Membrane Production Start-up Scrap Reduction

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Abstract *— A start-up process for two production lines of a biopharmaceutical company was generating more scrap than expected, generating lots of time and physical material waste 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.*

Keywords *— Biopharmaceutical, Continues Improvement, Process Improvement, Waste Reduction.*

PROBLEM STATEMENT

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, insure 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 during the set up process; however, there have been reports where production has produced more scrap than usual reaching an average of 415.1 square meters per lots in production line A and an average of 292.0 square meters per lots in production line B.

The objectives of this research are the following:

- Develop a process map of the start-up process to understand the variables impacting the set-up time and manufacturing process.
- Implement lean manufacturing tools that can reduce scrap and improve performance in the start-up process.
- Compare the start-up scraps process before and after the implementation of lean manufacturing strategies to prove their effectiveness.
- 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.

The contribution from this project will be to evaluate and optimize the start-up process. For this purpose, I will perform audits to gather information about the process performance, set-up scrap factors that affect the start-up process, and review the Standard Operating Procedures (SOPs) to review all the steps the operators of the area must perform, observer areas and steps have a major impact in producing scrap. Lean Manufacturing tools will be utilized to analyze and improve process performance, followed by implementing any necessary adjustments to standardize the process and maintain its improved efficiency.

LITERATURE REVIEW

The manufacturing process of the project produces membrane lots of approximately 5,000 square meters that are sent to a different department where they use the membrane as the main raw material for the cartridge filter.

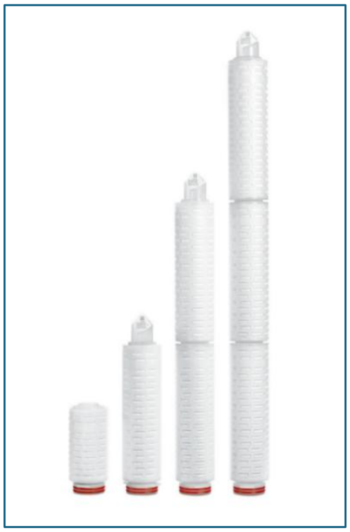

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Figure 1
Cartridge Filters Produced by the Biopharmaceutical Company of the Research [1]

Every Thursday, a solution is prepared by the mixing team taking roughly 40 hours for 3,500 kg of solution to be prepared and transferred to the production line to start the weekly production on the following week. In the production line, there is a machine where the solution is transferred from their storage bubble tanks through a cartridge housing for filtering any particles that may be present in the tube lines in which the solution flows to the casting machine, in which forms the membrane. The membrane must pass through the casting unit where it will take its form and go through a precipitation bath that is composed of 99% isopropyl alcohol (IPA), then passing through a set of baths of extractions composed of 99% IPA and a set of reverse osmosis (RO) water baths to wash any chemical residue and to sterilize it, and ends passing through a dryer and rolling up into a roll on a winder. The start-up process requires setting up the machine with 20 baths of RO water and/or 99% IPA while preheating the dryer and filling up the precipitation bath. While the precipitation bath is being filled, preparation of the cartridge housing is done by making the connection lines from housing and to the casting unit. A sample of solution must be extracted before filling the housing with membrane to avoid solid residue from a previous solution in the connection tube line from the bubble tanks be present. While the housing is been filled, the set up continues in parallel with the adjustment of the nozzle of the casting machine, make sure all baths and rollers are turned on and working fine, tension plates are ready for standby, and all machine parameters have reach specifications.

The start-up process consists of operators transferring solutions to the casting unit and pass the membrane manually over the extraction baths up 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.

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. To calculate the amount of scrap been produced during the start-up process, operators will use the following equation to calculate the amount of scrap produced during the start-up: [(Time of start-up) (Speed of the casting machine) – 100m](0.53m)

Because each production line runs at a different speed, each must use the following equations:

Line A Start-Up Scrap Equation	[(Time of start-up) (5.3m/min) – 100m](0.53m)
Line B Start-Up Scrap Equation	[(Time of start-up) (5m/min) – 100m](0.53m)

The amount of scrap is correlated with the start-up process time. If the start-up process takes longer than usual to complete, then more scrap will be produced.

According to the supervisor of the area, the cost of the product is $5 per square meters for both lines. If a lot was to be produced for a total of 5,000 square meters, the cost of the lot would be $25,000. Now, if line A were to produce 115.5 square meters of scrap due to the start-up process, then lot would have lost a total of $577.50, losing 2.3% of money in the end.

