

Acknowledgments: We are deeply grateful to the Polytechnic University of Puerto Rico and Medtronic Juncos for the invaluable opportunity to carry out the Capstone II project. The support provided has been essential in allowing us to apply and expand our academic and professional knowledge.

DEFINE

Problem Statement

Due to factors such as high cycle time, material costs and complex manufacturing process, the current price of Simplera is above the competitor's price. Moreover, due to high product acceptance by the customers, the product's demand is higher than projected. Therefore, employees are being encouraged to identify cost reduction opportunities that will have a positive impact on cost reduction.

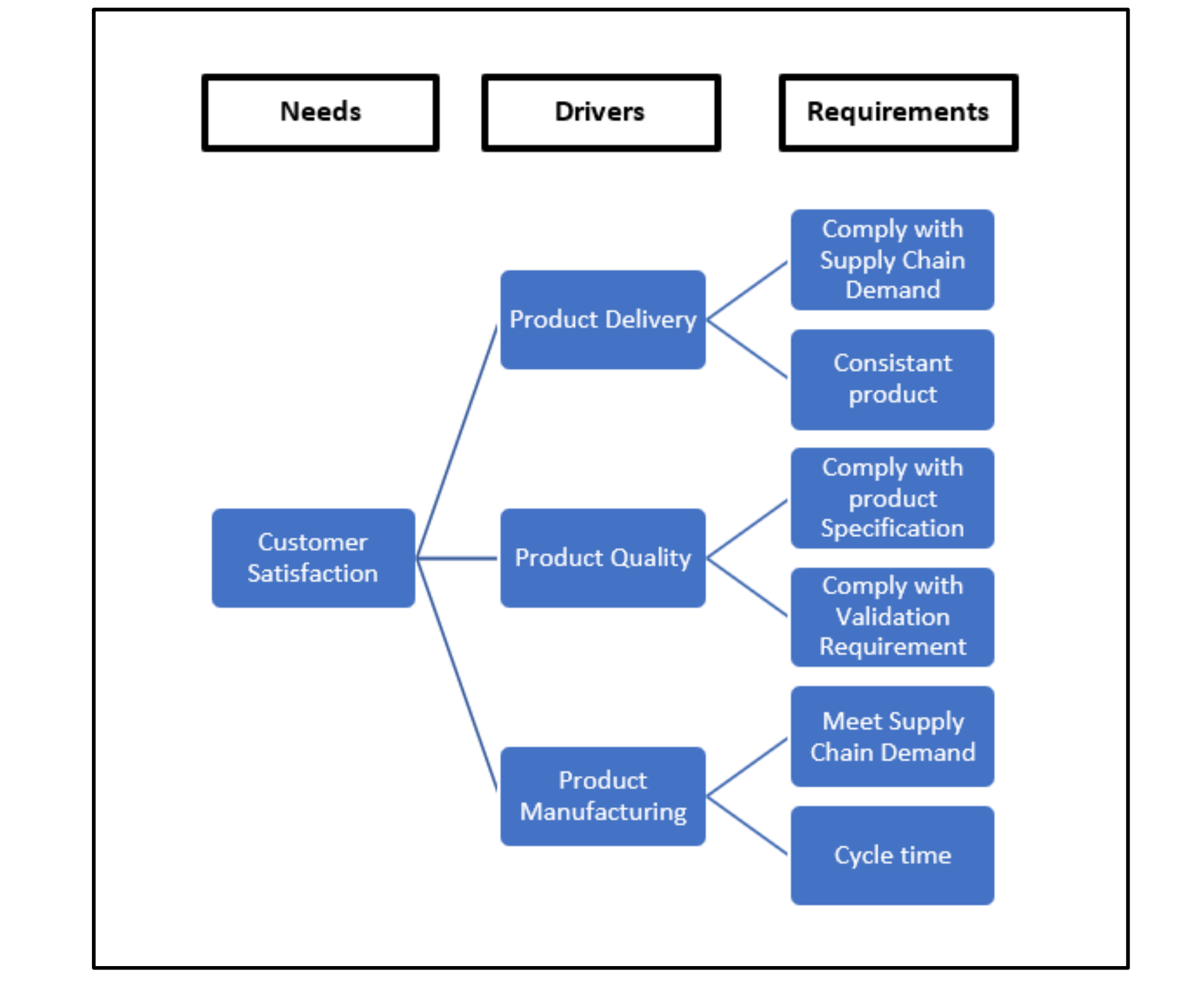
Financial Impact

Based on current information, a single unit takes 8.29 minutes to be manufactured through the assembly line. With a project to reduce 10% of the highest cycle time, students may enable up to 8,760 additional units per year which translates to \$473,040 in savings. Savings are based on the current unit cost of \$54.00.

