Process Workflow Optimization and Redesign for Packaging Line at a Medical Device Company

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Abstract — *This document describes the process of workflow optimization and redesign using Lean Six Sigma tools to better understand the Ivers Lee packaging lines (IL#1 and IL#2) issues and create alternatives to improve them. This is the case of two (2) packaging machines that were built in the 1960's and are currently packaging approximately seventy-three (73) million surgical blades per year. This is a manual filling, packaging and labeling process that implicates significant intensive labor tasks. This area currently faces several challenges. The main challenge is to increase the labor usage while balancing operator tasks. As project goals, these include increasing process consistency, improving capacity and utilization of resources to optimize production and maximize efficiency.*

Key Terms — *Lean Six Sigma, Line Balancing, Time Studies, Work Improvement.*

INTRODUCTION

High efficiency is crucial for packaging lines, it is an important aspect of cost control that results in an improved production and utilization of available resources. Lean Manufacturing is a practice based on preserving the value of a product or service, with the minimum work and materials required to complete it. It concentrates on eliminating waste and non-value-added work while maintaining high standards of quality and customer satisfaction.

This study aims to improve the productivity and efficiency of Ivers Lee packaging lines (IL#1 and IL#2) in a medical device company. Based on data collected through observations, interviews, and study of production, line balancing has been identified as a problem that is affecting the efficiency of the packaging lines.

The medical device company is named Aspen Surgical, a surgical division of the Hill-Rom company, and was established twelve (12) years ago in Las Piedras, Puerto Rico. It's a world leader in the manufacture of blades, scalpels and other surgical instruments. This company manufactures 110 million knives per year for different procedures, ranging from surgeries to specialized microsurgeries.

However, this study covers only the Ivers Lee packaging lines (IL#1 and IL#2) for the product with the highest demand which is are conventional blades. Data collected through observations, interviews and documentation study and identified the main problem related to productivity is that the tasks assigned in the packaging lines are unbalanced. The cause of the problems are related to man, machinery, material, method, measurement, and environment is presented in the form of cause and effect diagram, also known as Ishikawa diagram as shown in Figure 1. This situation causes the inefficient utilization of operators and machines in the packaging lines. This problem affects the company's packaging capacity to achieve daily demand.

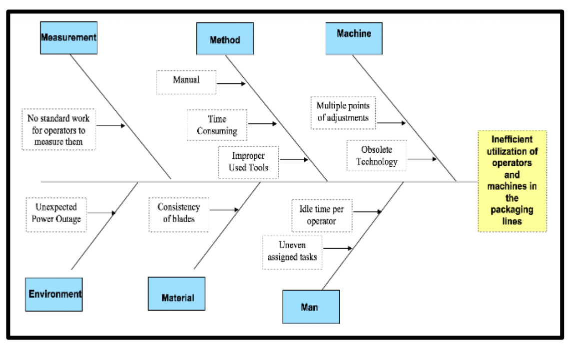

Figure 1
Cause and Effect Diagram

Although there are many causes to the problem of unbalanced packaging lines (IL#1 and IL#2) that have been identified, this study only focuses on solutions related to the method of work and line balancing.

THEORY

The main purpose of this chapter is to present and describe the main concepts behind the process to be improved in this design project. The specific research area in which the project is going to be developed is in the Ivers Lee packaging lines (IL#1 and IL#2) in a medical device company.

Ivers Lee Packaging Lines Process Workflow

The current layout of the Ivers Lee packaging lines are shown in Figure 2, the image shows the location of the operators and the description of the area.

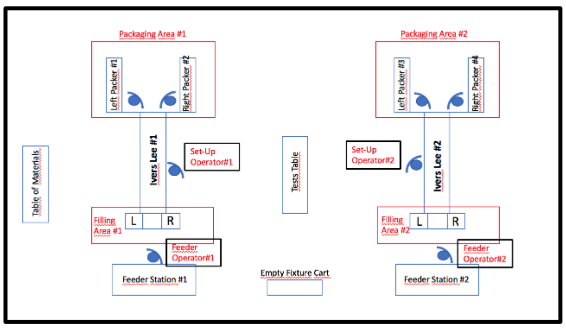

Figure 2
Current Layout

The packaging lines (IL#1 and IL#2) of the medical device company consist of three (3) main stations, which are: The Feeder Station #1 and #2, the Filling area #1 and #2, and the End of the line (EOL) packaging area #1 and #2. The tasks of each operator are described as follows:

