

Abstract

A start-up process for two production lines of a biopharmaceutical company was generating more scrap and loss of time than expected during the process. The objective of this project was to reduce the amount of scrap generated and improve the efficiency in each production line. Data was gathered by consulting supervisors, interviewing operators, and observing the workflow to understand the start-up process. Through data analysis, it showed that the major factor of scrap produced was caused by pinholes or scratches. To reduce this, a cleaning step was added to avoid particles being present in the machine. Results showed a significant reduction in average waste generated on the production line. Due to one of two production lines not passing a hypothesis test, further study is recommended to be performed with more samples to be collected to have better statistical proof statistically that the process was improved.

Introduction

A biopharmaceutical company produces different types of membrane for filter cartridges used to separate impurities from liquids delivering high quality filters for multiple applications related to biopharma, medical devices, health and chemical processes. The raw material used for the manufacturing of the filters produced in a chemical manufacturing process using two machines that runs 24 hours, 5 days a week, where operators need to perform a weekly start-up procedure to set up the machine, ensure the machine is running, and performed tests to the final product in compliance with the validated process. The standard process for the set-up of the machine takes approximately one hour and generates 115.5 square meters in production line A and 106 square meters in production line B of scrap being produced.

Background

The start-up process consists of operators transferring solutions to the casting unit and pass the membrane manually over the extraction baths until the membrane reaches a wet winder at a standardized speed, depending on the production line (5.3 meters per minutes on production line A and 5 meters per minutes in production line B). Operators will use tension plates to push down the membrane into the extraction baths. Once all the plates are placed in the extraction baths and the membrane passes through the baths, the membrane will be broken in the wet winder and move through the water baths, where a similar process from the extraction bath is repeated. Once the membrane has passed through all the baths, operators open the dryer and quickly pass the membrane through it. The dryer will be closed, the parameters of the dryer will be set, and the membrane ends in a winder section where it will roll the membrane. Once the membrane feels dry, the winder will begin to roll a new membrane where tests on the membrane will be performed by the operators. If the membrane passes all the quality parameters, then production will begin from the moment the winder switches to a new roll. Membrane that were placed on the wet winder will be considered as scrap and the amount of scrap will be calculated at the end of the process.

Problem

The start-up process ideally should take up to an hour to complete from the moment the solution begins to cast in the casting unit to the moment production starts with no delays; however, there are times when this process can take more time creating more waste of scrap and downtime in the process. The objectives of this research are to understand the variables impacting the start-up process, and reduce the start-up time to less than an hour so that the amount of scrap is less than the standard of 115 square meters in line A and 106 square meters in line B.

Methodology

Table 1
Production Line A Start-up Scrap and Failures before Improvement

Lots	Date	Time (minutes)	Amount of scrap (m ²)	Failure modes for scrap of start-ups present										
				Broken membrane	Dirt on Nozzle	Illumination test failed	Pin holes or Scratches	Wrinkles	High or low thickness	Flow or Bubble Point	Bubble Point (Sartochack)	Normal Start-Up	Gas Conditioning Failure	
1	8/6/2025	38	53.7											
2	8/11/2025	210	536.9											
3	8/18/2025	283	741.9											
4	9/1/2025	172	430.1											
5	9/7/2025	130	312.7											
Avg / lot			415.1											

Table 2
Production Line B Start-up Scrap and Failures before Improvement

Lots	Date	Time (min.)	Amount of scrap (m ²)	Failure modes for scrap of start-ups present										
				Broken membrane	Dirt on Nozzle	Illumination test failed	Pin holes or Scratches	Wrinkles	High or low thickness	Flow or Bubble Point	Bubble Point (Sartochack)	Normal Start-Up	Gas Conditioning Failure	
1	8/2/2025	106	227.9											
2	8/4/2025	130	296.8											
3	8/11/2025	105	225.3											
4	8/26/2025	228	551.2											
5	9/8/2025	80	159.0											
Avg / lot			292.0											