SIPOC

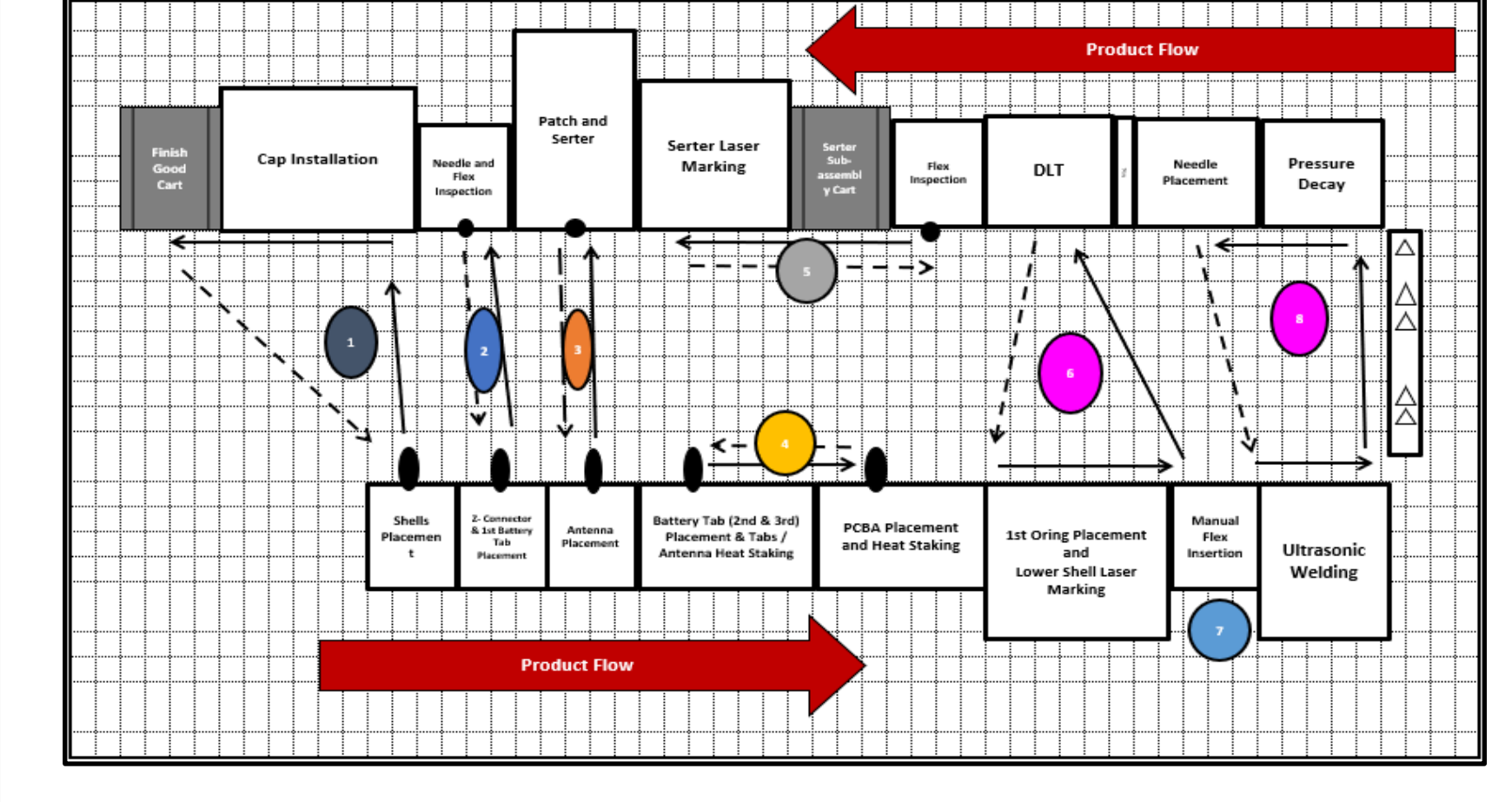
Suppliers	Inputs	Processes	Outputs	Customers
Who supplies the process inputs?	What inputs are required?	What are the major steps in the process?	What are the process outputs?	Who receives the outputs?
Component Suppliers (Over 15 suppliers)	Components	COS Cell Assembly Process	Product within Specification	Distribution Center
Sterilization Company	Machines	Palletization Process	5-Pack	Patients
	Operators	Sterilization Process	1-Pack	
	Design Specification	Depalletizing and Sorting Process	Starter Kit	
	Machine Parameters	Final Packing Process		
		Finish Good is sent to Distribution Centers		

