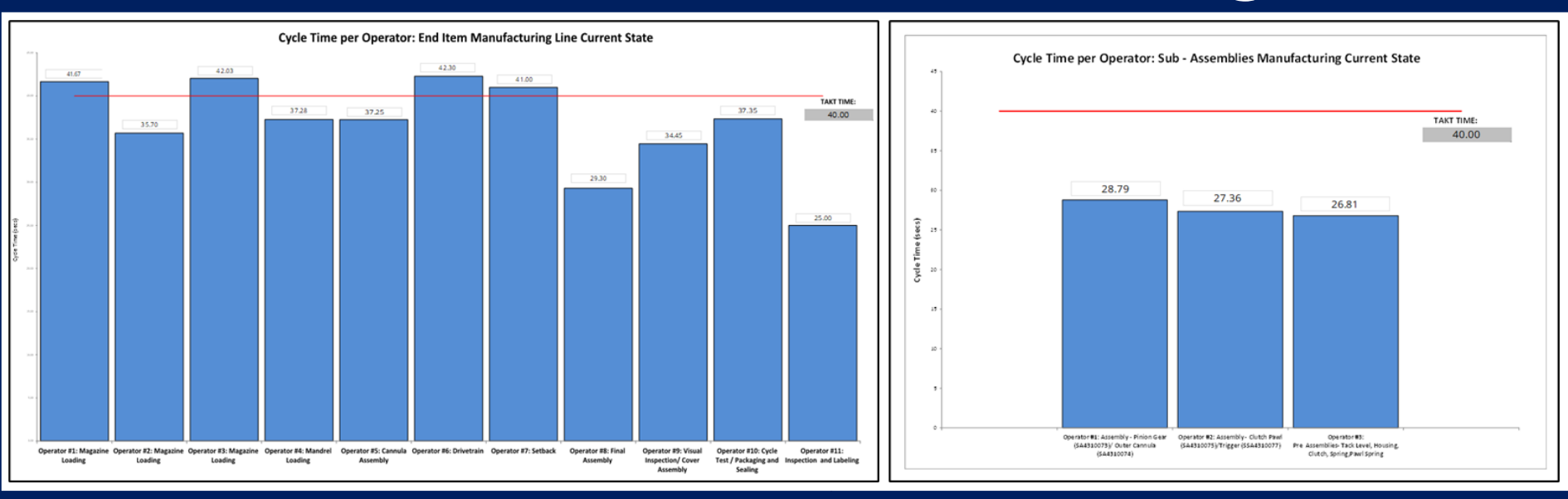
The hypothesis test for Units per Day was performed to determine whether the average production is equal to the target demand of 610 units per day. The analysis resulted in a sample mean of 589.5 units, a T-value of -0.95, and a p-value of 0.345, which is greater than 0.05. Therefore, the null hypothesis was not rejected, indicating that there is not enough statistical evidence to conclude that the average production is significantly different from 610 units per day. For the Downtime variable, the analysis produced a mean downtime of 43.35 minutes with a T-value of 5.82 and a p-value of 0.000, which is lower than 0.05. Since the null hypothesis was rejected, it can be concluded that the average downtime is significantly different from zero, confirming that downtime has a considerable impact on the production process.

