Reduction of Cycle Time in Branson of Operation

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Abstract *— "With less, it can be accomplished more". On occasion, everybody wants more but does not want to invest. The company needs higher productivity and capacity, leading to a higher profit and a lower labor cost. A good way to achieve those goals is by optimizing the process and taking advantage of and using all the space, machines, and personnel working in the area. Considering that the scheduled order for the week is not finished at the scheduled time, as proposed. The majority of the orders are not finished on time as proposed. In order to finish, an overtime shift on the weekend must be kept in production to finish the orders for the week. If the orders are not finished in the extra shift, the order must be rolled over to next week, affecting cycle time, productivity of the operation, sterilization process, and estimated arrival time (ETA) for the client. During the investigation, it will be evaluated, applying the methodology of DMAIC, what is happening in the manufacturing process that the orders are being manufactured on an extra shift or rescheduled with a roll over for the next week. It must optimize the process in order to comply with the production schedule and have solid delivery reliability towards the client.*

Keywords *— 7 Wastes: Motion, DMAIC Method, Energy Director, Ultrasonic Welding, Voice of Customer.*

PROBLEM STATEMENT

The project aims to identify and address the root cause of the machine alarm using the DMAIC methodology, with an increase of efficiency in the ultrasonic welding process by 20%. This optimization is expected to increase manufacturing capacity, improve delivery reliability, and enhance productivity and efficiency, while maintaining a low investment cost. The research will involve analyzing the physical properties, dimensions, and parameters of the machine, understanding its limitations, and creating protocols for process improvement. By identifying the possible root cause(s) and correcting them, the project will contribute to the overall improvement of the manufacturing process and the local site as a company.

PROCESS DESCRIPTION

The ultrasonic welding process is essential and vital for the manufacturing process. Depending on the product, the configuration flange with the port is used. All these different ports shared dimensions with respect to a critical to quality dimension (CTQ), which in this case is the energy director. In the figure below, the energy director is the "triangle" cut that is below:

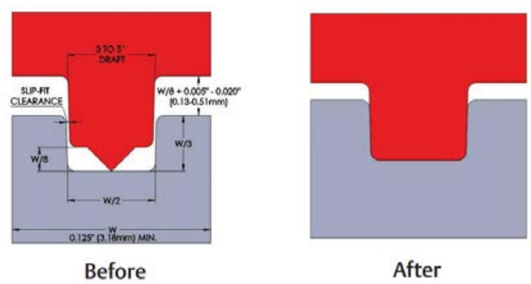

Figure 1
Energy Director Before and After Welding

The energy director is the designer where it is supposed to weld with the other component, which in this case, is a flange. In Figure 1, it can be seen how the design of the port must be and how it must be welded between components. The dimensions represented as "w/8" and "W/3" are known as CTQs for the process. After the ultrasonic welding process is completed, the two components must be joined, as shown on the right side of Figure 1. As mentioned, depending on the product code requirement, the position of the ports on the flange. Therefore, every groove and dimension must be within the nominal or tolerance.

PROJECT OBJECTIVES

Among the project objectives there is to reduce re-inspection rates by 50% (reducing time of inspection for a single unit). Minimize the need for repeated inspections, thereby reducing delays and improving the efficiency of the packaging process. The current rate of re-inspection will be measured and confirmed during the Measure Phase of this project.

It is also pursued as part of the objectives of the project to improve the Quality Assurance / Seal inspection Accuracy. Meaning that the system must only report a pass result when identifying the seal edges.

PROJECT SCOPE

The project will seek a reduction of the re-inspection rates (time of inspection of a single unit/ inspection attempts to obtain and pass result) and improve seal presence inspection accuracy by conducting an investigation to identify the causes impacting the system's ability to accurately detect the seal edges, particularly for Tyvek Film material and other problematic pouch materials, if any. The project will also cover the design/proposal of updates or new hardware/ software (system) for the inspection. This could include lighting conditions, new recipes, and different hardware, among others.

Out of the scope of the project objectives will be to qualify for the new solution. Testing will be made in a validation environment where the alternatives found during the project activities will be proven or tested.