CTQ Diagram

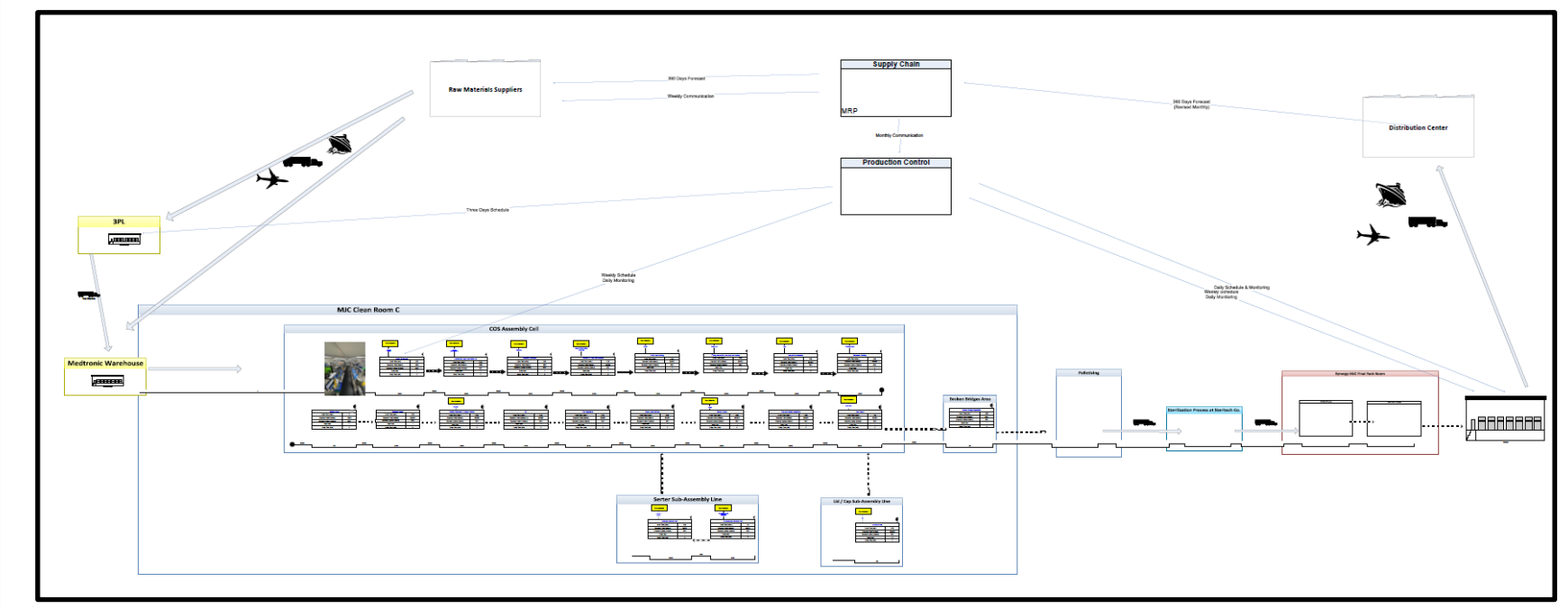


MEASURE

Process Flow with Walk Paths



Value Stream Map



Using information provided by Medtronic Juncos, a Value Stream Map present, the highest cycle time is 0.63 minutes (37.8 seconds) for the Patch to Solder Process.

Cycle Time Study

	Time Element 1 (seconds)	Time Element 2 (seconds)	Time Element 3 (seconds)	Time Element 4 (seconds)	Cycle time (seconds)
Average Time	9.51	15.42	6.13	6.03	37.09

DOE

Sample	Pressure (lb)	Time (s)	Patch Lot	Pull Test Result (lbF)	Pass/Fail
1	55	4	2	8.914	Pass
2	100	4	1	8.938	Pass
3	100	1	1	8.98	Pass
4	77.5	2.5	1	7.803	Pass
5	100	4	2	8.167	Pass
6	77.5	2.5	1	8.905	Pass
7	77.5	2.5	2	8.546	Pass
8	55	1	1	8.836	Pass
9	55	4	1	8.673	Pass
10	77.5	2.5	2	8.758	Pass
11	55	1	2	8.918	Pass
12	100	1	2	8.429	Pass
13	100	1	1	8.857	Pass
14	77.5	2.5	2	7.854	Pass
15	55	4	2	7.41	Pass
16	100	4	1	8.815	Pass
17	55	1	2	8.891	Pass
18	55	4	1	7.439	Pass
19	77.5	2.5	2	8.276	Pass
20	77.5	2.5	1	8.937	Pass
21	55	1	1	8.967	Pass
22	100	4	2	8.267	Pass
23	77.5	2.5	1	8.698	Pass
24	100	1	2	7.042	Pass
25	66.25	1.75	1	7.882	Pass
26	66.25	1.75	2	8.763	Pass
27	66.25	1.75	1	8.756	Pass
28	66.25	1.75	2	8.833	Pass
29	88.75	3.25	1	7.761	Pass
30	88.75	3.25	2	7.809	Pass
31	88.75	3.25	1	8.361	Pass
32	88.75	3.25	2	8.143	Pass