Time Series Plot



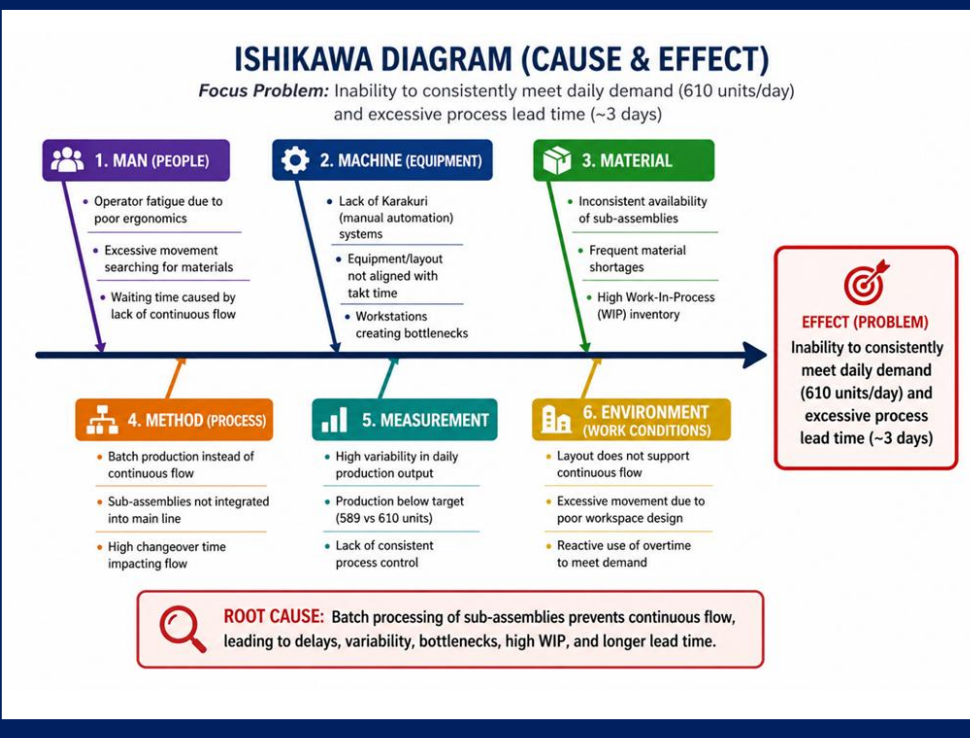
The time series plot for Units per Day demonstrates high variability in the production process throughout the study period. Production output fluctuated significantly around the average of approximately 600 units per day, with extreme values ranging from a minimum of 147 units to a maximum of 1,209 units. These variations indicate inconsistent production performance and suggest the presence of operational interruptions, overtime production periods, and process instability affecting the assembly line.

