Using Lean Six Sigma Tools for Packaging Machine Rebuild and Automation Process Improvement

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Abstract — *This document describes the process of improving an existing packaging machine using lean six sigma tools and automation technology for the medical device industry. The ideal manufacturing site that has volume increase and high demand, will have no problem in spending capital for new machine or lines. In the case of a manufacturing site that has managed to maintain market share and has a steady volume rate for years, the machinery and process lines will eventually reach obsolete technology and a decrease in output. This is the case of a packaging machine which was built in the 1960's and is currently packaging forty (40) million surgical blades per year. Using Lean six sigma tools and automation process improvement it will be possible to understand better the causes of machine issues and create plans to improve them. Analysis from process data shows the major causes of quality issues are empty packages and major downtime comes from lot changes. This type of analysis can be used to include in the machine rebuild scope and process improvement technology as-well.*

Key Terms — *Empty Packages, Lot Changes, Medical Device, Surgical Blades.*

INTRODUCTION

During the past years there has been a slight increase of the demand for single use, surgical blades from a company that manufactures such medical device. These products are packaged through a cam driven machine that was built in the 1960's, an old machine, which has been fitted with controls to operate in a regulated industry. The demand or volume increase of these products does not justify capital investment for new machinery. Currently the machine runs three shifts for five days a week. Company reports the use of overtime in order to achieve deadlines due to downtimes and machine process issues that occur during the packaging of the product. This can lead to a potential loss of market share and also company profit. In order to reduce downtime and quality issues with a machine rebuild and automation process improvement, we need to understand what are the major factors for production downtime and quality issues. The mayor downtimes associated with the packaging line involve lot changes, mechanical repairs, machine jams and machine parameters out of spec. As-well as the quality issues include empty packages, multiple blades per package and out of registration package. Having these issues in mind, the project scope of the machine rebuild and automation process can be defined and pursue a target for improvement.

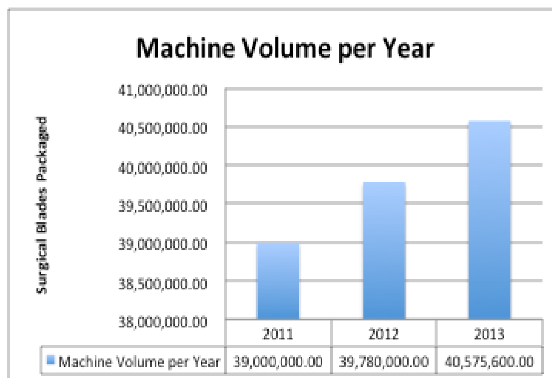

Figure 1
Surgical Blades Production

This project will be focused on a Surgical Blade Packaging Machine used to package over 40 million blades per year. Statistical Data shows an increase of 2% in volume from 2012 to 2014, and knowing this, the machine will need to improve capacity and process improvement is needed to achieve a higher efficiency. Statistical data from downtime reports and quality issues will be analyzed; a Pareto analysis will be conducted to select the major issues affecting the process. Having this issues selected, using cause and effect diagrams it will be possible to identify the cause of downtimes and quality issues. The objective of this project is to use lean six sigma tools to identify issues and improve with the use of automation processes technology on a medical device packaging machine [1].