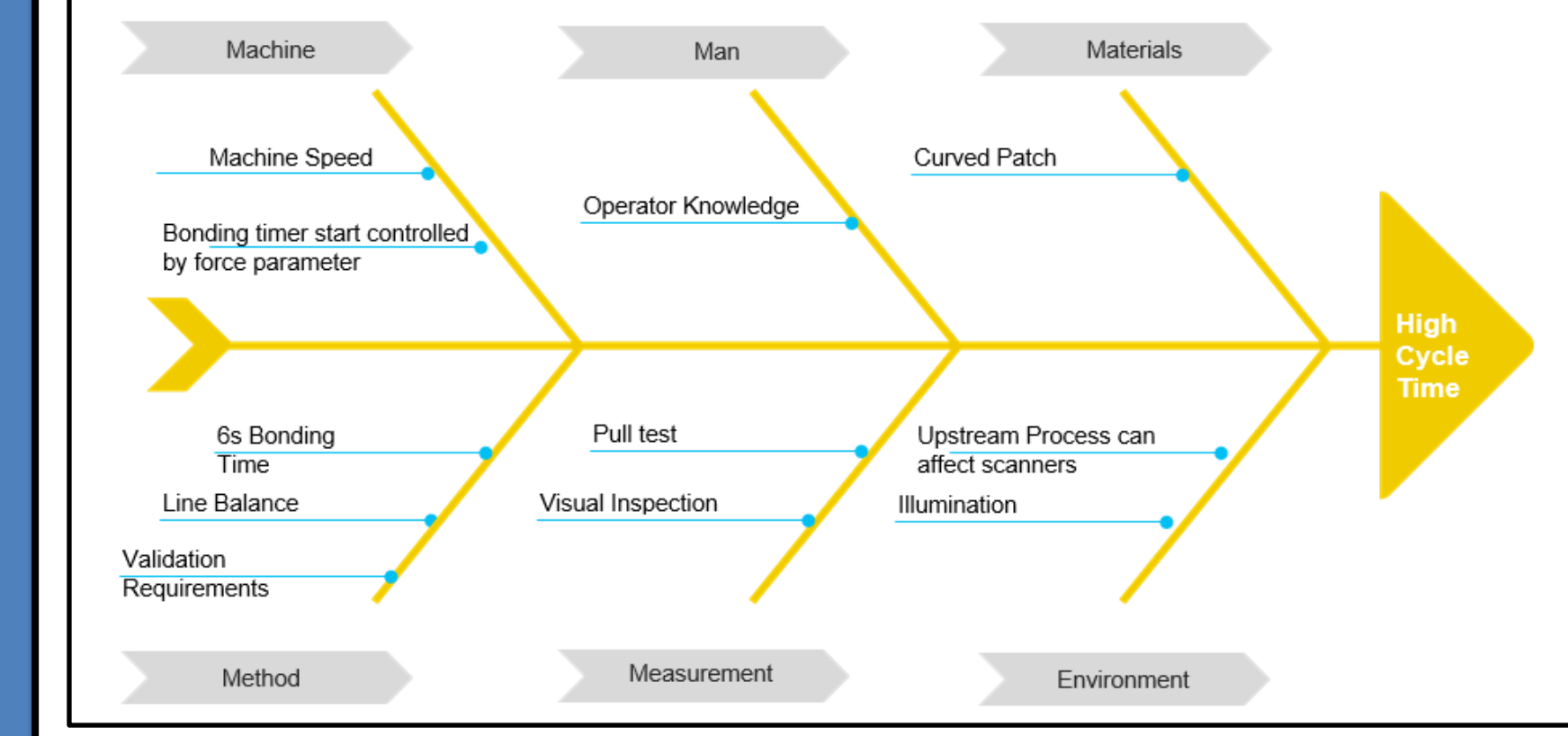
DOE Study was performed to understand relationship between Inputs (time and pressure) and Outputs (Pull Test)