Figure 1: Process Flow Chart

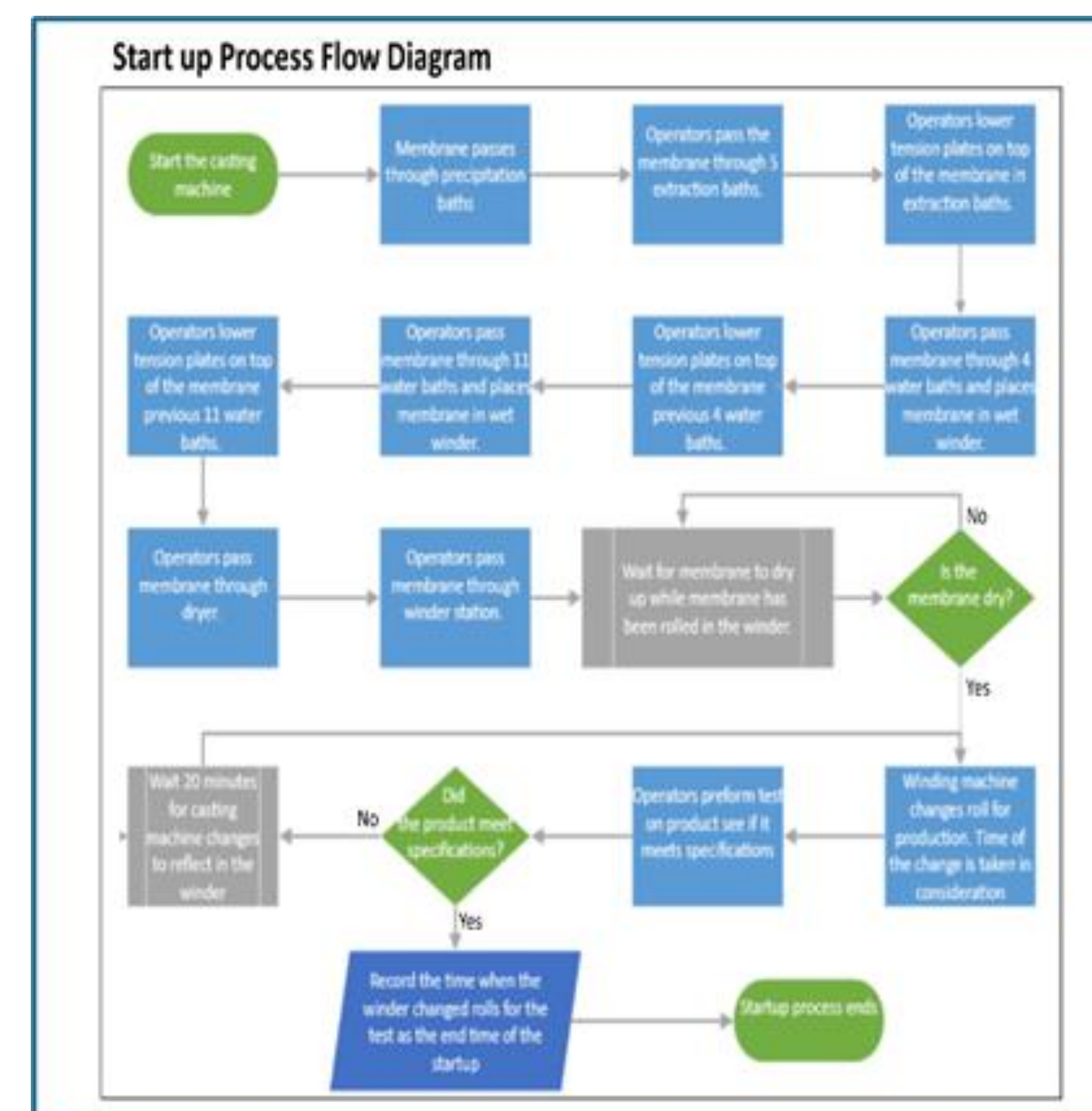
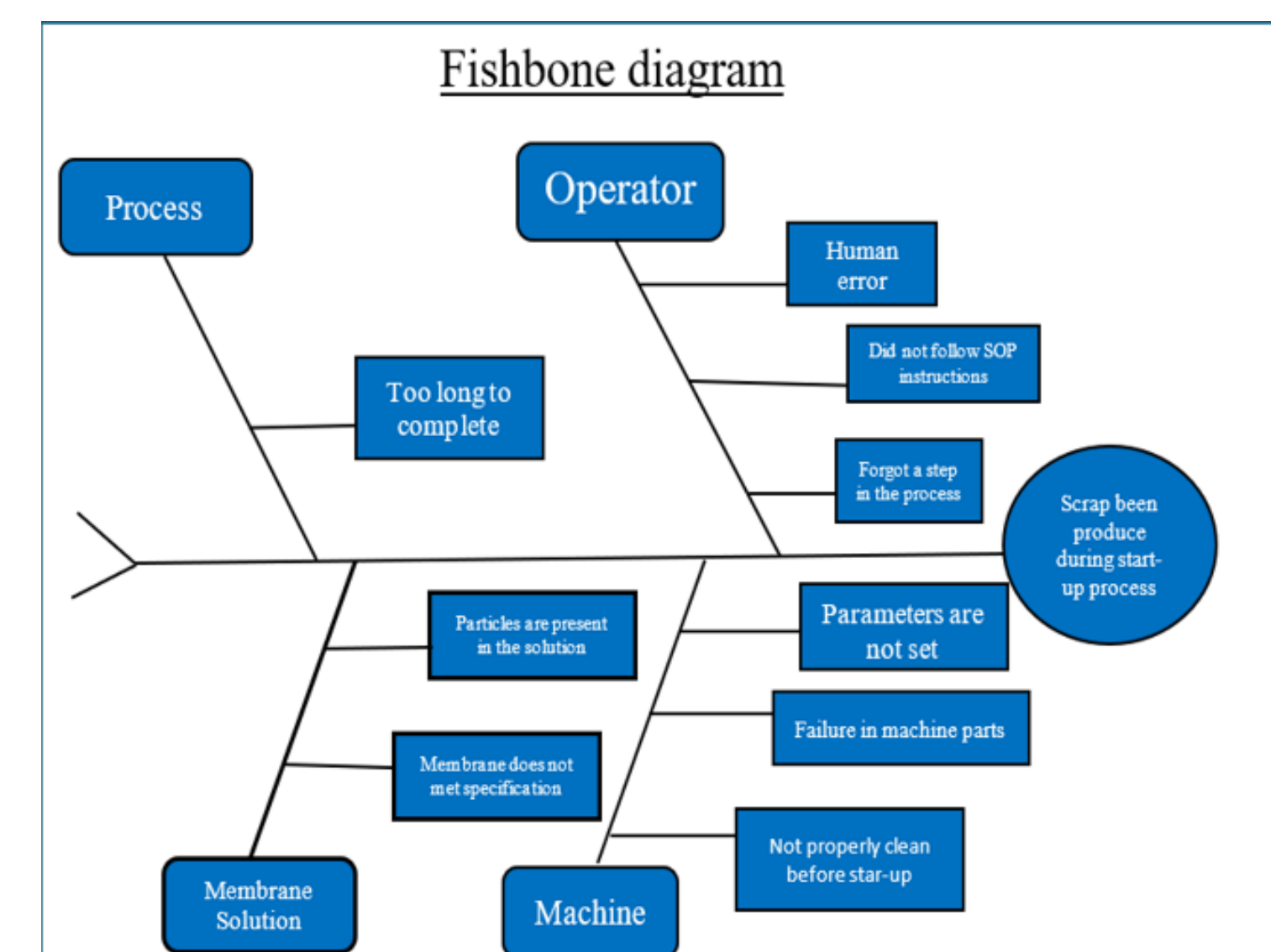