LITERATURE REVIEW

In the biopharmaceutical industry, where the organization is considered a Customer Made to Order (C.M.O) company, the demand can be very high, even higher than expected. Entering the process, in a manufacturing line, fluid technology to a certain type of fluid or solution. These types of fluid management products are known as Flexel and Flasafe bags, drums, or even pallatanks. These types of family products can be manufactured from a 500mL bag to a large volume of 300L bag. Hence, it's the CMO who determines what the customer requires, which must be manufactured. The products are also classified as 2D and 3D bags. The 2D bags can only open in the direction of X and Y. However, the 3D bags can expand and open in X, Y, and Z. In the manufacturing area, there are over manufacturing lines that work directly with the manufacturing process of these products. This product is very similar for these families, independent of the volume sizes. The first method is to start with the bag marking of the bag, to mark dimensions, components, for example, canotier, UPS1, UPS4, impeller, among different components. Then, after cutting, the sealing of the bags comes into place, assuring the bag is well sealed. It must be well sealed; hence, the fluid or solution creates pressure against the seal that could break it or lead to a leakage of the solution on the hands of the client. Afterwards, the most important part is the sealing of the components to the bag. Afterwards, every seal is good and in compliance with the standard operating procedure, then it goes to insert the sub-assemblies that the product requires. The sub-assemblies are extensions of the product that are made outside the manufacturing line. In the moment of operation, it is only the connection between the sub-assemblies and the product. Finally, but not least, the product, after inserting the sub-assemblies, passes through a control template to ensure that the manufacturing dimensions are in compliance with what the customer requested. Here is a challenge to the sealing of the components, the position of the components in the bag, embedded particles, etc. Afterward, the final product is introduced to the polybags and sealed.

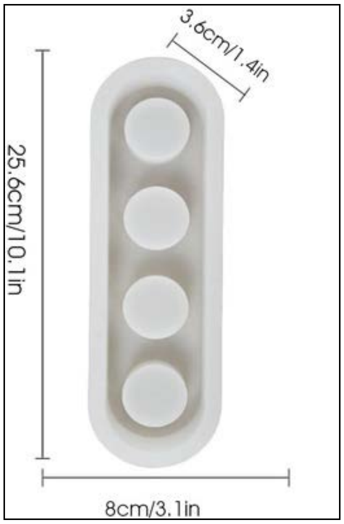

Figure 2
Similar Representation of UPS4

These components of UPS1 and UPS4 are considered the center of the operation. After the welding by ultrasonic, the components are then sealed at a specific temperature and pressure. These components contact the fluid or solution at the hands of the client. If the sealing or welding of these components is not at a high-quality level, the risk of leakage increases, which could lead to a complaint.

"Ultrasonic Welding is an extensively used technique in manufacturing, and as with every other process, there is the potential for defects in the weld joint that could be catastrophic to the manufactured products" [1]. As cited, the ultrasonic welding in the manufacturing process is one that has been increasing over time. The purpose is to weld strong and reliable bonds without the use of other materials, for example, adhesives, etc. In the particular case, it is used for welding plastic components, which are commonly used in various industries. The parameters, such as speed, trigger force, and absolute distance of ultrasonic welding, make it a good alternative for high-volume demand, ensuring a high-quality component. Also, positively impacting the efficiency, productivity, and consistency in the manufacturing process. Additionally, ultrasonic welding is a eco-friendly process, which does not produce any type of emissions or gases and require consumables. Regardless of the potential for defects, improvements in quality inspection of welds, as highlighted by R. Mohandas and P. Mongan, are continuously improving the reliability and safety of this essential technique.

Currently, a validation process is ongoing, but it has had to stop. The reason for stopping is that during the validation process, an alarm appears every time the cycle starts for the welding process. It needs to apply lean manufacturing concepts and Six Sigma concepts to discover the possible root cause of the alarm. "Lean manufacturing refers to a company's ongoing, systematic effort to eliminate the sources of waste in a production process" [2]. On the other hand, in the other machine, every time an alarm is triggered, the manufacturing operator must walk a certain distance to perform an air leak test. It will also be discussed.

In the products, one vital operation inside the clean room is the preparation area for the products. As mentioned, preparation consists of sub-assemblies, connections, wrapping, and welding two components using an ultrasonic welder. The components welded in the ultrasonic welder are known as UPS1 and UPS4. The first component is a single port flange that welds different types of ports. Following the same line, the UPS4 is a flange with four holes to seal any type of configuration of ports that must be welded. In Figure 1, a figure similar to what a UPS4 is for the manufacturing area.

METHODOLOGY

"Let the data speak on its own", that is a good saying. An appropriate way to support a project is through data and having facts, acquiring a more quantitative style of project. However, this will be confirmed with the steps of DMAIC. The first objective is to understand and analyze the physical properties and differences of the raw material of products.