As the main objective of this project is to reduce scrap produced in the start-up process, it is important to understand the types of waste defined by lean manufacturing and how Lean Manufacturing (LM) can help understand the problem present in the process and improve the efficiency and performance of the process by eliminating or minimizing the waste produced. LM focuses on systematically eliminating waste or non-value added activities from organizational operations through a series of synergistic work to produce products and services as needed. There are seven waste types that companies can produce that affect production efficiency. Some of the benefits and results of applying LM in an operation are to reduce lead time, eliminate bottlenecks in the process, and optimize the utilization of company resources [2] [3].

Methodology

For this process, reference and historical performance data were gathered to understand the amount of scrap produced during the star-up of previous lots to establish the baseline. The project will include trending analysis, top offenders, where for, and fish bone chart which will present the cause-and-effect relationship of the scrap that has been produced.

The start-up process will be observed in real time to see what actual steps have been taken and identify opportunity, gaps, or best practices. A process flow chart will be made to better visualize the start-up process with the data gathered about all the tasks performed to identify which steps impact the start-up process and better understand the root causes, implement corrective actions to improve, standardize and reduce the set-up time and amount of scrap that generates during the star-up.

Once the corrective actions are implemented, the process of start-up will be evaluated again to measure the scrap generated versus the baseline data. The following graph is Gantt Chart that will show a visual process of how the project will be conducted:

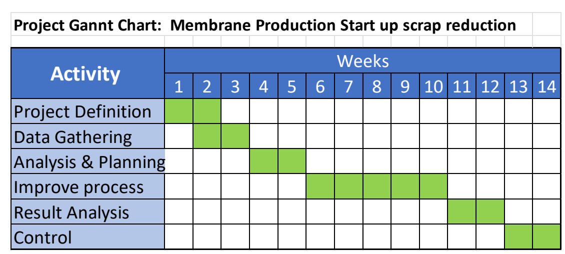

Figure 2
Project Gannt Chart

Results and Discussion

A meeting with the supervisor of the production line was conducted to gather data of previous lots that started productions. With the information gathered, two tables were formed with each production line showing the number of lots, the amount of scrap been produced in square meters during the start-up process, and the factors that operators had marked as to the reason of the start-up.

For line A, an extra factor has been added: gas conditioning failure. The tables for production line A (table 1) and production line B (table 2) are below:

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	Iluminati on test failed	Pin holes or Scratches	Wrinkles	High or low thicknes s	Flow or Bubble Point	Bubble Point (Sartocheck)	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 Failure Before Improvement

Lots	Date	Time (min.)	Failure modes for scrap of start -ups present									
			Amount of scrap (m^2)	Broken membrane	Dirt on Nozzle	Iluminati on test failed	Pin holes or Scratches	Wrinkles	High or low thicknes s	Flow or Bubble Point	Bubble Point (Sartocheck)	Normal Start-Up
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									

Table 1 shows that the average of scrap per lot in line A is 415.1 square meters and one out of five lots have been documented as a normal start-up process for scrap that was produced, performing better than the expected scrap target by producing less than 115.5 square meters. Some of the lots show to have more than one reason for scrap been produced during start-up, for example lot number 3, with 741.9 square meters of scrap produced, has four reasons for scrap been produced, and lot number 3 and 5 having two reasons for scrap been produced. The major factor the causes scrap in the start-up process is pin holes or scratches, with four out of five lots been identified as the cause of scrap. A third table (Table 3) and a Pie chart (Chart 1) of the factors that affect start-up process to produce more scrap were developed with the information gathered of the first table of production line A to visualize better the number of factors that were the major reason for scrap during the start-up.

Table 3
Factors Produced in Start-up of Production line A Before Improvement

Reason for scrap	Number of lots
Pin Holes or Scratches	4
Illumination test failed	2
Normal Start-Up	1
Dirt on Nozzle	1
Flow or Bubble Point	1
Gas Conditioning Failure	1
Broken Membrane	0
Wrinkles	0
High or Low Thickness	0
Bubble Point (Sartocheck)	0