Current State - Line Balancing

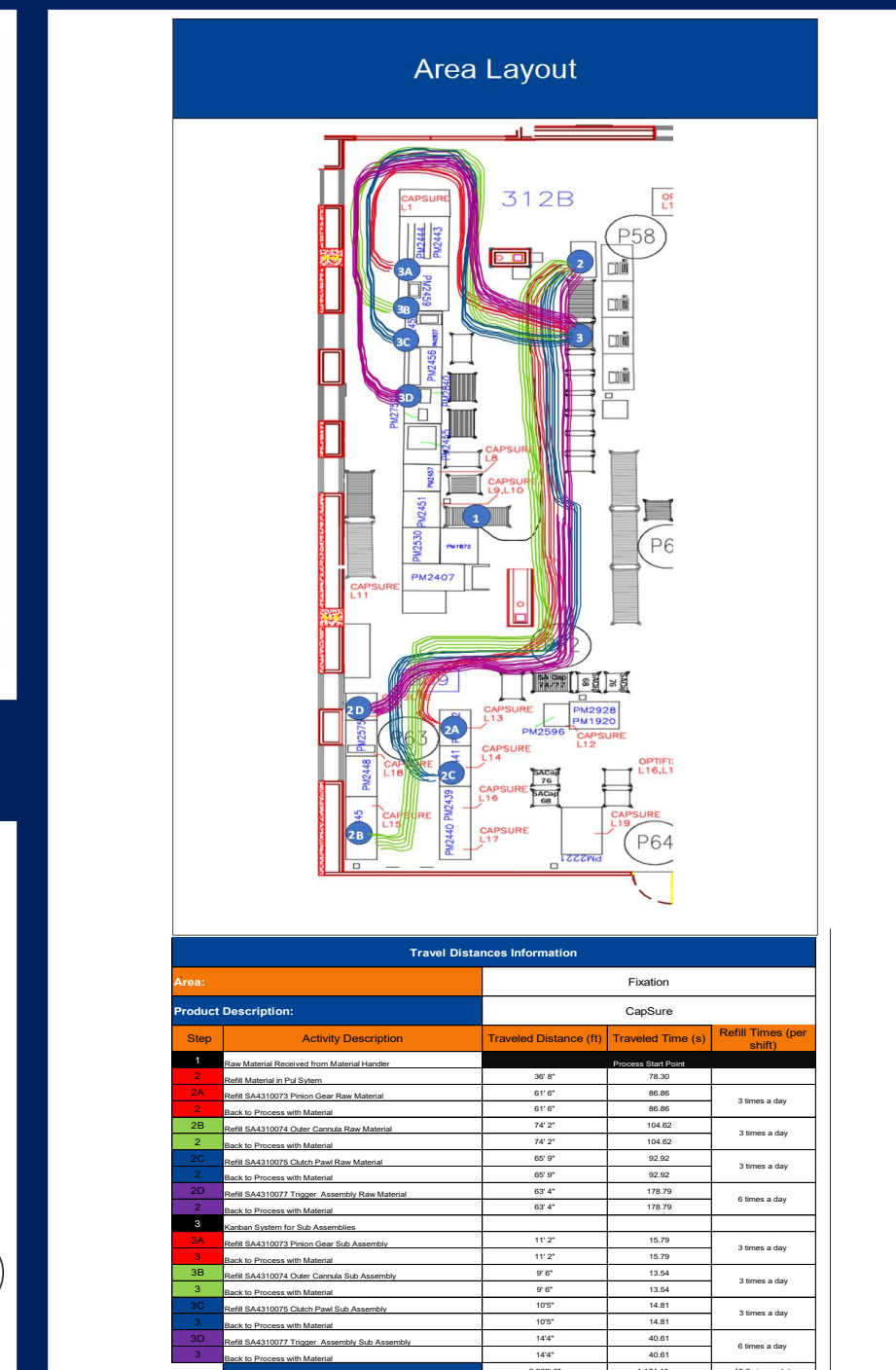


The current state line balancing shows significant imbalance in cycle times across operators. The longest cycle time is 120 seconds, while the shortest is 40 seconds, indicating inefficient workstation design and potential bottlenecks.

