Improving efficiency on surgical device's manufacturing process

Jeanette Rivera Rodriguez
Advisor: Dr Hector J. Cruzado
Master of Engineering Management Program

Abstract

A global medical device company is suffering a significant efficiency decrease in one of their most important manufacturing processes. The purpose of this project was to improve this line efficiency by a minimum of 10%. The implementation of the following actions was completed: cross training between different shifts to discuss critical manual tasks, creation of Autonomous Maintenance Checklists for Welder and Insulation Tester equipment, re-schedule of quality technicians breaks to avoid downtime related to quality, vacuums implementation, and meetings with supplier to discuss major offender defects and rewards program. The line efficiency increased from 74% in February 2022 to 87% in May 2022. Therefore, the combination of all actions provided an increase of 13% of efficiency to this process.

Introduction

The subject of this project is a global medical device company which produces instruments designed for cutting minute tissues and structures when performing laparoscopic, gynecologic, general, urologic and endoscopic procedures. The company is suffering a significant efficiency decrease in one of their most important manufacturing processes, as shown in Table 1. These procedures are frequent surgeries performed worldwide and this situation produces backorder on market. This decrease negatively impacts the product delivery, and the situation could be turned in hospitals without medical devices to perform required surgeries. It must be addressed to meet company's mission of contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.

Table 1.Monthly efficiency data

Month	Efficiency
Aug 2021	99%
Sep 2021	99%
Oct 2021	91%
Nov 2021	0 (Line Down)
Dec 2021	88%
Jan 2022	88%
Feb 2022	74%

The objective of this project was to increase manufacturing line efficiency by a minimum of 10% during the next quarter. Efforts focused on people, equipment, and methods were performed to meet the objective.

Literature Review

Production efficiency has been always an interested topic in the manufacturing field. This is because an organization is a business which must report revenues to investors. Therefore, cost and budget are very important. However, efficiency topic is more complex than cost and budget. A management team with excellent knowledge in tools to maintain a health efficiency will ensure a stable process and a successful organization. Management must contemplate the following when efficiency wants to be evaluated: technology tools available, personnel or staff effectiveness (individual and group performance), facilities, and management, among others [1]. Equipment's performance needs to be positive in order to plan, develop, launch, and manage successful products which can expand in the market. The understanding of each process step can help to consider more potential operational improvements. In addition, root cause analyses could help management team to find new ways to carry out operational activities [2].

Different strategies can be implemented to improve efficiency in a manufacturing process. Currently, one of the most famous strategies is lean six sigma. Concepts such as lead-time analysis and reduction, 5S are useful to simplify our processes, reduce or eliminate waste and develop projects focused on improve manufacturing process. Value-flow map can help us to evaluate the process step by step and identify where lead time can be reduced and improve quality. In addition, this kind of exercise helps to identify bottlenecks to be improved. Another tool such as takt time allows the identification of waste in the process [3].

In order to have the most possible stable process, most of companies have opted for automated systems implementation. This kind of technology helps to have a robust manufacturing process with less human dependence and less human errors. Industry 4.0 creates some alternatives to be competitive in the market. These alternatives are the following [4]:

- Lean philosophy in manufacturing
- Formation of the industrial revolution related to social, economic, and technological changes
- Cyber-physical systems/software and big data
- Simulation modelling improvement on value stream mapping method and intelligent logistics solutions

Experts express that system in the work environment should be designed to perform a specific task. Therefore, workers, equipment (machine) and facilities must be aligned and in optimal conditions/performance. Important factors for an effective work system include [5]:

- Worker should have a good physical condition and psychological capabilities to perform his/her tasks.
- Machine should be in optimal conditions to support the worker in accomplishing required tasks.
- Facilities (environment) should be in optimal conditions to ensure a good performance of the worker and the machine.

Methodology

Cross Training

This manufacturing process is approximately 80% manually. Therefore, the operator technique and expertise are essential to obtain the desired output and comply with customer's demand. Efficiency per shift of Feb 2022 was evaluated (Shift A 80%, Shift B 74%, and Shift C 69%) and a significant difference was identified. A multidisciplinary team (Process engineer, Quality engineer and supervisor) met to discuss the data and it was concluded that it could have direct relation with seniority and highest expert resources in Shift A. Key resources of each shift were identified and most difficult manual techniques were discussed with them. Three stations where operators take more time if he/she does not have expertise were identified (center rod, jaws and rivet, and cut functional test). Operators reviewed step by step of these stations using the procedure to detect the best technique for each assembly and/or step. Material for trainings sections were assigned.

Quality Inspections

Some of quality sampling tests required manufacturing equipment to be performed. A schedule change on quality technician breaks was evaluated and discussed with quality supervisors. Quality inspections during manufacturing personnel breaks was proposed to reduce downtime related to quality. Quality sampling inspection could take between 8 to 10 seconds per unit with a total of 80 inspected units per lot.

Major offenders on Quality Defects

All defects detected on 100% inspection of manufacturing process are documented. This data was verified, and particulate and insulation defects were identified as major offenders of quality defects during last months. Vacuums on critical stations were implemented to reduce the particulate generated by the manufacturing process. On the other hand, insulation issues can be related to raw material, welder and/or insulation tester performance. Meetings with supplier of shrink wrap component were performed to discuss possible situations which could cause insulation failures. In addition, Autonomous Maintenance Checklists for Welder and Insulation Testers help to correct any possible issue in the equipment and will help in their performance efficiency.