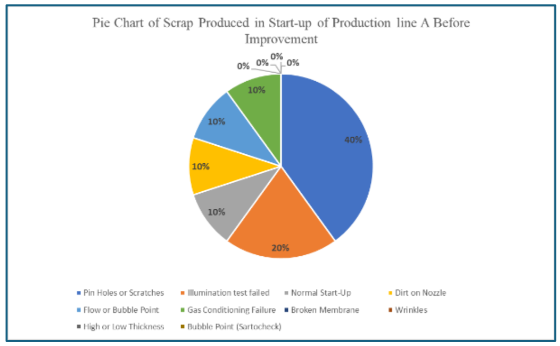

Chart 1
Pie Chart of Scrap Factors Produced in Start-up of Production line A

When studying Chart 1, we can see that 10% of the scrap from the start-up of the line have classified as normal start-up. Since the start-up process will always produce scrap, it is ideal the percentage factor of normal start-up should be high since it is below the expected range of scrap. The top offenders were identified as the reason why scrap was produced were pin holes or scratch with 40% and illumination test failed with 20%.

When evaluating Table 2 of line B, the lot with most amount of scrap was a total of 551.2 square meters for dirt on nozzle been identified and the lot with lowest amount of scrap was 159.0 square meters. All the five lots gathered had more than the expected amount of scrap, meaning that none of the lots had been reported in having normal start-up by the operators. The average amount of scrap per lot in line B was a total of 292.0 square meters, which is less than line A. In the table below (table 4) we can see that pin holes or scratches and dirt on nozzle are the two consistent reasons reported for scrap from the start-up process in high amount, with both having two lots been identified.

Table 4
Factors Produced in the Start-up of Production Line B Before Improvement

Reason for Scrap	Number of lots
Pin Holes or Scratches	2
Dirt on Nozzle	2
Flow or Bubble Point	1
Normal Start-Up	0
Broken Membrane	0
Illumination test failed	0
Wrinkles	0
High or Low Thickness	0
Bubble Point (Sartocheck)	0

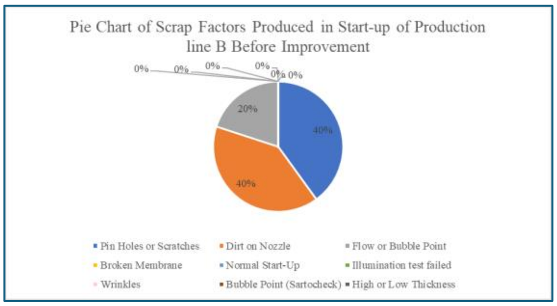

Chart 2
Pie Chart of Scrap Factors Produced in the Start-up of Production Line B

A pie chart of line B (Chart 2) that represents the number of times a reason or factor was identified as the leading cause of scrap during start-up shows that pin holes or scratches and dirt on nozzle were the major reason of scrap with both having a 40%, followed by flow or bubble point with 19%, and normal start-up and broken membrane represented 14%. This shows that all start-ups were not reported under the ideal target of scrap to be considered a normal start-up. This observation was taken seriously to find a reason to find cause and resolution to the problem to ensure a normal start-up procedure.

To understand how the process is performed, the team was present during the start-up process during the first day of the week (Monday) when production was going to start. The start-up process was observed where notes were taken for later analysis and questions about the start-up process were asked to the operators about what kind of problems they encounter during the process. With this information, a process flow diagram of the start-up process was developed to better visualize and understand the steps operators need to perform during the start-up:

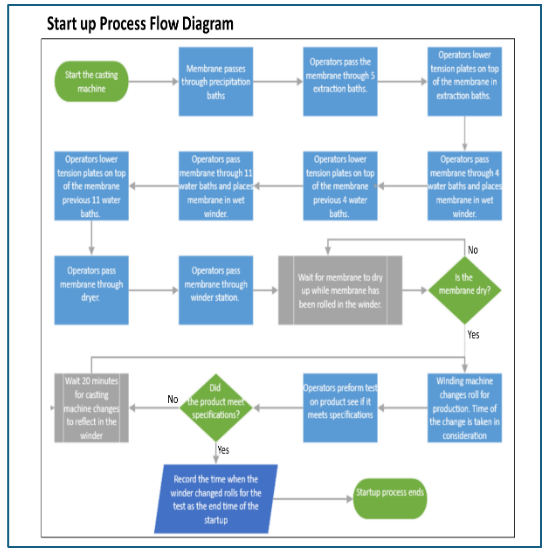

Figure 3
Start-up Process Flow Diagram

From the process flow diagram, operators must perform a total of sixteen steps to complete the start-up process from start to finish without any problem or delays for both production lines A and B. Nine of these steps in the process are performed manually by the operators, two of the steps are performed by the casting machine of the line, and one step that involve waiting, meaning that is does not add value to the process. There are two decisions based steps where, if the answer is no for both decisions, operators must either make additional or repeated steps to meet the desired result.