BACKGROUND INFORMATION

As a result of the continued growth over time, the amount of machine hours increases and the cost of maintenance, obsolete technology and process issues affect operations and costs to the company through replacement parts, valuable downtime and overtime. For each downtime or unscheduled repair, the company pays extra for overhead, expedited shipments and loss in absorption. An economic analysis was made to understand the losses in production time and maintenance of the machine. In the year 2013 the average use of replacement parts was around $1,800 per month, and an average of 26 hours of overtime were needed weekly to achieve the goal of the month. Machine downtime could be defined as a time in which the machine is scheduled to be in operation and instead is stopped or operating a slower rate. Quality issues also present downtimes and an adverse effect on product end user, which could lead to customer complaint or unsatisfied customer. Issues that impact downtime can be described as a defect found during lot process that leads to product inspections or re-work in order to approve such lot. Some of these issues are empty packages, out of registration packages and multiple blades per package. An empty package can be defined as a package in which the product is not found inside, this is normally a machine issue that leads to scrap but in some cases it is not discarded and does go to the market. An out of registration package can be described as a package that is not within the specified length or width; this happens when machine is out of registration and could lead to an open seal condition. Same as the empty package, a double blade package is supposed to be part of scrap material, in some cases two blades are packaged in one blister and is then packaged. The manufacturing of surgical blades is considered a medical device class I, the companies US market share is around 62%. Customer loyalty and conformance is critical to maintain market share and therefore product demand is maintained. The downtimes analyzed include lot changes, machine jams, part replacements and electrical problems. A lot change can be defined as the act of finishing an order processed in the machine and preparing the next order, in this particular machine and process, the lots are of 150,000 products. The lot change involves line clearance, lot number change, parameter changes, product identification changes and material changes. Machine jams occur during machine operation, this happens when the material for packaging clusters or folds causing jam in the machine. This then has to be cleared, machine downtime is wasted clearing jam, passing material through the machine once again and scraping product. A product identification change has to be conducted when a different product is going to be processed through the machine. Surgical blades all have a type; these are standard types, normally identified with numbers such as #10, #12, #15 etc.

Figure 2
Surgical Blade Variety

This information is changed during the lot, using a die change on a printer. Material changes need to occur depending on material used, this company manufactures different blade materials such as stainless steel and carbon steel, to each blade composition and configuration a specific material is used for the packaging. Electrical problems are a continuous issue on these machines, due to the nature of the control system, PLC technology with mechanical degree switches. The machine presents issues from failed circuits, consumption of electrical relays and fuses. Over the time, several sensors and modification have been added to the system over charging the original design of the system. During the year 2013, 9.44 shifts were reported to downtime caused by electrical issues.

METHODOLOGY

This section provides a detail plan of how the project will be designed and implemented. Using the data from the company concerning downtime and quality issues, a Pareto analysis will be presented. A Pareto chart is a tool that helps to identify and categorize the source of problems or common causes. In this case is to identify the major downtime issues and quality issues. See figure below for an example of a Pareto analysis.

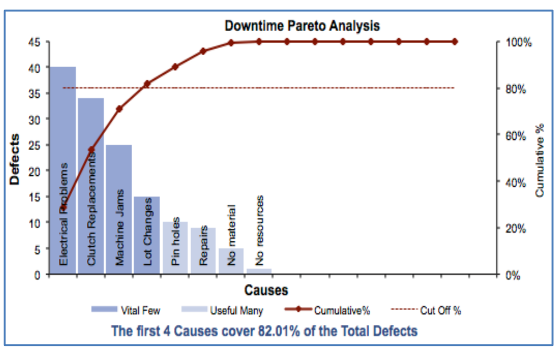

Figure 3
Pareto Analysis

This tool will show us the top causes found on the process, in this case the packaging machine downtime. Having these major offenders an Ishikawa or fishbone diagram can be used in order to identify causes and overall effects of the issues. The figure below shoes the diagram in its simplest form. The fishbone diagram is a graphical method for finding the root causes of an effect. The effect can be either a negative one, such as process defect or an undue process variation; or a positive one, such as a desired process outcome. Kaoru Ishikawa, a famous Japanese consultant developed this method in the 1960's [2]. First we identify the process effect to be analyzed, writing the effect on the right side box. Then identify the main categories of causes in the effect under consideration; these are typically people, environment, material, method, machinery and measurement. Identify as many causes corresponding to each individual element using distance from issue as the level of possibility, see figure below [3].