Improve Preventive Maintenance Program

Equipment downtime data from Aug 2021 to Feb 2022 was evaluated to identify major offenders which are directly affecting line efficiency. Figure 1 demonstrates that welder and insulation tester are the equipment to be focused and must be improved with 64.70% of equipment downtime distribution.

Autonomous Maintenance Checklists were created for both equipment. The purpose of these checklists was to provide a detailed tool to operators with key points to be verified and recommended actions in case of findings to be corrected. Some of equipment verifications are presence of particulate, adjustments, and lubrications, among others. Operators received an "On the Job Training" with mechanics before the checklist's implementation. This kind of initiative helps the manufacturing process to identify equipment issues at point zero.

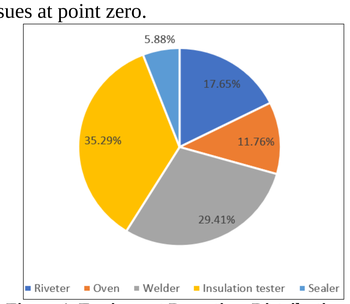

Figure 1. Equipment Downtime Distribution

Rewards Program Implementation

Rewards Program was implemented to highlight employees which demonstrate commitment, leadership, critical thinking, problem solving, teamwork and/or achieve/exceed company goals. Budget proposal was approved, and the recognitions are being presented in a weekly basis during manufacturing tiers. This kind of initiative changes the work environment positively and focuses personnel to achieve the production goals.

Results

Cross Training

After the completion of benchmarking sections, operators expressed more confidence in the technique. The efficiency per shift was evaluated in May 2022 and the improvement was significant. Table 2 details these results.

Table 2. Efficiency Data per Shift

Shift	Feb 2022	May 2022	Difference
Shift A	80%	91%	+11%
Shift B	74%	85%	+11%
Shift C	69%	86%	+17%

This task was considered the most challenging due to the process is 80% manually. Each person has different opinions, and the harmonization was a very challenging but successful activity.

Quality Inspections

The inspection of each unit could take approximately between 8 to 10 seconds per unit for a total of 80 inspected units per lot. After the change implementation on quality breaks, the line showed a reduction of 13.33 minutes of downtime related to quality inspections per lot. The manufacturing line could produce more or less 100 units per hour (1.67 units per minute). Therefore, it can be estimated, with the process recovery time, to produce 22 more units (1.67 units x 13.33 minutes).

Major offenders on Quality Defects

Particulate incidence did not present a significant reduction with vacuums implementation. However, additional options will be evaluated as part of Continuous Improvement Projects. On the other hand, insulation defect incidences showed a reduction which could be attribute to the constant equipment verification using Autonomous Maintenance Checklists. This checklist tool allows that operator to ensure that the equipment is in optimal conditions prior to starting the manufacturing process, therefore reducing significantly nonconformances or defects caused by equipment.

Improve Preventive Maintenance Program

Autonomous Maintenance Checklists were monitored after implementation. Operators have more technical knowledge and understand how to operate their equipment. A reduction on equipment downtime was reflected due to that most of the equipment issues can be corrected by the operator instead of losing time waiting for availability of mechanics.

The implementation of Autonomous Maintenance Checklist can be considered the major improvement in this process due to this activity provides to operator knowledge, development, ownership of their equipment and confidence performing their responsibilities. In addition, the constant equipment verification provides a better performance of the equipment and less downtime because the process is being more preventive than corrective.

Rewards Program Implementation

Rewards program has been well received. Different production goals with applicable rewards were published to incentive and motivate personnel with their daily tasks. One of the rewards program purposes is help management to motivate employees to work hard for what they want. They can obtain the best of employee's performance.

Conclusions

Manufacturing Line efficiency was re-evaluated in May 2022 after the implementation of the following actions: cross training between different shifts to discuss critical manual tasks, creation of Autonomous Maintenance Checklists for Welder and Insulation Tester equipment, re-schedule of quality technicians breaks to avoid downtime related to quality, vacuums implementation and meetings with supplier to discuss major offender defects and rewards program.

The line efficiency corresponding to May 2022 was 87%. This result complies with project purpose of improve the efficiency of this manufacturing process by a minimum of 10%. The efficiency of February 2022 was 74%. Therefore, the combination of all actions performed provided an increase of 13% of efficiency to this process. Additional actions will be worked to return the manufacturing line to a stable status (95%-100%).

References

[1] The Water Environment Federation (WEF). 2017. "Operating Efficiently." Chap. 3.10 in Operation of Water Resource Recovery Facilities, Manual of Practice No. 11. 7th ed. New York: McGraw-Hill Education.

[2] Haines, Steven. 2014. "Integrating other aspects of the strategic mix for the product's business" Chap. 20.6 in Product Manager's Desk Reference. 2nd ed. New York: McGraw-Hill Education.

[3] Martin, James William. 2014. "Lead-Time Impact on Lean Six Sigma Projects." Chap. 4 in Lean Six Sigma for Supply Chain Management: A 10-Step Solution Process. 2nd ed. New York: McGraw-Hill Education.

[4] Illes, B. Tamas, P. (2016). Process Improvement trends for Manufacturing Systems in Industry 4.0. Academic Journal of Manufacturing Engineering, Vol. 14, Issue 4/2016.

[5] Tillman, Barry, David J. Fitts, Wesley E. Woodson, Rhonda Rose-Sundholm, and Peggy Tillman. 2016. "INDUSTRIAL SYSTEMS." Chap. 6 in Human Factors and Ergonomics Design Handbook. 3rd ed. New York: McGraw-Hill Education.