Ishikawa Diagram



Spaghetti Diagram



IMPROVE

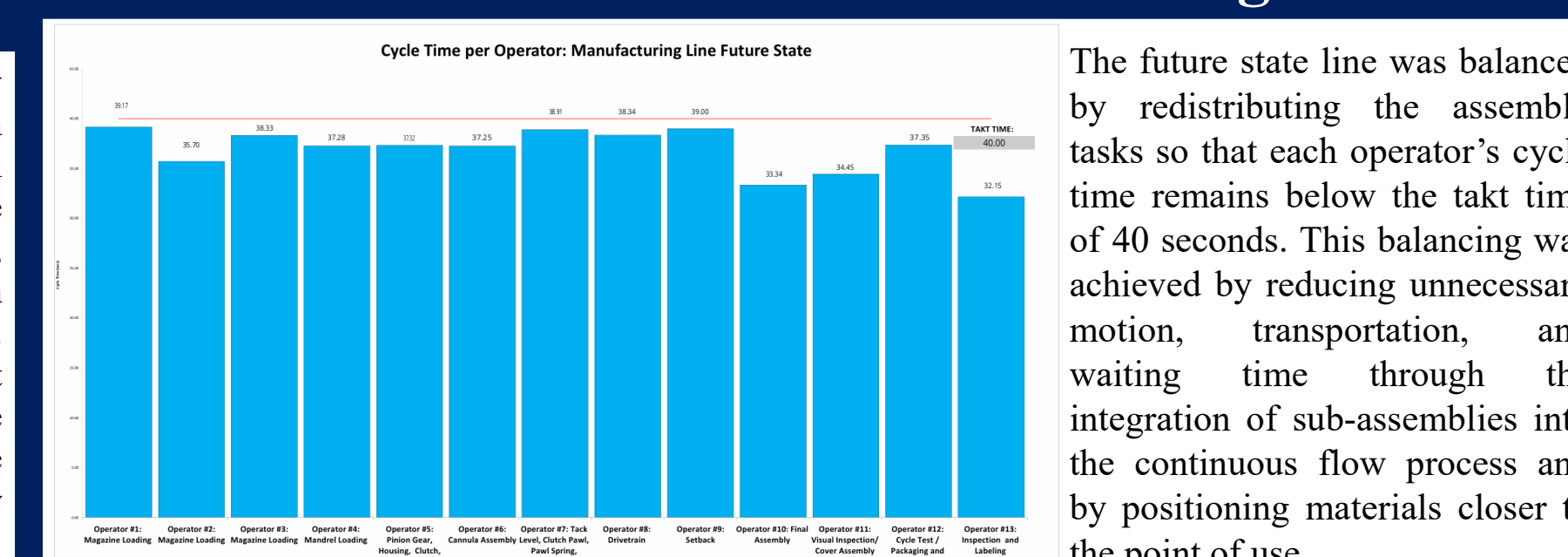
ONU Goals

The ONU Goals 9 (Industry, Innovation and Infrastructure) and 12 (Responsible Production and Consumption) are applied by improving the efficiency and innovation of the assembly line through a continuous flow process. The improvements directly contribute to reducing production waste, waiting time, unnecessary movement, and process interruptions. These goals promote not only economic efficiency, but also environmental responsibility by aligning production processes with more sustainable practices and greater awareness of global impact.

Table of Recommendation

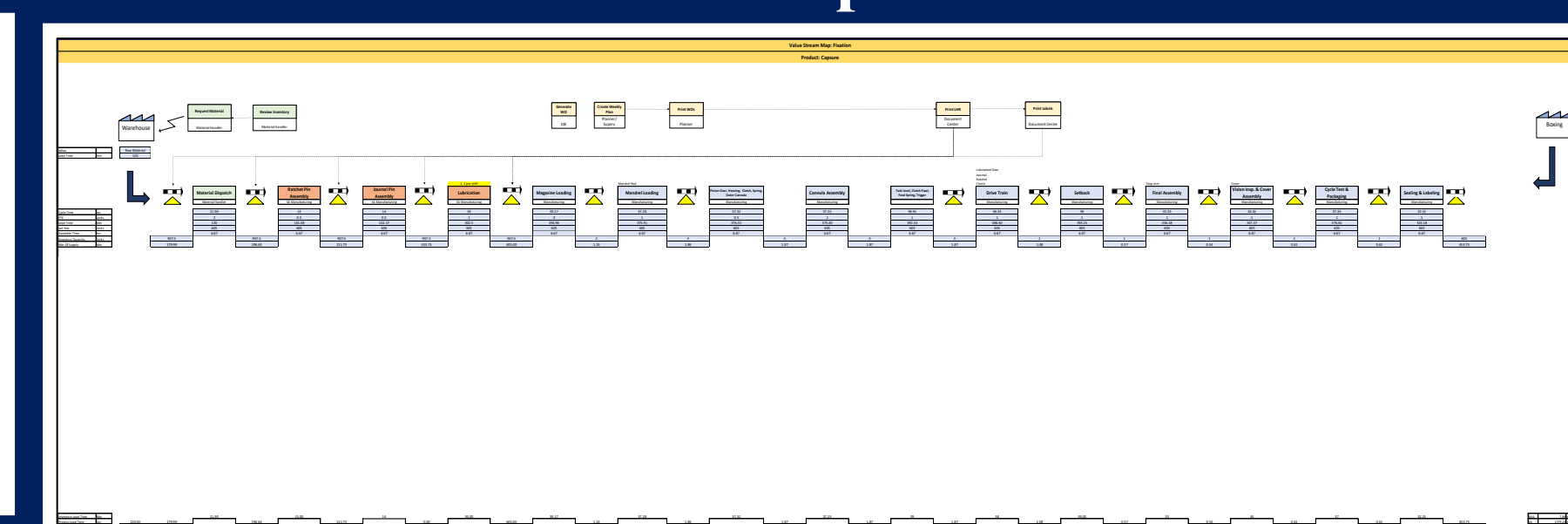
Recommendation	Description	Root Cause Addressed	Expected Impact	Priority
Eliminate Sub-Assemblies & Integrate into Continuous Flow	Redesign the process by incorporating sub-assembly tasks directly into the End Item Assembly line to achieve one-piece flow.	Batch processing preventing continuous flow	Significant lead time reduction, elimination of waiting, reduced WIP, improved throughput	High
Line Balancing Based on Takt Time	Reallocate tasks across stations to align with ~40 sec/unit takt time after integration	Bottlenecks and uneven workload	Increased efficiency and consistent output meeting demand (610 units/day)	High
Redesign Layout for Continuous Flow	Modify workstation arrangement to support sequential flow and minimize movement	Inefficient layout and excessive motion	Reduced transportation waste, smoother operations	High
Point-of-Use Material System	Ensure all components are readily available at each station within the new flow	Material shortages and delays	Elimination of WM downtime, improved flow reliability	High
Implement Karakuri Mechanisms	Introduce simple mechanical systems to assist material movement between stations	Manual handling and operator fatigue	Improved ergonomics, reduced motion waste	Medium
Reduce Changeover Time (SMED)	Streamline setup and transition activities to minimize downtime interruptions	High changeover downtime	Increased uptime and flow continuity	Medium
Standard Work Implementation	Establish standardized procedures for the new integrated process	Process variability	Consistent performance and quality compliance	Medium
WIP Reduction Strategy (Flow-Based Control)	Maintain minimal WIP by enabling pull-based flow within the integrated line	Excess inventory from batch processing	Faster throughput and improved visibility	Medium