Figure 2: Fishbone diagram



Results and Discussion

Table 3
Production Line A Start-up Scrap and Failures after Improvement

Lots	Date	Time (min.)	Amount of scrap (m ²)	Factors for scrap of start-ups										
				Broken membrane	Dirt on Nozzle	Illumination test failed	Pin holes or Scratches	Wrinkles	High or low thickness	Flow or Bubble Point	Bubble Point (Sartochack)	Normal Start-Up	Gas Conditioning Failure	
1	11/3/2025	120	284.1											
2	11/10/2025	50	87.5											
3	11/17/2025	56	104.3											
4	12/1/2025	85	185.8											
5	12/8/2025	47	79											
Avg / lot			148.1											

Table 4
Production Line B Start-up Scrap and Failures after Improvement

Lots	Date	Time (min.)	Amount of scrap (m ²)	Factors for scrap of start-ups										
				Broken membrane	Dirt on Nozzle	Illumination test failed	Pin holes or Scratches	Wrinkles	High or low thickness	Flow or Bubble Point	Bubble Point (Sartochack)	Normal Start-Up	Gas Conditioning Failure	
1	11/3/2025	46	68.9											
2	11/10/2025	47	71.6											
3	11/17/2025	52	111.3											
4	12/1/2025	37	45.1											
5	12/8/2025	53	87.5											
Avg / lot			76.9											