- **Feeder Operator #1 and #2:** Packaging lines (IL#1 and IL#2) have two (2) feeder operators per line, where the feeder operator is tasked with turning blades so that the stamp or print of the packaging foil is facing upwards when opening the package. This is done because the blades come from the manufacturing area with its edge facing the left side, so the operator has to turn them to the right side. This is a tedious task as the operator has to be grabbing and removing the mandrel from the machine and transport it to the "Filler/Filling Station", then place the mandrel in the fixture and slide the blades so that they can be turned sideways. Afterward, grab the mandrel and place it in the machine, this is called Filling. This task has to be done on both sides Left and Right for both packaging lines (IL#1 and IL#2) constantly. The Feeder, while waiting for the machine mandrels to empty, is also tasked with assembling "dispenser boxes" which are the boxes that carry the foils with the blades inside. In addition to that, the Feeder operator is tasked every half an hour (30 min) to realize two types of quality tests, these are the "Burst Test" and the "Functional Test". These tests are performed to inspect the foils and the liners containing the blades to verify if they comply with certain specifications.
- **Set Up Operator #1 and #2**: Packaging lines (IL#1 and IL#2) have two (2) Setup operators per line. Machine setup operators ensure that the machines they are responsible for work properly and efficiently. This job requires extensive knowledge of the machine or machines for which the operators are responsible. When the machine is working properly, they are tasked with giving support to the Feeder by assembling "dispenser boxes", turning blades and feeding the machine.
- **Folding/ End of the Line Packer Operator #1 and #2:** Packaging lines (IL#1 and IL#2) have two (2) end of the line (EOL) operators per line a total of four (4) operators, where the EOL packer operator is tasked with the receiving of the product (Blade) on it primary package. Each packed blade goes into a dispenser box which contains fifty (50) blades per dispenser. Those dispensers are packed into a folding carton with a capacity of holding three (3) dispensers' box each. In the end, the operator is responsible for the packing of a hundred and fifty (150) units on each folding. They examine and inspect containers, materials, and products in order to ensure that packing specifications are met.

This area currently faces several challenges. The main challenge is to increase the labor usage while balancing operator tasks. As project goals, these include increasing process consistency, improving capacity and utilization of resources to optimize production and maximize efficiency.

METHODOLOGY

Productivity in manufacturing industry plays an important role in keeping the company competitive for the market as well as for its survival. Many leading companies are implementing changes and new work methods in order to survive in an environment where only the leanest, and most responsive will survive [1]. It is important for a company to earn profit and this may be increased through improvement on productivity [2].

Six Sigma is a quality improvement program that looks at processes with a view to analyzing process steps, determining what process elements need improvement, developing alternatives for improvement, then selecting and implementing one.

Most CI practitioners will know that one of the core techniques behind any process improvement, particularly in Six Sigma, is DMAIC. DMAIC is a data driven improvement cycle designed to be applied to business processes to find flaws or inefficiencies – particularly resulting in output defects – and to combat them. The goal of employing DMAIC is to improve, optimize, or stabilize existing processes. Hence, because this project is about improving capacity, utilization of resources to optimize production and maximize efficiency, DMAIC is the selected problem- solving methodology.

Define

The initial step of the lean six sigma problem-solving methodology is the define step. Properly defining the problem is the most important part of solving the problem. Opportunities for this project were defined using the Five Whys, sometimes written as "5 Whys" analysis method to get to the root of a problem quickly. This technique involves asking why with regards to the problem, getting answers, then continuing to ask why in order to uncover layers of the issue, eventually revealing the root cause of the issue. The following Figure 3 shows the "5 Whys" analysis.