Future State - Line Balancing

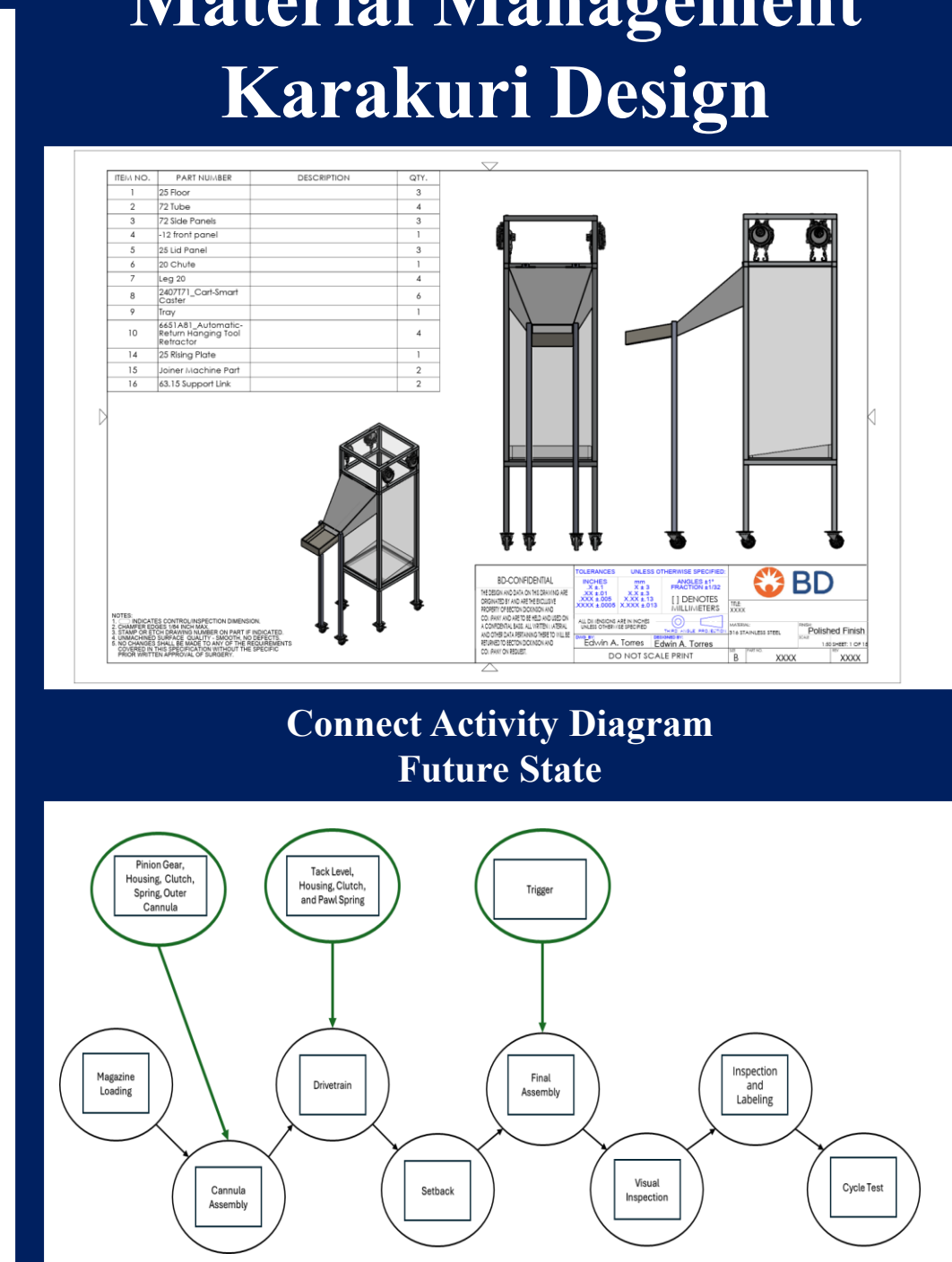


The future state line was balanced by redistributing the assembly tasks so that each operator's cycle time remains below the takt time of 40 seconds. This balancing was achieved by reducing unnecessary motion, transportation, and waiting time through the integration of sub-assemblies into the continuous flow process and by positioning materials closer to the point of use.