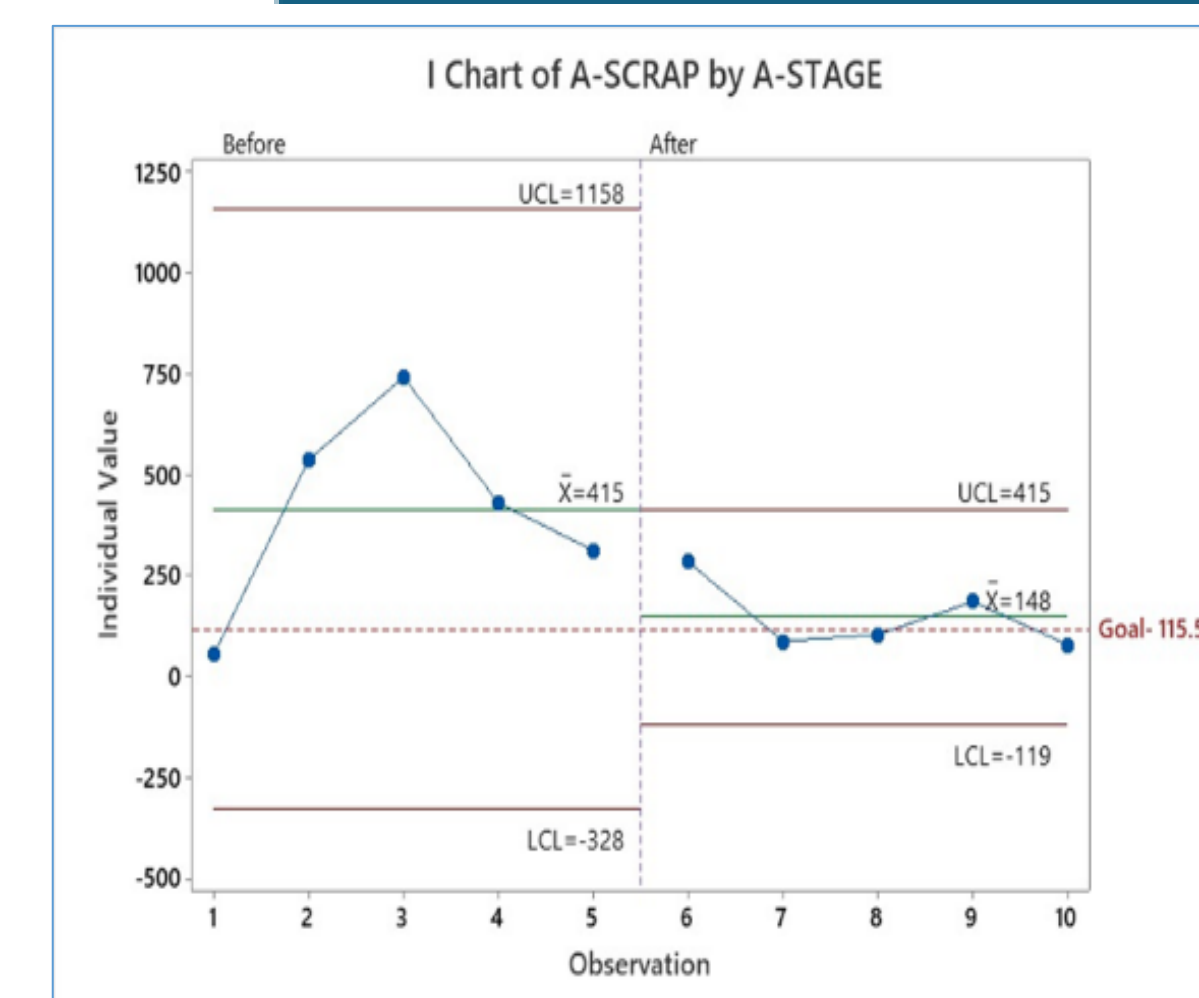


Chart 1: Individual Control Chart of Production Line A Scrap Generated During Start-up Before & After