ANALYZE

5 Whys?

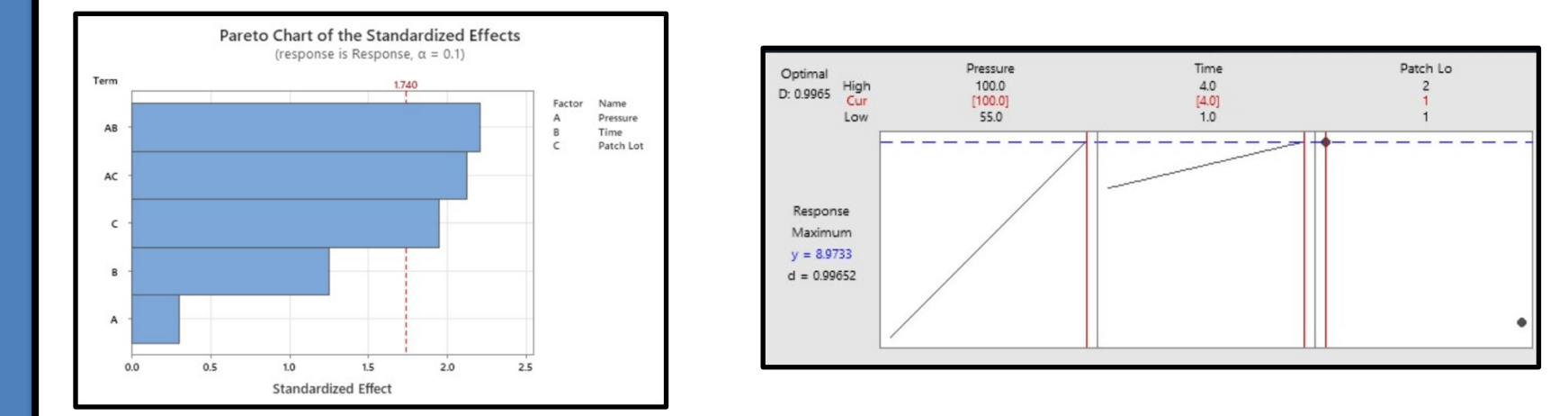
- Why is the the Patch to Solder consider a bottle neck?
 - Because it has one of the highest Cycle time in the cell
- Why?
 - Because Process requires Bonding Time =6s and an inspection after unit is completed
- Why?
 - It was defined through Validation Process
- Why?
 - Time input studied through validation was 5-8 seconds.
- Why?
 - Because study was performed based on highest pull test result.

Fishbone Diagram



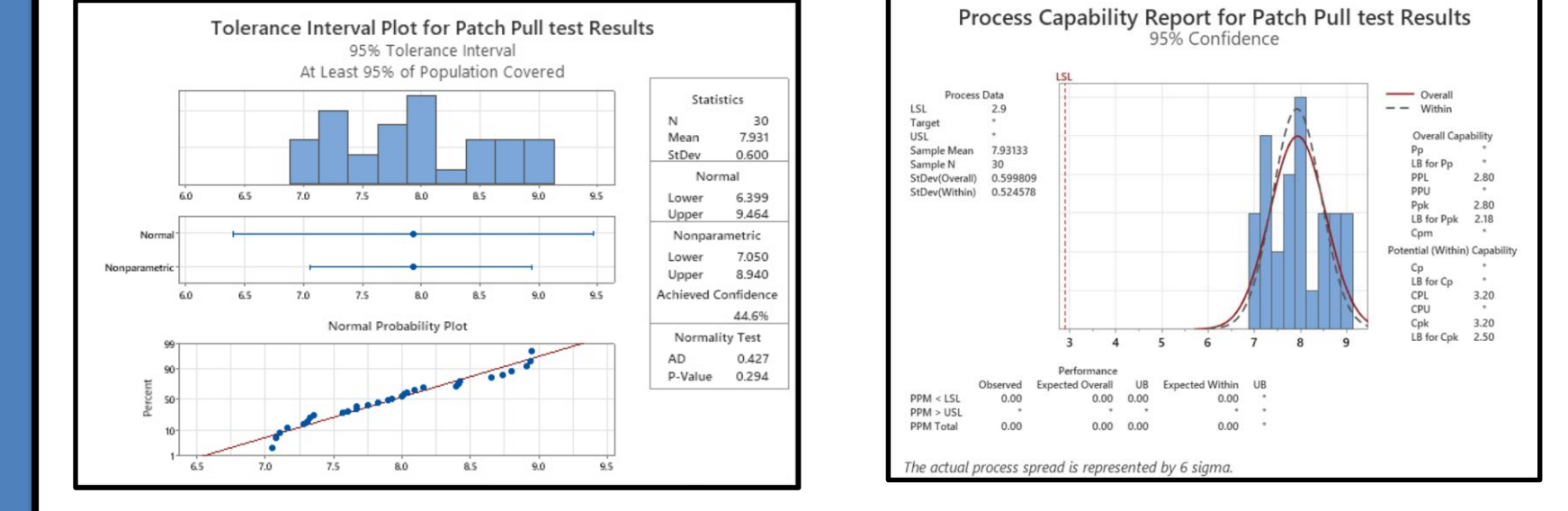
DOE Analysis and Optimization

Regression model was performed Backward Screening Fit. Fit was selected based on the highest r-square adjusted value (35.60%) when compared with other models.