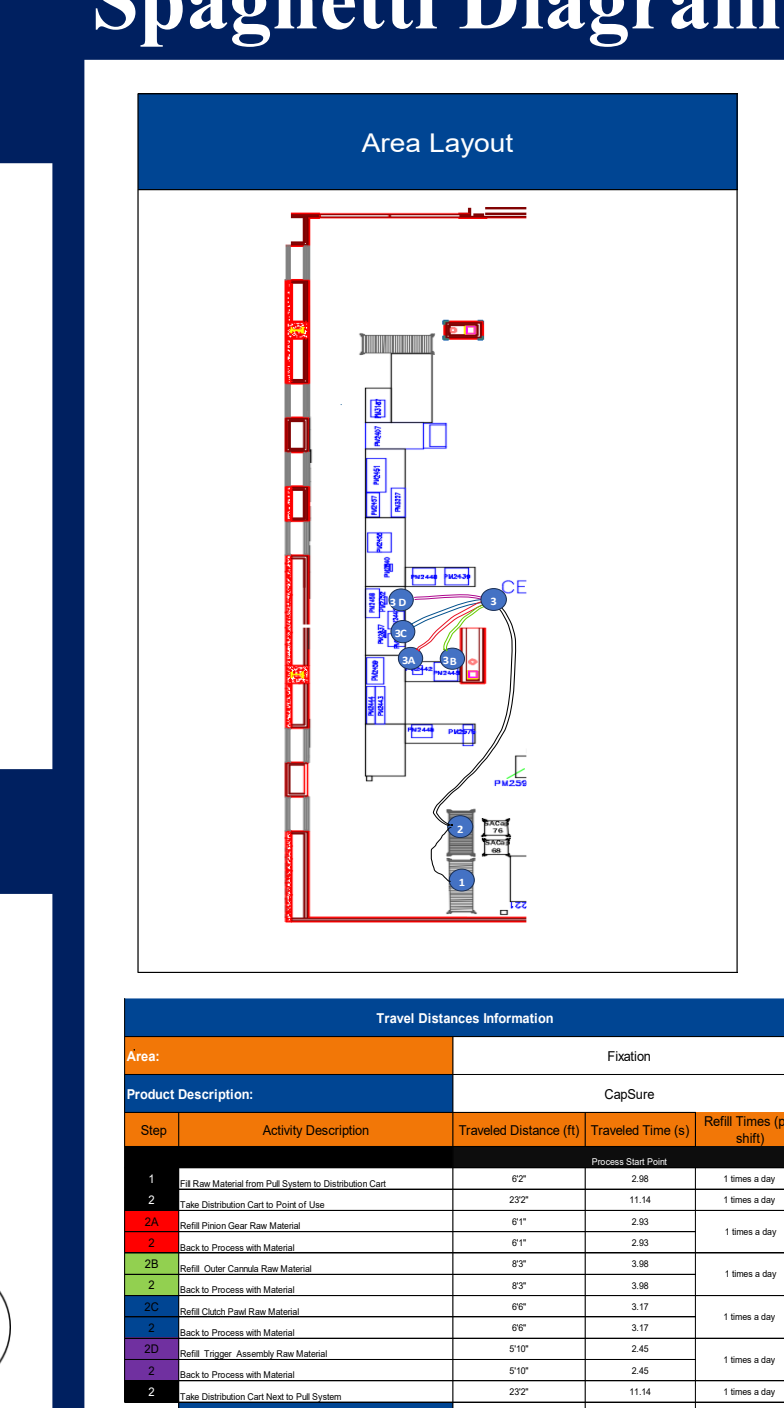
Value Stream Map - Future State



Material Management Karakuri Design

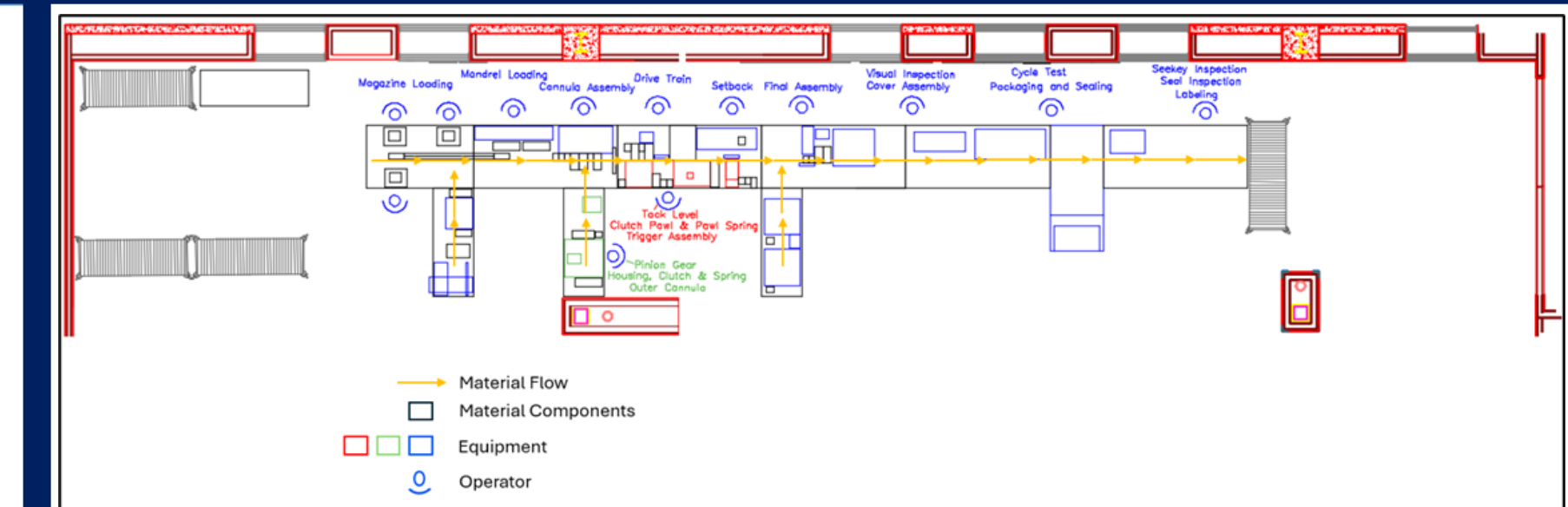


Spaghetti Diagram



CONTROL

Layout Design Implementation



Waste Analysis



Control Monitoring Method

Process Step	Control Method	Metric / KPI	Monitoring Tool	Frequency	Responsible	Reaction Plan
Continuous Flow	Standard Work	Cycle Time (~40 sec/unit)	Work Instructions + Observation	Daily	Supervisor / Operator	Retrain operator and correct method if deviation is observed
Entire Production Line	SPC (Control Charts)	Units per Day (Target: 610)	X-bar / Run Chart	Daily	Process Engineer	Investigate variation and identify root causes if out of control
Material Supply System	Pull System (Kanban-Based)	Availability / WIP Levels	Kanban Cards / Visual Signals	Continuous	Operators / Materials Team	Trigger replenishment and adjust flow to prevent shortages or excess WIP
Workstations	Visual Management (Andon)	Downtime / Delays	Andon Board / Signals	Real-Time	Operators / Supervisor	Immediate response to resolve issues and restore flow
Setup / Changeover	SMED Monitoring	Changeover Time	Downtime Tracking System	Per Event	Supervisor / Engineer	Analyze and reduce setup time if above standard
Process Compliance	Audits (Layered Process Audit)	% Compliance to Standard Work	Audit Checklist	Weekly	Supervisor / Quality	Implement corrective actions and retraining
Overall Process Performance	KPI Dashboard	Output, Lead Time, Downtime	Digital / Visual Dashboard	Daily	Management / Engineer	Review performance and implement improvement actions

Financial Analysis