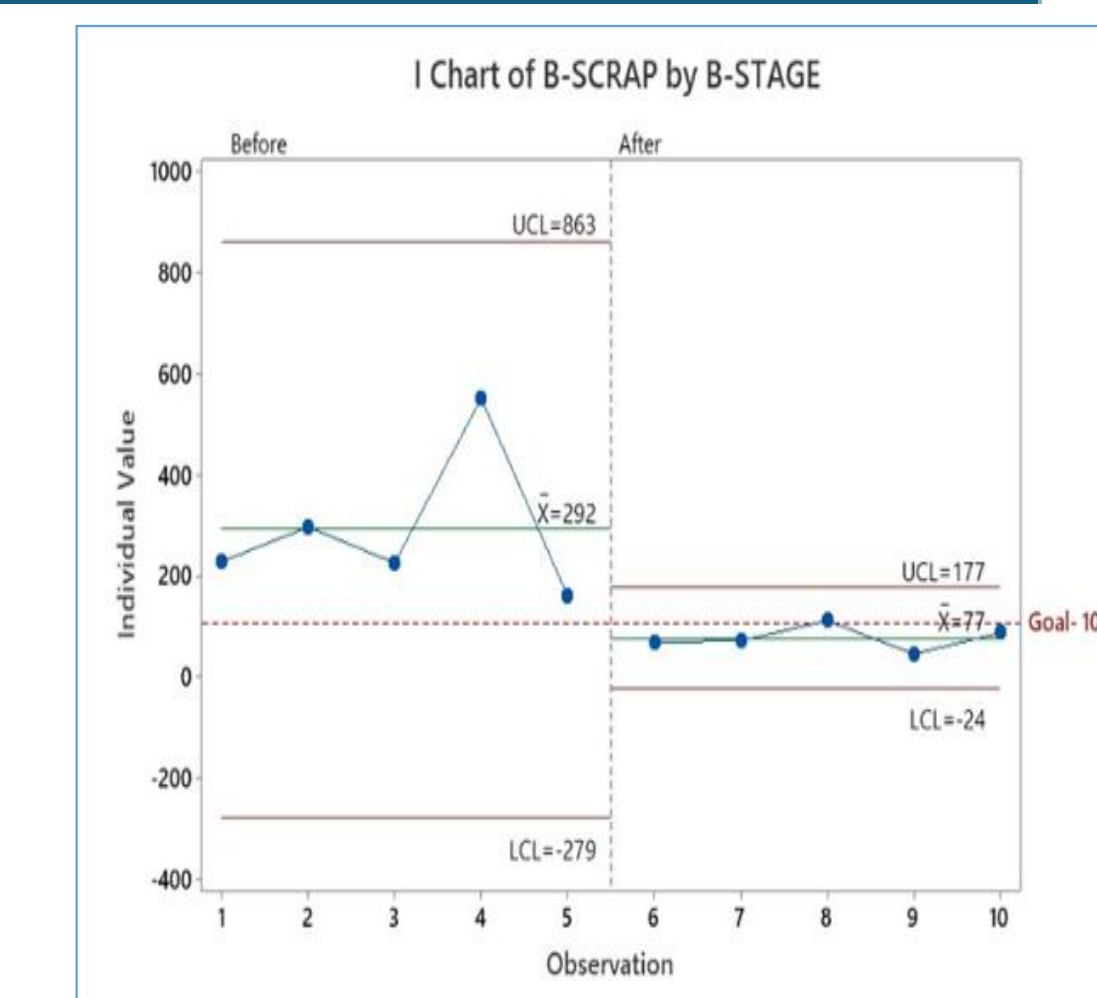


Chart 2: Individual Control Chart of Production Line B Scrap Generated During Start-up Before & After