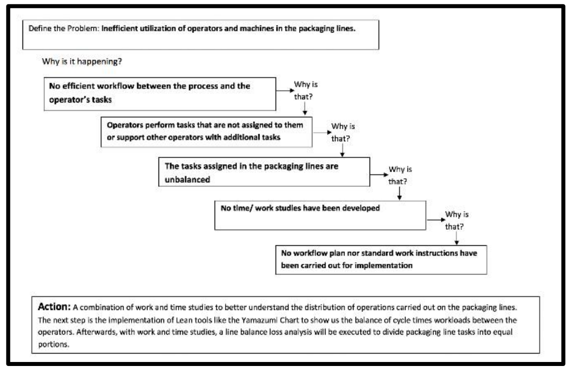

Figure 3
5 Whys Diagram

After performing the "5 Whys" analysis, the root cause of the problem was identified; the main problem is inefficient utilization of operators in the packaging lines. The issue causes assigned tasks in the packaging lines to be unbalanced due to lack of work/ time studies to develop and establish a Standard Work procedure. This affects the company's packaging capacity to achieve daily demand.

The main outcomes from this phase were to develop a high-level overview of the process, through the use of process mapping tools, and to understand the needs of the process stakeholders.

Measure

The goal for this phase was to define the project performance measure, establish the data collection plan, gather data, establish the baseline, and begin monitoring this KPI if possible.

In this second stage of DMAIC, a detailed process level map was developed for the current state of the process – the as-is process. The process level analysis tool used for the study was a Spaghetti diagram; which is primarily used for Lean manufacturing in production facilities. A spaghetti diagram is a visual representation of the physical flow of materials, papers, and people through the tasks or activities of a process. It details the flow, distance and waiting time for the transportation of items in the process. It also traces the walking patterns of people, shuttling back and forth of materials between tasks and workstations. Figure 4 illustrates the operators flow specifically in the packaging line (IL#1).

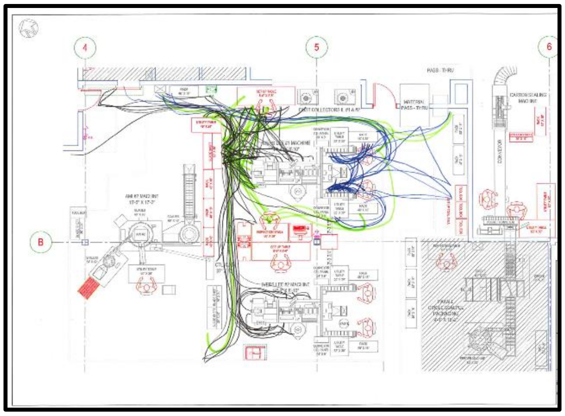

Figure 4
Spaghetti Diagram for Each Workstation

Creating the spaghetti diagram was done with the operators that use the process. It was performed by recording the path with a pencil and by using a measuring wheel to document distances. The figure shows three (3) different colors, each representing different operators' paths. The Black line depicting the Set-Up operator, the Green line the Filler operator, and the Blue line the EOL packer operator.

Monitoring movement is a crucial part of lean. It is important to remember how excess movement one of the seven wastes are. By identifying movements, we could better understand and organize the operating layout and improve its efficiency.

Another important stage for the Measure phase is data collection. It is a necessary step in identifying the problems in the current production line. During the observation of each process in different stations, direct time study was carried out. Time study was used to establish the standard time for each workstation. The result of the time study is shown in Table 1.

Data in Table 1 is represented in Figure 5 as a histogram to illustrate the distribution of workload between the workstations. It shows that the workload between the stations are not balanced and some will be idle for a long time while others will experience bottleneck, especially in the Filling/Filler process.

Table 1
Standard Times for Packaging Line Operations

Standard Times per Operator Tasks				
Process Tasks	Operator Assigned per Task	Mean Cycle Time (min) per Task	Normal Time (min) per Task	Standard Time (min) per Task
Dispensers	Filler	183.29	183.29	214.4493
Filling "Feeder"	Filler	81.97	81.97	95.9049
EOL Packaging	EOL Packer	193.61	193.61	226.5237
Change Foils	Set Up	15.23	15.23	17.8191
Change Liners	Set Up	6.2	6.2	7.254
Quality Tests	EOL Packer	0.31	0.31	0.3627
Air Tests	Filller	109.93	109.93	128.6181
Pressure "Burst" Test	Filler	6.69	6.69	7.8273
Tab Seal Pull Test- Front/Back	Set Up	5.66	5.66	6.6222
Sensor Test	Set Up	4.8	4.8	5.616
Lot Change	Set Up	23.19	23.19	27.1323
Cleaning Area	Filler	3.92	3.92	4.5864
Total Time		**634.8**	**634.8**	**742.716**