Category	Description	Quantity	Price per Quantity	Total Cost
Materials	Ergonomical Worktables	10	\$109.35	\$1,093.50
	Remove and relocate utility chases	3	\$219.36	\$658.08
	Supply and install conduits and cables for 120V/220V electrical circuits	5	\$414.24	\$2,071.20
	Supply and install compress air piping	3	\$393.95	\$1,181.85
	Install SS data chase	1	\$345.53	\$345.53
	Install floor and roof	45	\$50.56	\$2,275.20
	Equipment	1	\$545.71	\$545.71
	Engineers	2	\$845.00	\$1,690.00
	Technicians	6	\$245.45	\$1,222.25
	Supervision	2	\$308.15	\$616.30
Insurance	1	\$345.00	\$345.00	
Total				\$11,448.27

Category	Description	Calculation	Savings
Hard Savings	MUV	\$34K monthly x 12 months	\$408,000
	Labor	1 HC: \$33K	\$33,000
	Space Utilization	(1284 ft² - 1020 ft²) = 264 ft² x \$610	\$161,040
Soft Savings	Water Spider Pre-Assemblies	\$1090.35 hr/year x \$17.64	\$19,233.77
	Workload Reduction	\$76.63 hr/year x \$17.64	\$1,351.75
	Water Spider Travel Distance Reduction	\$25,502 x 12 months	\$306,024.00
Total Savings			\$928,649.52

Conclusion

This project allowed to apply Industrial Engineering and Lean Manufacturing tools in a real manufacturing environment at BD Humacao to improve CapSure assembly line. Based on the findings obtained from the study units per day and downtime, we were able to implement recommendations that improved line balance, operational efficiency, and workflow continuity. Our recommendations, based on analysis and studies, provided improvement strategies that maintain a more efficient, sustainable, and competitive manufacturing process while continuing to meet quality and production standards.