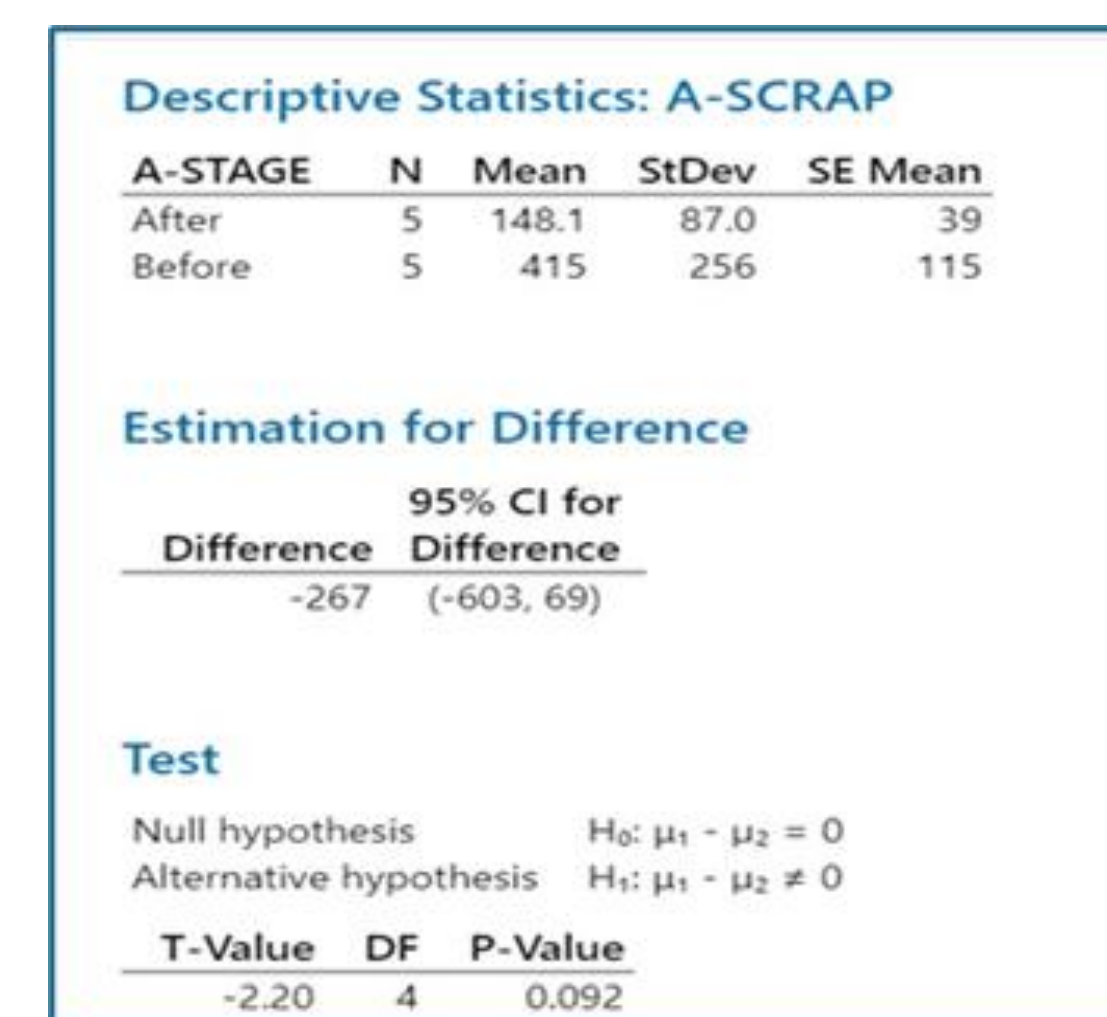


Figure 3: Two-Sample T-Test for Production Line A Start-Up Scrap Improvement

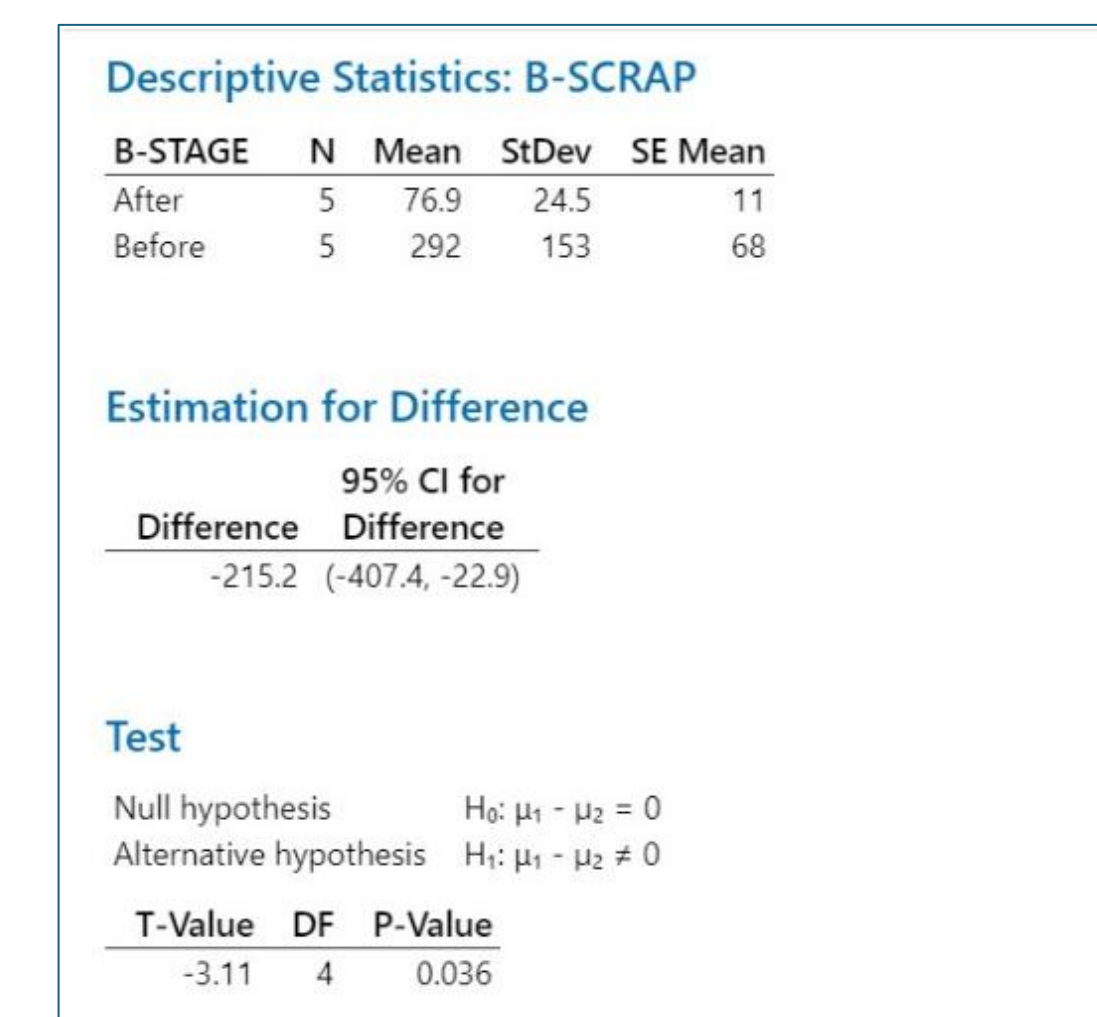


Figure 4: Two-Sample T-Test for Production Line B Start-Up Scrap Improvement

Conclusions

Through the data collected it was discovered that the amount of scrap generated related to pin holes or scratches present in the product. The root cause of this came from the bubble tanks in which the membrane solution is stored and transferred to the casting machine, where residue of previous membrane solution was left at bottom building up. A cleaning procedure was created for operators to follow for five weeks and results showed more than 65% of scrap been reduced on both production lines, where average amount of scrap per lot generated reduced from 425.1 to 148.1 square meters in production line A and from 292.0 to 76.9 square meters in production line B. Based on all of the hypothesis test that were presented, only the Two Sample T-test of production line A failed to give a significant difference between before and after the improvement of the process was done even though there was reduction of scrap generated.

Future Work

Due to one production line A failing the Two Sample T-test, it is recommended that for future evaluation perform the study with a larger sample size to prove there was an improvement in the start-up process.