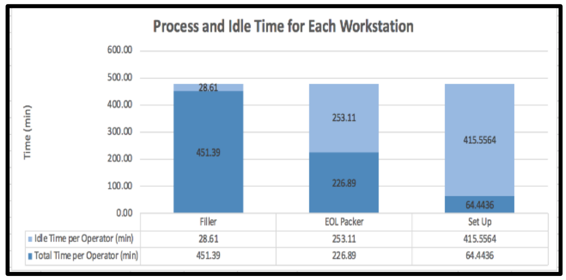

Figure 5
Idle Time for Each Workstation

This means that there is a big gap of underutilization of labor capacity which is impacting the challenges of increasing the labor usage while balancing operator tasks.

Analyze

In this phase, the data that was collected in the previous step was analyzed for waste root causes. After conducting a Process Walk, creating high level detailed process maps, and collecting process performance data; the team was able to analyze the process and list the concerns or pain points. These activities allowed to take advantage of the collective wisdom of the process participants. We proceeded with further process analysis by conducting takt time analysis revealed in Figure 6.

In Lean, takt time is the rate at which a finished product needs to be completed in order to meet customer demand. For this case the Ivers Lee Packaging Lines (IL#1 and IL#2) have a takt time of .33 minutes/unit, that means every .33 minutes a complete product (Blade) on its primary package is produced off the packaging line because on average a customer is buying a finished product every .33 minutes.

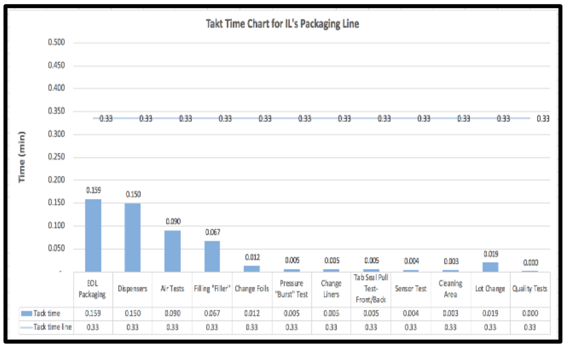

Figure 6
Takt Time Analysis for Each Workstation

Subsequently collecting data and analyzing the takt time for each workstation, I was able to display it using charts and graphs providing visual indications of process problems. The transformation of numbers into visuals allows us to easily communicate findings to leadership and other process participants. Selecting the right chart and graph provides the team with valuable insights about the causes of process issues; which in this case is the inefficient utilization of operators in the packaging lines. The issue causes assigned tasks in the packaging lines to be unbalanced due to lack of work/ time studies.

The type of chart selected to depict the issue was a Yamazumi chart, which is a stacked bar chart that shows the balance of cycle time workloads between the number of operators typically in an assembly line or work cell. The Yamazumi chart can be either for a single product or multi-product assembly line.

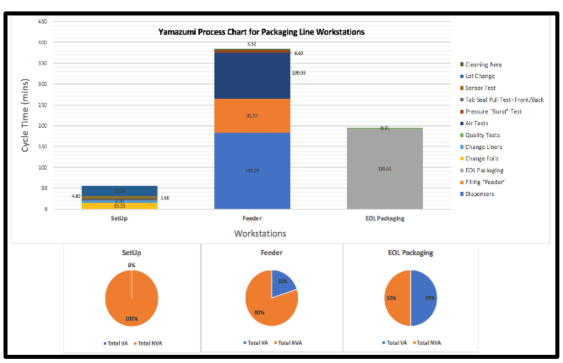

Figure 7
Yamazumi Process Chart for Packaging Lines Workstations

For this project we used a Yamazumi work balance charts to visually present the work content of a series of tasks and facilitate work balancing and the isolation and elimination of non-value-added work content, as you can appreciate in Figure 7.

Improve

After analyzing all the opportunities for improvement in this manual process, various recommendations were proposed. The focus areas that would be most valuable and feasible at the moment were reducing the number of operators per packaging lines. Instead of two (2) Filler operators per line, we proposed one (1) operator for both lines (IL#1 and IL#2) to conduct all the Quality Tests (Air Test, Burst Test, Tab Seal Pull Test, and Functional Test) only. For the Set-Up operator, we suggest reducing from two (2) operators per line to one (1) for both lines. This operator will be tasked with ensuring that the machines work properly and efficiently while also changing the foils, liners, and being in charge of filling/ feeding both machines (IL#1 and IL#2). As for the EOL Packer, we will stay operating with the four (4) operators, which are tasked with the receiving of the product (Blade) on it primary package; but will also be assigned to assemble dispenser boxes while waiting for machine. If all these recommendations are taken into consideration the new redesigned process should look as follows. See Figure 8.

