Packaging Lines Minor & Minor/Major Changeover Time Reduction on a Pharmaceutical Company

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Abstract *— Every company that wants to be competitive has to implement SMED or changeover reduction in every process that this technique could be applied. The two major difficulties that companies encounters are: Product diversification and Low volume production. The greatest difficulty in a setup operation lies in adjusting the equipment correctly to produce the first good part. Changeovers have become a big topic over the past few years with diversification of products, globalization and economic consumer response. None of this helps the producer, and in fact there is very little over the last five years that has. Manufacturing has had to cope with reducing costs, which inevitably means less resources, shorter runs and more stock-keeping units. This article discusses the improvement of the reduction changeover in a packaging line of a Pharmaceutical Company. The methodology used for the improvement was Lean Six Sigma using the DMAIC tool as a systematic approach.*

Key Terms *—Changeover Time, DMAIC, Lean Six Sigma, Packaging Line.*

INTRODUCTION

Pharmaceutical companies around the world are competing against each other in order maintain their clients with a product that has to be of excellent quality at the right price. For that they have to be more aggressive in the use of new techniques like Lean Six Sigma in order to obtain the results they need to be successful. This type of technique helps by decreasing the non-value added to our operations. To be competitive every company have to focus on what consumer wants. The product has to be when they need it, at the right cost and available as much they want it. For that the company has to appeal for sensible planning, rationalization of product - in order to reduce the level of changeovers, and innovation that fits as closely as possible to manufacturing facilities already available. Short changeover times have always been critical in manufacturing business. Set-up duration reduction initiatives have been associated with Shingo´s 'Single Minute Exchange of Die' (SMED) method. To justify any project of changeover reduction, the analysis show management information of how efficient the company could be if our process could run more smoothly and the company don't waste time in waiting for: Materials, Parts, tools, etc. Creating more uptime for our equipment than rather making downtime. SMED is a low- no cost project to be performed and implemented. The benefits of quick changeover include: Reduction on defect rates, reduction on inventory costs, increases on production flexibility and improve on-time delivery.

Research Description

Currently Packaging Line 1 is dedicated to the manufacturing of Product A 60mg, Product B (different mg's) and Product C. (different mg's) The minor changeover process takes an average of 11.5 hours with a standard deviation of 3.3 hours. This has a negative impact on shop floor performance and area productivity.

Research Objectives

Reduce Packaging lines Minor & Minor /Major Changeovers time from **11.5** and 19.4 hours to **4** hours and reduce the variability. (Business Process Efficiency). In Scope Packaging lines Minor & Minor/Major Changeover process starting from the log entry of the cleaning and ending with the first good packaged case.

Out of Scope: Major cleaning and runtime activities.

Research Contributions

The financial benefit will be directly impacting SAP standard set up time. This benefit will be approximately $305,000 per year. Other benefits will include Capacity Improvements, inventory management and replication opportunities in other Packaging Lines.

LITERATURE REVIEW

Since Lean Six Sigma starts with customers, its goal is clear to eliminate anything that does not meet their needs. In Lean Six Sigma, things that don't meet customer's needs are called defects. [1]

- Defects - defective products and rework to fulfill customer needs.
- Overproduction – produce more than or sooner than is required by internal or external customers
- Waiting – any delay between activities; idle time due to operator, machine or material
- Transportation – transport or double handling of materials or products
- Inventory – excess supply of raw material, sub-assemblies, work in progress (WIP) or finished good at any point in time
- Motion - physical motion of people or machinery that do not add value (searching, walking, stretching, bending, etc.)
- Extra Processing – to do more than the customer requires, activities that are transparent to the customer.

That is why the best argument for getting involved in Lean Six Sigma is that the benefit is enormous. By using Lean Six Sigma in your work area you can:

- Help your company become more profitable
  - Grow revenue
  - Cut costs
  - Improve delivery time
  - Reduce inventory
  - Increase customer satisfaction
- Develop valuable job skills on personnel
  - Decision making
  - Problem Solving
  - Teamwork
- Make your own job & workplace work better
- Get rid of a lot of waste which will save you time and make your work more meaningful.

To put it very simply, Lean Six Sigma is a problem-solving methodology that reduces costs and improves customer satisfaction by greatly reducing waste in all the processes involved in the creation and delivery of your products and/or services.

Is a problem-solving technology that uses data, measurements, and statistics to identify the *vital few* factors that will dramatically decrease waste and defects while increasing predictable results, customer satisfaction, profit, and shareholder value.