When the operators were asked what kind of problems they can encounter during the start-up process, they highlighted problems related with too much or too little tension in the membrane that can cause it to break in the process, pin holes or scratches present in the membrane that can last from minutes or an hour to resolve, and test of the product failing to meet quality specifications, where they must adjust the machine parameters based on the SOP troubleshooting section and wait until the adjustment is reflected for retesting.

To better visualize the cause and effect, a fishbone diagram was made to understand the relationship between the factors that affect the start-up process:

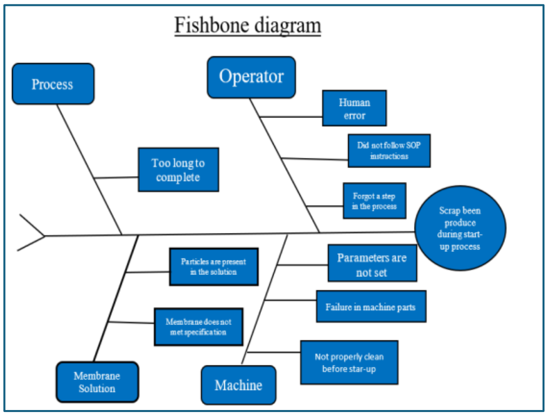

Figure 4
Fishbone Diagram of Start-Up Process

With the information gathered by previous lot, observing the process, interviewing the operators about the process, and analyzing the area where the process is been performed, we can observe that pin holes and scratches are the major outcomes of why there is more scrap been produced during the start-up process because of the quality of the solution and whether the machine is thoroughly cleaned by the operators. Thing to point out is that the bubble tanks in which the membrane solution stored for production are not completely clean and have chunks of residue from previous lots at the bottom of the tank. Part of the reason there is residue left at the bottom of the bubble tanks is because not all the solutions are used at the end of the production lot and it ends up mixing with the new solution when the mixing department transfers it to the bubble tank. If the residue was found at the bottom of the tanks, operators are meant to drain and wash away most of the solution left at the bottom of the tank with a chemical solution, 2-Pyrrolidone, but it does not wash all of it, still having some solid residue in the bubble tanks.

The solution proposed is to have the operators properly clean the bottom of the bubble tanks by washing the residue with their chemical solution and scraping the bottom of the bubble tank with a dedicated tool that can reach the bottom of the tank and remove it manually. The operators will perform the task if the machine is shut down or when one of the two bubble tanks of each production line does not have a fresh batch of solutions ready for production in the tanks. Once the operators have finished cleaning and removing any solid residue of old solution from the bubble tanks, the team will monitor the amount of scrap produced during startup of the machine for 5 weeks and take notes of the end results. During this time, operators were instructed to monitor the bubble tanks once the solution lot was done during production to drain any solution left from production to avoid getting the solution to solidify and mix with the new solution.

After five weeks of applying the cleaning process of the bubble tanks after production of a lot is finished, a total of ten data results were gathered, five from line A and five from line B. Two tables were made to demonstrate these results demonstrating the time it took to perform the start-up process, the amount of scrap produced during the process, and the reason for the scrap per lot, which are demonstrated below:

Table 5
Production Line A Start-up scrap after improvements

Lots	Date	Time (min.)	Amount of scrap (m^2)	Factors for scrap of start-ups									
				Broken membrane	Dirt on Nozzle	Ilumination test failed	Pin holes or Scratches	Wrinkles	High or low thickness	Flow or Bubble Point	Bubble Point (Sartocheck)	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 6
Production Line B Start-up scrap after improvement

Lots	Date	Time (min.)	Amount of scrap (m^2)	Factors for scrap of start-ups									
				Broken membrane	Dirt on Nozzle	Ilumination test failed	Pin holes or Scratches	Wrinkles	High or low thickness	Flow or Bubble Point	Bubble Point (Sartocheck)	Normal Start-Up	Gas Conditioning Failure
1	11/3/2025	46	68.9										
2	11/10/2025	47	71.6										
3	11/17/2025	62	111.3										
4	12/1/2025	37	45.1										
5	12/8/2025	53	87.5										
		Avg / lot	76.9										