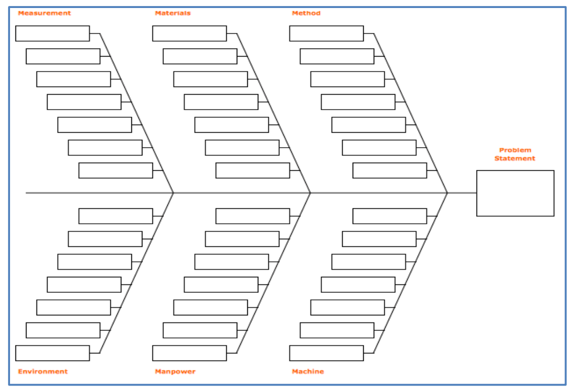

Figure 4
Fish Bone Diagram

Both analyses will lead to key issues at a major impact in the process or machine. With the results we can define project scope and design the process improvements to be included in the machine rebuild.

RESULTS AND DISCUSSIONS

The first step was to analyze data for major downtime and quality issues of the machine and packaging process. In the figure below, the Pareto chart for the downtime reasons demonstrates that that the first 4 causes cover 82% of the total downtime, therefore these become part of the project scope in order to improve and reduce downtime. The quality issues shown below in the Pareto analysis shows the first 3 causes cover 80% of the total defects, these will also be part of the project scope of the machine rebuild and automation process improvement.

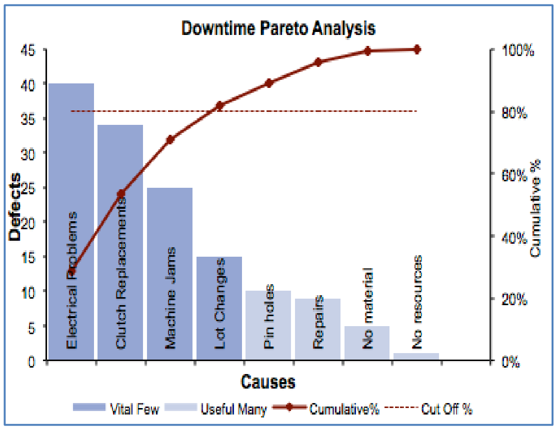

Figure 5
Downtime Pareto Analysis

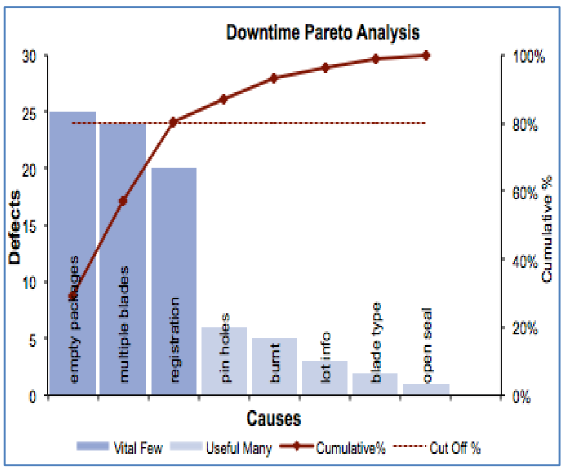

Figure 6
Quality Pareto Analysis

Using these tools we have now clearly defined the major offenders of downtime and quality issues of the packaging process and/or machine to be rebuilt and process automation improved, see figure below.

#	Causes	Defects
1	Clutch Replacement	Downtime
2	Electrical Problems	Downtime
3	Machine Jams	Downtime
4	Lot Changes	Downtime
5	Empty packages	Quality
6	Multiple blades	Quality
7	Registration	Quality

Figure 7
List of Major Offenders

It can be observed from the above table, that some downtime issues are aligned with the quality issues. Empty packages for example, present a downtime issue of clutch replacement, which is the section of the machine that rejects or accepts a package. The same happens for multiple blades, an electrical problem causes these sensors to not work properly and give false reading to PLC. Other aligned issues are machine jams and registration, as quality registration is a defect when package artwork is not aligned with top and bottom of package, and machine downtime occurs when machine is out of registration, materials in machine bend and machine then creates a jam. Lot changes represent a downtime from machine process; several tasks need to be taken in order to change from one lot to another. Having all these defined, fishbone diagrams show the root causes of the issues.