Confirmation Run

A confirmation Run was performed using Time= 1s and Pressure= 77.5lb, since process has a one-sided specification and DOE screening suggests that a lower bonding time can be used.



Line Balance Evaluation

Line Balance Evaluation was performed following information provided by VSM.

	Walk Path 1	Walk Path 2	Walk Path 3
Component Placement 1:	0.22min	Component Placement 2:	0.23 min
Cap To Solder:	0.60 min	Inspection 2:	0.23 min
Idle Time	0.38 min	Patch to Solder:	0.63 min
			0.40 min

IMPROVE

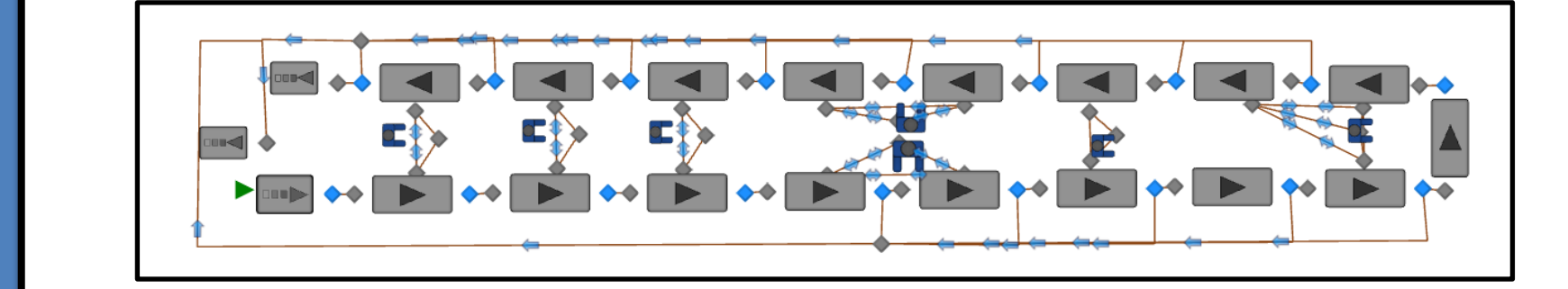
Proposed Solutions

Potential Solution	Root Cause	Advantages	Disadvantages
Proposed Solution 1 (PS1) Reduce Bonding Time and increasing Bonding Pressure	Development Process did not take into consideration Cycle Time implications	Reduces Cycle Time Increases Productivity Optimize the Patch to Solder Process	Further analysis is required to ensure the unit does not crack under the new pressure parameter. Requires approval of regulatory agencies
Proposed Solution 2 (PS2) Implementation of new Walk Path	Unbalanced Line	Reduces HeadCount	Adaptation of operators to new walk path (Learning Curve)
Proposed Solution 3		Combination of PS1 and PS2	

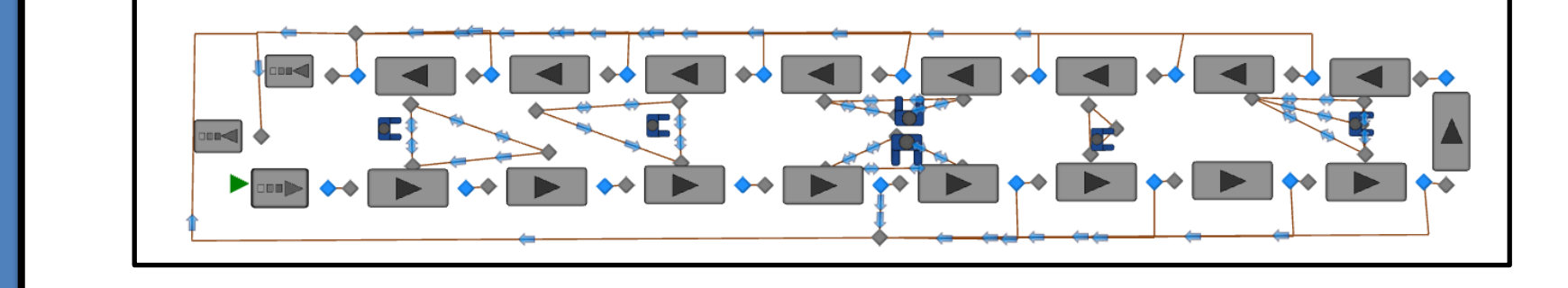
Simulation Analysis

Simulation analysis was performed to evaluate the implications of the Proposed Solutions. A triangular distribution with $\bar{x} \pm 10\%$ for upper and lower limit was used to simulate operators' differences