Table 5 represents the lots produced from line A after the improvement and it shows that three out of five start-ups had a normal start-up with less than 60 minutes of time to be completed, with the lowest been 47 minutes producing 79 m² of scrap. The lot that produced with highest amount of scrap of 284.1m² due to the casting machine nozzle having particles in the entry, causing the membrane to have pin holes and/or scratches present. The second highest lot with most scrap was of 185.8m² because the membrane did not pass one of the product quality test when it reached the winder, and the operators had to adjust machine parameters and retest the membrane until it met specification. This table shows that out of the five lots recorded, 60% of the factors of scrap produced were identified as normal start-up because they were less than the expected scrap, 115.5 square meters, and 40% were identified as other factors that increased the scrap produced over 115.5 square meters. The average scrap produced per lot was 148.1 square meters. Compared to the pre-improvement average of 415.1 square meters, this represents a reduction of 267.0 square meters, which has been a significant improvement.

Table 6 represents the lots been produced from production line B after the improvement, and it shows that four out of five start-ups had a normal start-up process with less than 60 minutes of time to be completed, with the lowest being 37 minutes, producing 45.1 m² of scrap. The lot with the highest amount of scrap was of 111.3m² and the duration of the start-up just 62 minutes because of pin holes or scratches presents during the process. Although lot 3 had pin holes or scratches present, the amount of scrap produced was only 5 square meters over the expected amount of scrap that the company want from the start-up process, meaning the amount of waste generated was minimal. The average scrap produced per lot was 76.9 square meters and when compared to the pre-improvement average of 292.00 square meters, this represents a reduction of 215.1 square meters, which also has been a significant improvement.

Because both lines showed significant reduction in scrap produced, this can also result in a reduction of cost in scrap. Two tables were developed to analyze the cost in scrap generated of both production lines before and after the improvement is implemented. When comparing and analyzing both table 7 and table 8, it shows that the reduction of scrap during the start-up process helped the company save an average of $2,410.35 per week by reducing the average scrap cost from $3,535.45 a week to $1,125.10, been an overall of approximately 68.2% of total cost saved. If we were to evaluate this annually, the amount saved will be $115,696.80. Applying this improvement did not only will reduce scrap in start-up, but also save money that was lost to waste, making this an optimal improvement in efficiency in the process.

Table 7
Scrap Cost Analysis Before Improvement Line A & B

Average Scrap before changes Lines A & B (Sq m)		707.09
Membrane Cost per square meter	$	5.00
Avg scrap cost per week Lines A & B	$	3,535.45
Weeks x year		48
Yearly estimate scrap based on 48 weeks / year	$	169,701.60

Table 8
Scrap Cost Analysis After Improvement Line A & B

Average Scrap after changes Lines A & B (Sq m)		225.02
Membrane Cost per square meter	$	5.00
Avg scrap cost per week Lines A & B	$	1,125.10
Weeks x year		48
Yearly estimate scrap based on 48 weeks / year	$	54,004.80

To better visualize and analyze how the improvement impacted the start-up process, two individual control charts (I-Charts) were developed for each line to detect any changes of spikes due to high amount of scrap produced and monitor the stability of the start-process before and after the improvement. Chart 3 represents an I-Chart of line A, where it is divided into two sides where the left shows the start-up process before implementing the improvement in five lots gather from table 1 and the right side shows the start-up process after implementing the improvement in five lots gather from table 5. Analyzing the process before improvement shows that the control limits are wide and spread apart from each other's with the Upper Control Limit (UCL) being 1,158 square meters and the Lower Control Limit (LCL) being -328 square meters. While the goal for scrap produced should be lower or equal to 115.5 square meters, the average of the process is 415 square meters; however, we can see most of the lots generated over their goal of scrap and three out of four generated over the average. This made the process hard to predict how it will perform over time since the amount of scrap produced during start-up is spread widely apart between each lot. After the improvement was applied to the process, the control limits got closer to one another with the UCL being 415 square meters and the LCL being -119 square meters, making the process more stable and better to predict the scrap at the start-up. When comparing the before and after results, you can see that all the lots after the improvement are more ailing and closer to the desired goal and average, meaning that the process is more predictable and stable now [4].