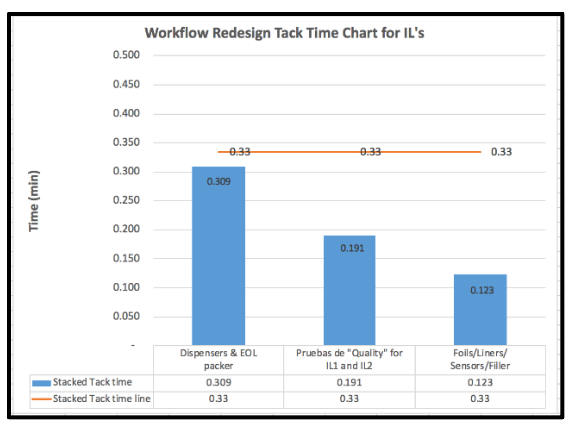

Figure 8
Workflow Redesign Takt Time Chart for IL's

To assure the project goals have been met, measurements of the proposed improvements will be realized. The line should be operating efficiently with six (6) operators instead of eight (8). This new redesign will lead us to increase the labor usage while improving the balance of operator tasks.

In addition, a significant Kaizen event was held with some of the packaging line operators with the goal of interviewing them to solicit new suggestions for the improvement of the existing process. Some of these suggestions were very valuable and taken into consideration. These were: the acquiring of self-assembling boxes that do not take too much time for the EOL packer to fold lids and assemble, currently this task occupies the EOL packer too much time and is a waste activity.

Secondly, to create and design a part or piece that its mechanism and purpose is for the blade come from the manufacturing area with its edge facing the right side (the correct side); this suggestion was made so that the Filler/ Filling operator does not have to be turning the blades sideways, this mechanism will avoid this tedious task that right now cannot be improved.

Thirdly, enhancement of visual management which the purpose is to improve the effectiveness of communication and reaction. Visual aids can convey messages quicker and invite more interest than written information. Some common types of visual management in the workplace are: Cross-Training Matrix of employees, 5S (signs, labels, tapes, color coding, etc.), preventive maintenance boards, and FMEA's [3].

These proposals will ameliorate capacity and utilization of resources to optimize production and maximize efficiency. It should be disclosed that waste minimization will be an ongoing improvement in this area due to the nature of the process.

Control

Successful implementation of any process requires a control phase. This will assure the sustainability of the improvement to be implemented [4]. Appropriate documentation and training will be needed to sustain the proposed improvements.

Standardized operating procedures (SOPs) will need to be created for the new roles for each of the operators; which will include step-by-step instructions that will act as guidelines for employee processes. When employees follow the (SOPs) for each particular job, we will ensure they are realizing their assigned task and supervisors can use the SOP framework to develop target ranges and make assessments of individual performance. This implementation of standard work procedure will make it an easy matter to measure them against the standards established.

CONCLUSION

All industries are moving towards becoming for what is known as World Class Manufacturing companies. Lean Six Sigma was used because this is one of the methodologies used to reach this type of goal. In order to be competitive, continuous improvement is essential. Continuous improvement is a constant upgrade of the process or technique being used that will be beneficial for any process.

For this project the method selected to improve these lines was a combination of work and time studies to better understand the distribution of operations carried out on the packaging lines. Subsequently, was the implementation of Lean tools like the Yamazumi Chart to show us the balance of cycle times workloads between the operators. Afterwards, with work and time studies, a line balance loss analysis was executed to divide packaging line tasks into equal portions. Well-balanced lines will avoid labor idealness, optimize production and maximize efficiency.

These proposals for improvements will eliminate two (2) full time operators' employees for the (IL#1 and IL#2) packaging lines, equivalent to sixty-two thousand and four hundred ($62,400) dollars per year in savings. And helped achieve the main challenge which was to increase the labor usage while balancing operator tasks. As project goals, these included increasing process consistency, improving capacity and utilization of resources to optimize production and maximize efficiency.

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