Acknowledgements

I would like to acknowledge the people that help and supported through the process of the design project: advisor José Morales Morales, article Editor: Dainmarik Torres, and the supervisor and operators from of the biopharmaceutical company.

References

- [1] J. P Womack, D. T. Jones & D. Roos, "The machine that changed the world: the story of lean production," in Harper Perennial eBooks, 1991. Available: <https://ci.nii.ac.jp/ncid/BA14012737>.
- [2] A. Saenagri, O. Usman & G. Ishak, "Implementation of Total Productive Maintenance and Lean Manufacturing in the Pharmaceutical Industry: An Empirical Study," in Journal of Business & Management Studies, vol. 5, no. 3, pp. 114–124, 2023. Available: <https://ezproxy.pupr.edu:2093/10.32996/jbms.2023.5.3.10>
- [3] Interpret the key results for Individuals Chart - Minitab. (n.d.). (C) Minitab, LLC. All Rights Reserved. 2025. <https://support.minitab.com/en-us/minitab/help-and-how-to/quality-and-process-improvement/control-charts/how-to/variables-charts-for-individuals/individuals-chart/interpret-the-results/key-results/>
- [4] Interpret the key results for 2-Sample t - Minitab. (n.d.). (C) Minitab, LLC. All Rights Reserved. 2025. <https://support.minitab.com/en-us/minitab/help-and-how-to/statistics/basic-statistics/how-to/2-sample-t/interpret-the-results/key-results/>