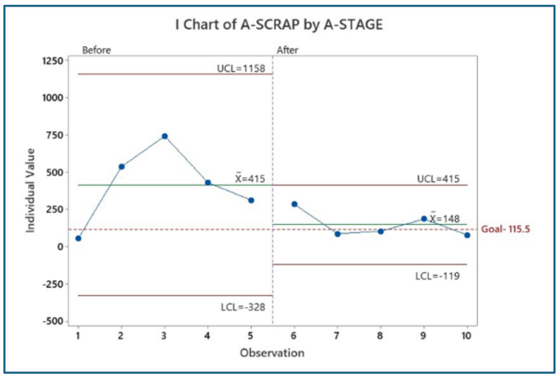

Chart 3
Individual Control Chart of Production Line A Scrap Generated During Start-up Before & After

Chart 4 represents I-Chart of line B, where it is also divided into two sides where the left shows the start-up process before the improvement in five lots gather from table 2 and the right side shows the start-up process after the improvement in five lots gather from table 6. The control limits before the improvement are also wide and spread apart from each other's when compared with the data of Chart 3 with the UCL being 863 square meters and the LCL being -279 square meters. While the goal for scrap produced in line B should be lower or equal to 106 square meters, the average of the process is 292 square meters, and looking at the results it the process produced a stable amount of scrap been close to the average amount. After the improvement to the process, the control limits got a lot closer to one another with the UCL being 177 square meters and the LCL being -24 square meters, making the process a lot more stable and predictable to determine the scrap at start-up. The average amount of scrap was reduced to 77 square meters, lower than the below target threshold. All data points after the improvement show that most of the start-ups performed less than the desired target with one producing just slightly above it, meaning that this improvement had a greater impact on reducing the amount of scrap produced per start-ups and making it more stable and predictable.

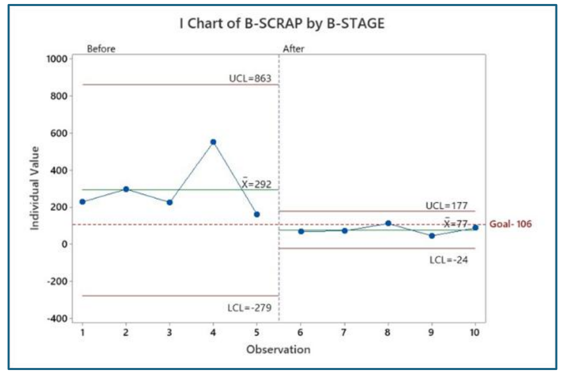

Chart 4
Individual Control Chart of Production Line B Scrap Generated During Start-up Before & After

Both Individual Control Charts help to visualize how much scrap the weekly start-up of production lines generated before and after the improvement was applied, demonstrating large reduction and better stability of the process. Although the charts show a visible reduction in scrap, it is not enough to simply state that the improvement in the start-up process reduced the amount of scrap generated. Because of this, a Two Sample T-tests was performed for each production line to guarantee if the improvement did in fact help reduce the scrap or if it was by chance.

Descriptive Statistics: A-SCRAP

A-STAGE	N	Mean	StDev	SE Mean
After	5	148.1	87.0	39
Before	5	415	256	115

Estimation for Difference

Difference	95% CI for Difference
-267	(-603, 69)

Test

Null hypothesis H_0: $\mu_1 - \mu_2 = 0$
Alternative hypothesis H_1: $\mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
-2.20	4	0.092

Figure 5
Two-Sample T-Test for Production Line A Start-Up Scrap Improvement

Descriptive Statistics: B-SCRAP

B-STAGE	N	Mean	StDev	SE Mean
After	5	76.9	24.5	11
Before	5	292	153	68

Estimation for Difference

Difference	95% CI for Difference
-215.2	(-407.4, -22.9)

Test

Null hypothesis $H_0: \mu_1 - \mu_2 = 0$
Alternative hypothesis $H_1: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
-3.11	4	0.036

Figure 6
Two-Sample T-Test for Production Line B Start-Up Scrap Improvement

Based on the results of the Two-Sample T-Test for Production Line A (Figure 5), the P-Value is of 0.092. Because the P-value is higher than 0.05, there is not enough data to prove a significant difference was made by the improvement and the null hypothesis is not rejected. As for the results of the Two-Sample T-Test for Production Line B (Figure 6), we can see that the P-Value is 0.036. Because the P-value is lower than 0.05, there is enough data to prove a significant difference was made by the improvement and the null hypothesis is rejected. When comparing both Two-Sample test, production line B showed more a significant difference of improvement than production line A. Part of the reason may be related to the results of line B were consistent and lower than line A and line A had a higher standard variation than line B. If the sample size gathered from line A was more than five or the results after the improvement the results were more consistently lower, the P-value could have been lower than 0.05 [5].