Figure 3
DMAIC Methodology

DMAIC Process

Define phase: In the define section. Some tools were used to better understand the situation or problem being addressed. The first tool used was a Critical to Quality in levels, where in level 1, it has the horn down verification. In phase, the parameters of distance, force, pressure, and velocity must be verified to confirm that they are within the validated parameters before starting operation. The second level is the welding process, where, depending on the configuration, the ports are positioned on the flange of UPS1 or UPS4 to weld. In level three, we have 3 categories that are also connected to level four. So, after the welding process, it must be verified that everything is good and that the unit is acceptable. If it is not welded, an alarm will trigger. Last, if it is welded but something goes outside the parameters validated, an alarm must be triggered. Then, an air leak test must be performed on the unit that triggered the alarm. The air leak test is performed to challenge the integrity of the weld performed on the unit.

Another tool used was a SIPOC to understand the process from the beginning and where the situation is occurring. For the Supplier, we have the external supplier, the planning department, which schedules the order, and the Warehouse department, because they perform the kitting process. For the inputs, it was established: production plan, engineering department, and the defect acceptance criteria or the standard operating procedure. In the process, the manufacturing process was established, where the alarm or situation occurs after the welding process. As an output, it can be seen that it is the final product or the alarm verification. Lastly, the customer is the other manufacturing lines, let's remember that the ultrasonic operation is a preparation before the manufacturing process starts in line.

Measure phase: For the measurement phase, a Voice of Customer (VOC) was used, where the customer is the manufacturing operators. The manufacturing operation noticed that an operation that takes only about 1 minute was taking 10 minutes to 30 minutes or maybe more, depending on the quantity of alarms. When asked about the three manufacturing shifts, specifically the manufacturing team leader and supervisor, what can be optimized in this process? They all said an impact on cycle time, excessive walking, and transportation. The impact on the cycle time is that every variable, and then adding the machine alarm, increases the cycle time of the operation, affecting also productivity and efficiency. Excessive walking can also be categorized as motion. Finally, the transportation of the material/units with alarms that had to be moved by hand from point A to point B.

A study was performed on the layout to confirm what was said before. Below is a diagram of how long the manufacturing operator must walk in order to perform an air leak test on the units. This is impacting the cycle time, walking towards the air leak machine:

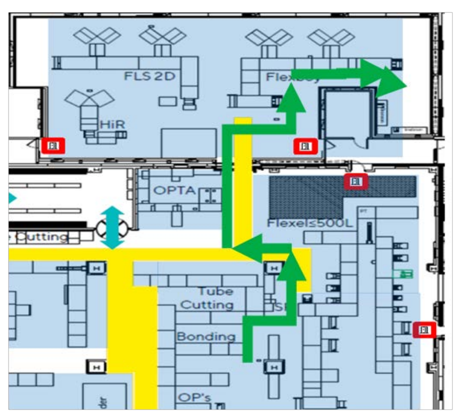

Figure 4
Path of Motion Towards Air Leak Tester Machine

To recollect data, an exercise was performed to see how much time it takes to walk and arrive at the air leak tester machine. A total of 20 operators recorded their steps and seconds taken in order to complete their tasks. Refer to Figure 5.

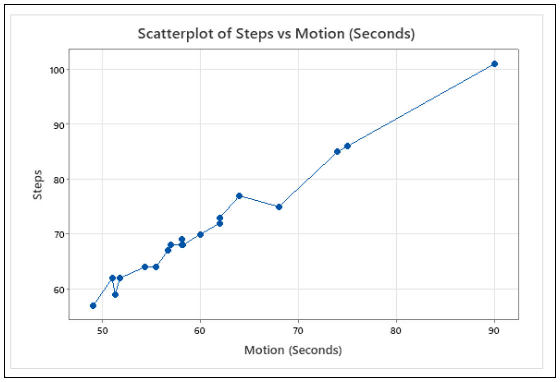

Figure 5
Scatterplot Graph: Motion (sec.) vs. Steps

As expected, the more steps a person takes, the longer the time is, in order to arrive at the air leak tester station. In the sample of 20 operators, the mean time to arrive is 60 seconds or 1 minute of motion.

Analyze phase: In this phase, anything could be a variable that affects the cycle time. That is why, to help us visualize with a better understanding of the situation, an Ishikawa Diagram analysis and a 5 Whys analysis were used until the possible root cause was reached and confirmed.

The first diagram took into consideration the Impact on Cycle time of the ultrasonic welding operation. With representatives of the manufacturing team, quality department, and engineering department, the fishbone diagram was developed. In order to identify the possible root cause of the problem and what should be address a Ishikawa diagram, also known as a fishbone diagram will be used [3]. There were a lot of variables considered, but a few of them were ruled out. It was taking into consideration the workspace layout, causing excessive walking. This variable can be confirmed through the VOC, and when the floor layout is shown, the green path is a long way. Furthermore, an analysis of the 5 Whys was performed to find and confirm a possible root cause.