Simulation for Manufacturing Cell with 8 operators



Simulation for Manufacturing Cell with 8 operators



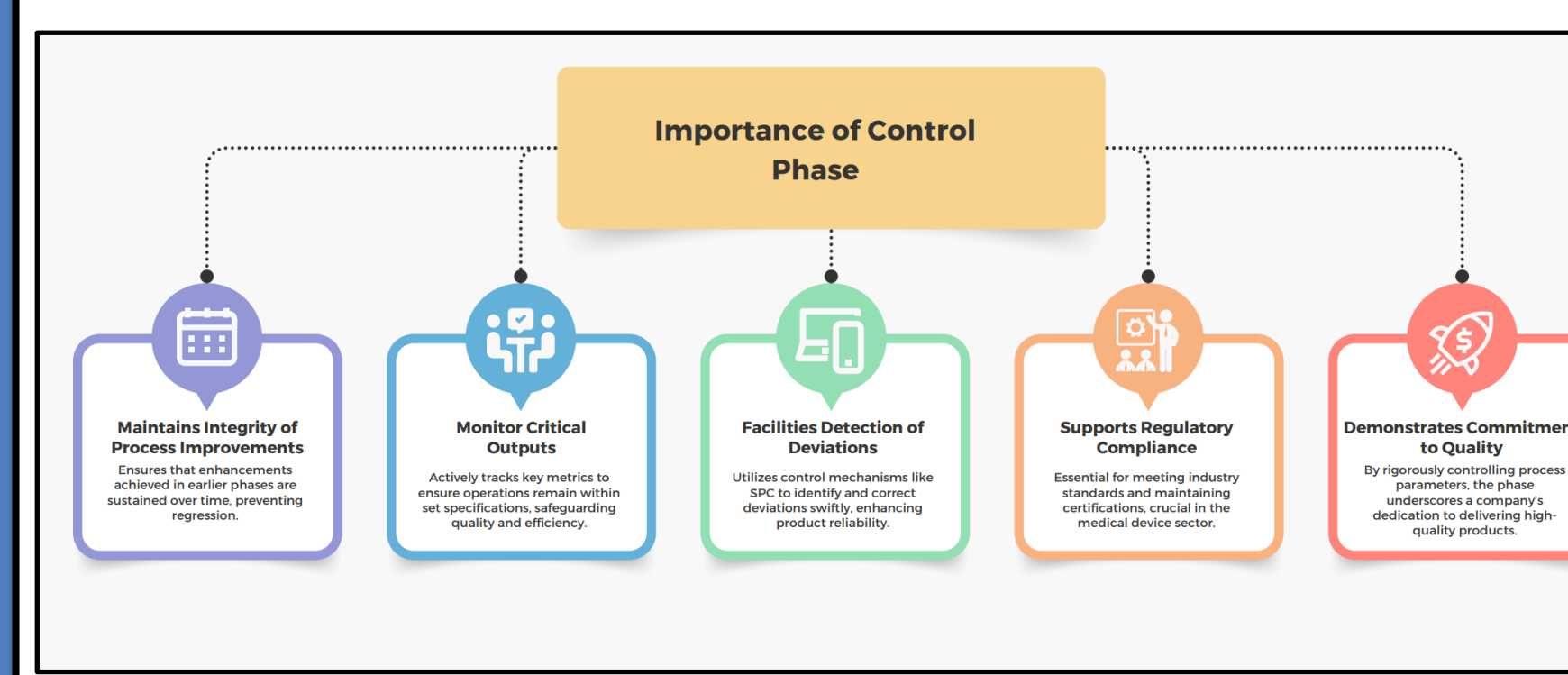
Simulation Results per Manufacturing Cell		
Scenario	Output per Day	Output per Year
Current Situation	586.75 units	736371.25 units
Proposed Solution 1	590.3 units	740826.5 units
Proposed Solution 2	583.5 units	732292.5 units
Proposed Solution 3	574.4 units	720872 units

Financial Implications

Situation	Parameter	Result
Proposed Solution 1 Reduce Bonding time and increasing Bonding Pressure	Actual State	586.75 units/day
	Proposed State	590.3 units/day
	Delta per cell	3.55 units/day
	Annual Profit based on Units	\$ 384,933.60
Proposed Solution 2 Implementation of new Walk Path	Actual State	586.75 units/day
	Proposed State	583.5 units/day
	Delta per cell	-3.25 units/day
	Annual cost per Operator	\$40,167
	Annual Profit based on Units	-\$ 352,404.00
	Overall Impact	\$ 611,604.00
Proposed Solution 3 Combination of Proposed Solution 1 and 2	Actual State	586.75
	Proposed State	574.4
	Delta per cell	-12.35
	Annual cost per Operator	\$40,167
	Annual Profit based on Units	-\$1,339,135.20
	Overall Impact	-\$ 375,127.20