In addition to the hypothesis test, two more hypothesis test for each production line were made to test if there was a significant difference in the percentage of lots that were given a reason of producing more than their desire amount per line and to test of defect per lot (unit) was lower before and after the improvement was applied.

Table 9
Hypothesis Test of % of lots without normal start-up in production line A

Means Hypothesis			P = % of lots without normal start-up		
Ho: µ before	EQUALS TO	µ after	Linea B		
Select one	MORE THAN	LESS THAN	NOT EQUAL		
1 = YES	1				
H1: µ a	MORE THAN	µ b	Mean Hypotheis Test Results		
Statistics	Before	After	Std. Dev.	0.0	0.2
N	5	5	X Bar	1.0	0.20
Miu	100%	20%	N	5	5
Std Dev	0.0	0.2	T exp	10.00	
			V	4.0	
			Pvalue	0.0003	
			Alpha	0.05	
			Miu Before is larger than Miu After		

Table 10
Hypothesis Test of % of lots without normal start-up in production line B

Means Hypothesis			P = % of lots without normal start-up		
Ho: µ before	EQUALS TO	µ after	Linea A		
Select one	MORE THAN	LESS THAN	NOT EQUAL		
1 = YES	1				
H1: µ a	MORE THAN	µ b	Mean Hypotheis Test Results		
Statistics	Before	After	Std. Dev.	0.2	0.2
N	5	5	X Bar	0.8	0.40
Miu	80%	40%	N	5	5
Std Dev	0.2	0.2	T exp	3.16	
			V	8.0	
			Pvalue	0.0067	
			Alpha	0.05	
			Miu Before is larger than Miu After		

The hypothesis test of % of lots without normal start-up in production line A (Table 9) shows that the results of the P-value is 0.0067, meaning that the null hypothesis is rejected because there was the was a significant difference between before and after the improvement. As for production line B (Table 10), it showed that the results of the P-value is 0.0003, meaning that the null hypothesis is also rejected because there was the was a significant difference between before and after the improvement

The hypothesis test of % of Defect per Units in production line A (Table 11) shows that the results of the P-value is 0.0087, meaning that the null hypothesis is rejected because there was the was a significant difference between before and after the improvement. As for production line B (Table 12), it showed that the results of the P-value are 0.0053, meaning that the null hypothesis is also rejected because there was a significant difference between before and after the improvement. If we were to look at the mean values of both tables, the Before mean values are larger than the After-mean values, also confirming that there was an improvement in both production lines. All the hypothesis tests from table 9, 10, 11, and 12 have demonstrated improvement applied to the process of the machine does statistically makes a significant change in improving the process of start-up.

Table 11
Hypothesis Test of Defects per Unit in Production Line A

Means Hypothesis			U = Defect per Units		
Ho: µ before	EQUALS TO	µ after	Linea B		
Select one 1 = YES	MORE THAN 1	LESS THAN	NOT EQUAL		
H1: µ a	MORE THAN	µ b	Mean Hypotheis Test Results		
Statistics	Before	After	Std. Dev.	0.4	0.2
N	5	5	X Bar	1.0	0.20
Miu	1.00	0.20	N	5	5
Std Dev	0.4	0.2	T exp	3.65	
			V	6.0	
			Pvalue	0.0053	
			Alpha	0.05	
			Miu Before is larger than Miu After		

Table 12
Defects per Unit in Production Line B

Means Hypothesis			U = Defect per Units		
Ho: µ before	EQUALS TO	µ after	Linea A		
Select one 1 = YES	MORE THAN 1	LESS THAN	NOT EQUAL		
H1: µ a	MORE THAN	µ b	Mean Hypotheis Test Results		
Statistics	Before	After	Std. Dev.	0.6	0.4
N	5	5	X Bar	1.8	0.80
Miu	1.80	0.80	N	5	5
Std Dev	0.6	0.4	T exp	3.10	
			V	7.0	
			Pvalue	0.0087	
			Alpha	0.05	
			Miu Before is larger than Miu After		

CONCLUSION

The project was designed because a biopharma company was having an increased number of scraps than expected during the start-up process of two production lines and the company wanted to understand what is causing this to find a way to reduce the amount of scrap generated. 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. 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.

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