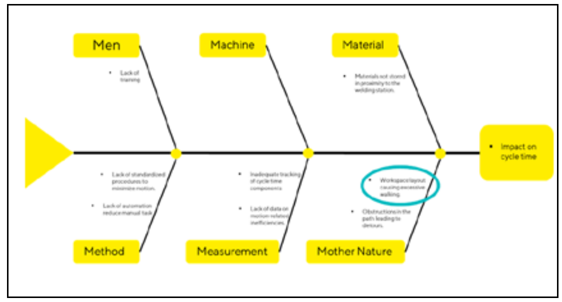

Figure 6
Fishbone Diagram Analysis Method

However, the members mentioned before wanted to address another variable, the reason why the alarms are triggered during the welding process. So, a second Ishikawa diagram was developed with the main problem as "missing part alarm". There were a lot of variables to consider regarding the missing part alarm. An error was found in the distance; many were ruled out, but it was decided to address another possible root cause: inconsistent dimensions of parts.

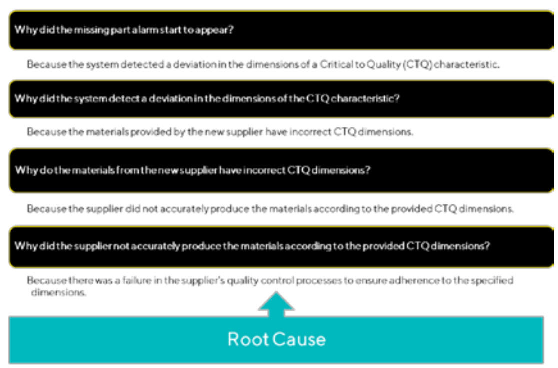

Figure 7
5Why Analysis Method

Also, another 5 Why analysis was developed, which led to a CTQ dimension out of specification.

Improve phase: Taking into consideration the first possible root cause, the workspace layout, it was confirmed with the exercise of motion recollecting data. Also, as part of the 5 Whys analysis, the possible root cause was the optimal workflow layout. That is why, through a work order, the machine was relocated from the original position to a position near the Branson ultrasonic welding machine. As shown below, the relocation of the machine will mitigate or reduce the motion of the manufacturing personnel to perform an air leak test, every time an alarm appears after the cycle.

Figure 8
Before and After Location of Air Leak Machine

For the second fishbone diagram, where the problem is the machine alarms, the possible root cause was an inconsistent dimension part. In this case, a series of actions were opened. The first action was to adjust the height of the horn to a specific measurement so that the alarm would disappear. Since the adjustment of a horn is totally manual, it was quite challenging to find the specific height. The process was the adjustment of the horn, through a horn down verification, to verify the new height. After identifying that specific height, within validated parameters, an engineering study was performed with a total of 460 units. The number of samples was determined by statistical guidance. The engineering study will be performed with 5 ports, with a total of 115 flanges. Each port will have 23 flanges with the same port. The exercise will consist of the following:

- Welding cycle process
- Air leak testing inside the clean room
- Air leak test under water at 0.5bar, 1 bar and 1.5 bar.

A third action is to send the material to measure the critical quality dimensions by an external supplier. This way, it can be confirmed that the measurements are within specification or out of tolerance. Lastly, but not least, a report must be generated in order to confirm that the height adjusted was the correct one.

The engineering study performed had magnificent results. All the units passed all three test cases mentioned. This represents a 99% confidence level and a 99% reliability during the process. Furthermore, it can be confirmed that the level of defective rate won't be greater than 1%. Even though there is additional contact with the energy director, the welding process is correct between the two components. This can be seen in Figure 9.

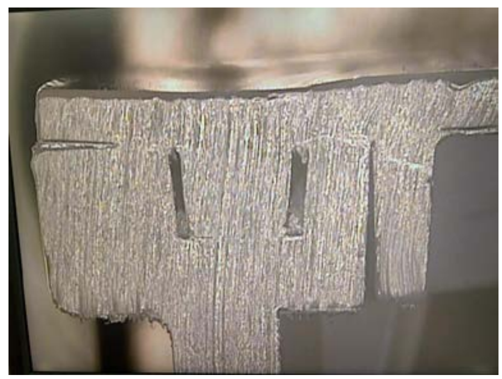

Figure 9
Cross Sectional View of Welding Result

The measurement report confirmed what the possible root cause, inconsistent dimension part of the CTQ. In yellow are the CTQ that were out of spec. Refer to following table.