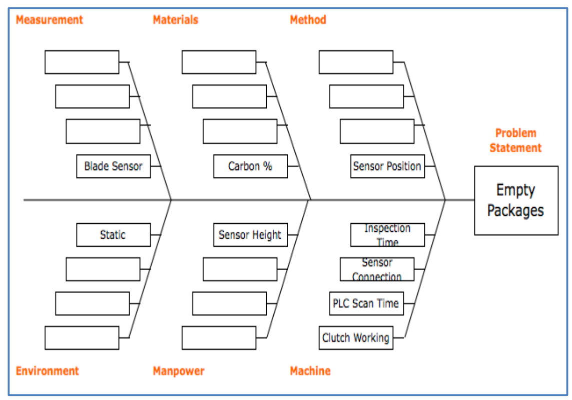

Figure 8
Fishbone Diagram Empty Blades

From the empty packages fishbone diagram, it has several causes from each category that represent a potential root cause. In method, the position of the sensor itself can be a contributor to the problem; lack of training or unclear instructions can lead to incorrect positioning of the detection sensor. Materials probable cause is the percentage in carbon percentage of the blades, this is unlikely to happen given the sensor operates within a wide tolerance of carbon percentage and is not sensitive enough to notice such variance. Manpower shoes adjustment to sensor as well as measurement itself. Static in the machine is also a possible contributor to the problem statement. Machine has the most probable causes from Machines capability to inspect or read sensor on time, the connection of the sensor itself, PLC capability to read sensor signals and inspection and rejection clutches that are working properly. These probable causes should be considered in the machine rebuild and automation process improvement. The same analysis was achieved for the previous selected problem statements.