CONTROL

Phase Overview



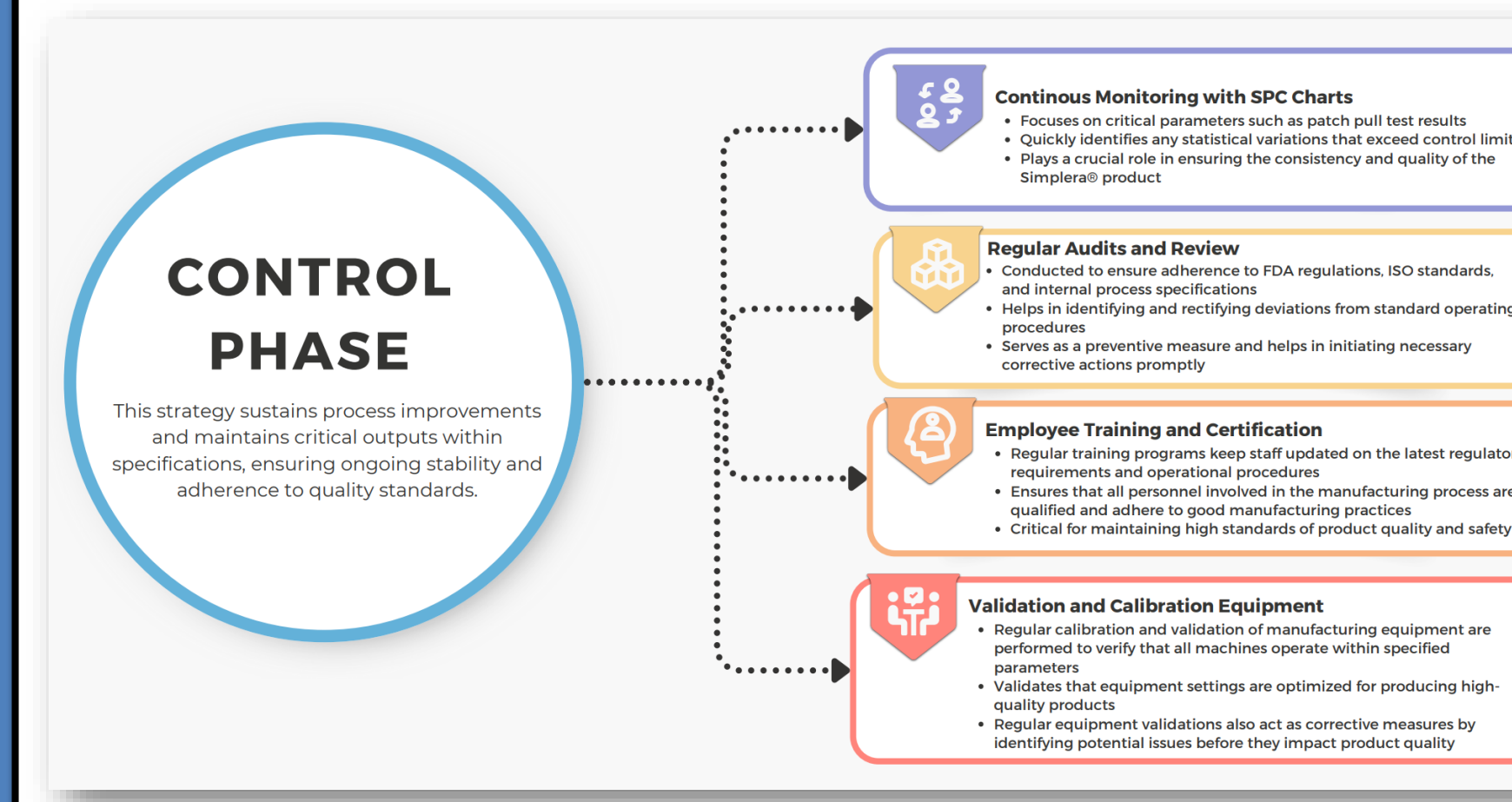
Justification for SPC Implementation

- SPC is crucial for monitoring project outputs continuously.
- Helps in detecting and controlling variability, which is vital for production consistency.
- Aids in maintaining the reliability and operational efficiency of the production line.
- Supports data-driven decision-making to improve process capabilities.

SPC Tool Contribution

- Provides both visual and statistical methods to monitor process performance.
- Utilizes control charts to ensure process stability over time.
- I-MR chart specifically helps in identifying any out-of-control processes that may indicate a shift in process parameters.

Controls Measures Employed



Project Conclusion

This DMAIC project was an example of how structured problem-solving methodologies can be applied to complex manufacturing environments to achieve both operational and financial improvements. The project not only met its objectives but also provided a sustainable model for ongoing improvements, which is critical in the highly regulated medical device manufacturing industry. The success of this project highlights the importance of Lean Six Sigma tools to enhance both process efficiency and financial performance.