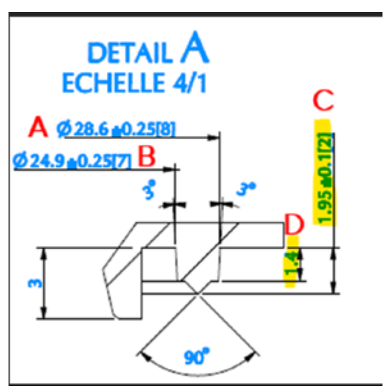

Figure 10
CTQ of Energy Director Diagram

Table 1
Measurements for TC112128 and TC112131

Measurements for TC112128 and TC112131			
Port part number	Cavities	C	D
TC112128	7.1.A	1.89727	1.28448
TC112128	7.2.B	1.75408	1.23188
TC112128	7.3.C	1.77138	1.22048
TC112128	8.1.A	1.89727	1.27828
TC112128	8.2.B	1.76838	1.23208
TC112128	8.3.C	1.76078	1.24938
TC112131	3.1	1.58738	1.02979
TC112131	3.2	1.67758	1.09498
TC112131	3.3	1.62418	1.06659
TC112131	4.1	1.70808	1.18358
TC112131	4.2	1.78427	1.7318
TC112131	4.3	1.74458	1.15378
TC112131	5.1	1.62258	1.03609
TC112131	5.2	1.61878	1.06819
TC112131	5.3	1.64958	1.09168
TC112131	6.1	1.65728	1.11618
TC112131	6.2	1.67658	1.10608
TC112131	6.3	1.69858	1.2788

Control phase: Lastly, but most important phase is this one. This phase is where the controls of the situation are explained to sustain the manufacturing process. So, due to the current situation, in the tier meeting in the morning and afternoon, where there is participation of all the departments, the operation of ultrasonic welding process is discussed daily and how its going. Also, another current control is the standard operation procedure, where if an alarm its still appearing after the welding process, it must be air leak to assure the quality of the unit. Also, if an intervention of a technician is required, by procedure, it must perform a few samples for the welding process, air leak test and compression test. This way, the technician assures that as he found the machine, he left it.

Since the air leak machine was relocated to a location very close to the machine. Ultrasonic welding machine, the motion is very controlled. In blue are the steps the operator took towards the air leak test machine which every one is over 50 steps. In the other hand, in yellow are the steps after the relocation where it can be seen that none of the operator, reached two steps to get to the machine.

Some of the benefits are:

- Reduction of motion
- Increased efficiency, goal exceeded
- Reduction of cycle time
- Cost reduction
- Improved safety
- Higher employee satisfaction

CONCLUSION

The investigation performed took into consideration several possible root causes. Through the actions performed, thanks to the tools of DMAIC, it gave us the opportunity to verify the following:

The investigation addressed a critical to quality (CTQ) of the ports, the length of the energy director, as the root cause of the machine alarm. By performing the engineering study, it was confirmed that the correct height of the horn and achieving a quality weld of components. Therefore, the 20% increase was exceeded.

By applying DMAIC methodology, it reduces overtime, improves cycle times, ensures a timely delivery, and impacts delivery reliability.

Lean manufacturing principles helped reduce waste and improve process, by reducing one of the lean manufacturing wastes, motion, the manufacturing personnel are satisfied. The personnel can see corrections in the process that they identified.

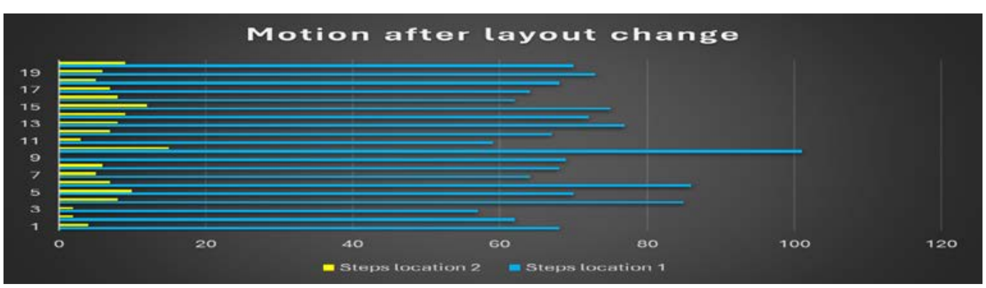

Figure 11
Motion After the Layout Change

ACKNOWLEDGEMENTS

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