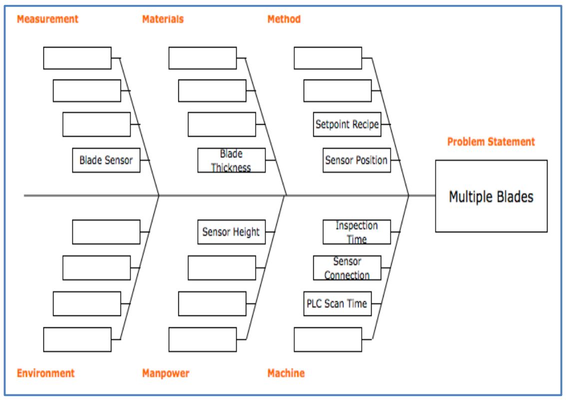

Figure 9
Fishbone Diagram Multiple Blades

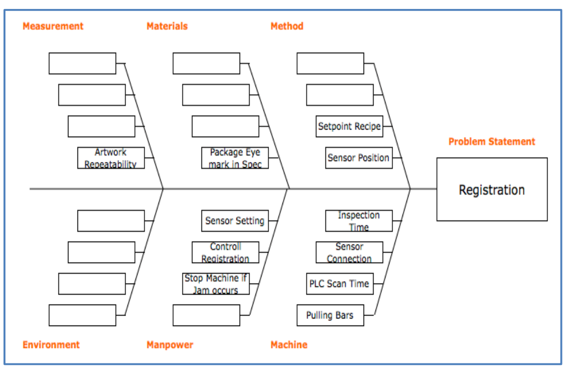

Figure 10
Fishbone Diagram Registration

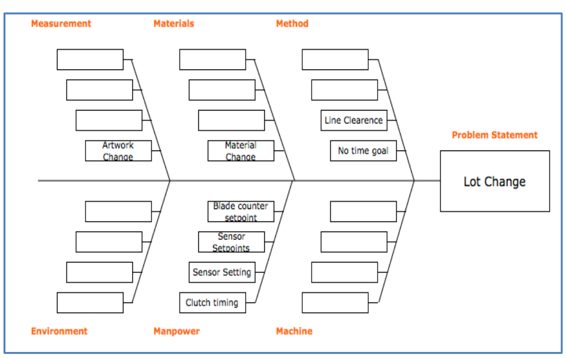

Figure 11
Fishbone Diagram Lot Change

The project scope for this project involves machine improvement by rebuild and automation process improvements of the process. Based on the fishbone diagrams of the issues related to quality and downtime, the most observed were under machine category with the exception of lot change downtime. It is observed that machine capability to interpret correctly sensors and process controls is the major cause, directly impacted by the above-mentioned electrical problems. Analyzing machine current equipment, the currently used programmable logic controller, PLC, was designed to operate the machine. Along the course of the years, there were several sensors, added equipment and changes done to the machine that over did the capability of the PLC. This is a major issue and affects the PLC scan time, Inspection time and sensory feedback as well [4]. This simple change may cover the major quality issues, which involve missing blade, multiple blades in package and registration issues which all, are controlled with sensors responding to the PLC. Involved with this change, electrical routing of power lines, control and logic wirings will need to be re-routed on the machine. Lot changes were not affected by machine, in fact greatly affected by manpower. Operator's responsibility in the lot change includes blade counter set points, sensor set points, sensor settings and machine timings to be entered and changed. These types of changes are aligned with the product to be run through the machine, therefore a recipe can be created for each product type and include that in the machine PLC programing. Another major offender to quality is empty packages which are affected by the current rejection system; this system consists of a main motor with belt and pulley assembly that maintains a rotating shaft. This shaft is connected to a conveyor which the product is placed per each cycle, is such package is acceptable, the clutch system activates rotating the conveyor and sending packaged unit to following processes. This system has a high cost replacement on the clutches and also it tends to stay activated when failing, sending non acceptable packages through the conveyor. The proposed technology to replace clutches is stepper motors. The stepper motors have a lower cost, replacement of the motor reduces downtime and also the main motor is eliminated minimizing parts in the assembly.

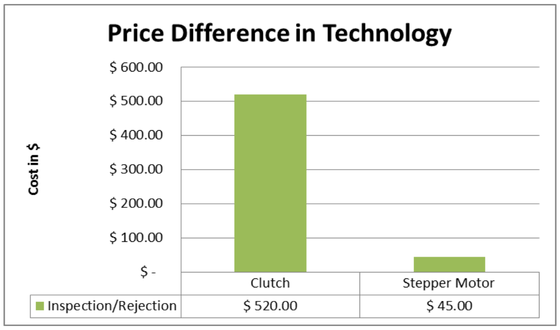

Figure 12
Clutch vs. Stepper Motor Costs

PLC selection was using the machine requirements of scan time, input/output signals and automation capability. The recipes for each program are managed by a Human Machine Interface, HMI, that machine operator may choose the needed recipe to run machine. This recipe will include all sensor setting, set points and parameters for each product to be processed. Proposed changes represent a cut on downtime, lower cost replacement parts and a positive impact in quality of the product sent to the market. The machine, although was designed in the 1960's now possesses a designed control system with the appropriate system and tools to execute the packaging process inspection and regulatory compliance effectively.

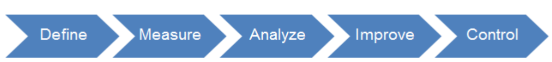

Figure 13
DMAIC Steps

Conclusions

This project was based on a machine that is currently in operation; production volume is increasing and issues concerning downtime and quality impact production performance and quality metrics. Machine issues were defined, measured, analyzed improved and now the control phase which is left to the manufacturing and operations team with the recommendations to take. This was an example of DMAIC methodology implemented and executed using various tools from a lean and six sigma perspectives [5]. Through the improvement process, the machine was fitted with new technology, PLC control, re-wiring of the system and HMI implementation for the machine and operator interface. An effect in downtime for lot changes is expected to minimize 60% of total lot change downtime; this alone will gain uptime and minimize weekly overtime. Through the improvement of the accept and reject station by the implementation of stepper motors, an improvement in cost and maintenance of 91.3% and an impact not yet measured but speculated of 50% reduced downtime in the replacement of the stepper motor when faulty. The project was completed within a two week timeframe including validation of the new system given machine operates under regulated requirements of a Class I Medical Device Industry. Additional and continuous improvement to the system will maintain and also improve the machine process at all levels, the rebuild of the machine acted as a kick start process improvement program that will be maintained with the use of the DMAIC tool and a continuous improvement culture.

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