Lean Six Sigma is about data and facts, and *not* about thinking, feeling, or believing what you conceive to be the solution to the problem. [2]

METHODOLOGY

Every organization has problems that get solved over and over again, only to reappear. Teamwork hard for months, generating solutions that people just knows will work… but do not. This is another type of failure that Lean Six Sigma not affords. That is why it uses a modern problem-solving method designed to avoid such problems. The model is called DMAIC (Figure 1), which stands for Define-Measure-Analyze-Improve-Control.

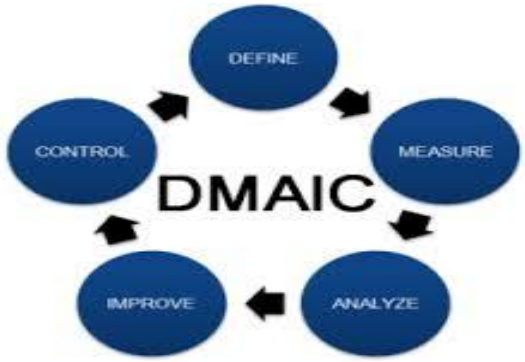

Figure 1
DMAIC Process Steps

Before getting into the DMAIC process itself, you should be aware that the management team has to go through a project selection process and then

they will prepare a project charter to document what they want the team to accomplish. [1]

Define Phase

The purpose of this fist stage of the DMAIC process is for the team and its sponsors to agree on what the project is. The kind of things you'll include:

- Discussing the project charter as a team
- Getting Customer data
- Reviewing existing data about the process or problem
- Drafting a high level map of the process
- Setting up a plan and guidelines for you team

A core principle of Lean Six Sigma is that defects can relate to anything that makes a customer unhappy: long lead time, variation in lead time, poor quality, or high cost, for instance. To address any of these problems, the fist tool use is creating a high level map of the process called SIPOC, which stands for Suppliers-Input-Process-Output-Customer.

Measure Phase

Measure is the heart of what makes Lean Six Sigma work when other approaches haven't. if you don't gather data, you will likely end up with a lot of quick hit projects with short lived or disappointing results. Combining data with knowledge and experience is what separate is true improvement from just tinkering with a process. In Measure you will:

- Evaluate the existing measurement system
    - Improving it if necessary
    - Developing a measurement system if you do not already have one
- Observe the process
- Gather data
- Map the process in more depth

The tools used in the phase are very helpful but is important that before you start using them first you make a process observation. There simply is no substitute for impartial observation as a way to confirm what really happens in a process that is built into how work is currently done.

Then you can use a time value map that is how time is spent in a process. The chart consists of a timeline with bars broken out highlights work that adds value in you customer's eyes and work that doesn't. Also use Pareto Charts, each bar represents different element of a problem; this help you focus your team on see what is happening on your process and what they need to fix.

Analyze Phase

The purpose Analyze phase is to make sense of all the information and data collected in Measure, and to use that data to confirm the source delays, waste, and poor quality. A challenge that all teams face in this phase is sticking to the data, and not just using their own experience and opinions to reach conclusions about root causes of problems. The things you will include:

- Looking for patterns in the data
- Targeting places where there is a lot of wasted time

These actions will allow you to find clues to the real causes, find ways to make the process faster without sacrificing quality and identify the most critical process factors to control. On this phase you can use tools like: cause and effect diagrams, scatter plots, among others.

Improve Phase

The sole purpose of Improve is to make changes in a process that will eliminate the defects, waste, cost, etc. that are linked to the customer need identified in the Define stage. The links in the last sentence are critical. The team must make sure that the causes they are looking at in Improve affect the problem or need defined in its charter. The changes they make must affect the causes they confirmed in Analyze. The things you will do include:

- Using creativity exercise to identify a range of possible solutions
- Reviewing existing Best Practices (documented procedures known to produce good results) to see if any can be adapted to your situation.
- Developing criteria for selecting solutions

- Piloting the chosen solution
- Planning for full scale implementation

Control Phase

The purpose of Control is to make sure that any gains your team makes will last. That means creating procedures and work aids that will help people do their jobs differently from now on. The team must transfer what they learned to the process owner and ensure that everyone working on the process is trained in using the new, documented procedures. In Control you will:

- Document the new, improved procedures
- Train everyone
- Set up procedures for tracking key vital signs
- Hand off ongoing management to the process owner
- Complete project documentation

The tool that is very important to be used in this phase and it will depend on each project is how you will track results from now on; for that is very important that you used a type of controls charts that help you tracking the results and shows that the results are the one expected to make sure the improvements will last.

RESULTS AND DISCUSSION

The results obtained during the project execution are discussed in this section following the systematic approach of DMAIC.

Define Phase

The Define phase is the start of the DMAIC process and is where you start to identify the problem that need to be solve. The project sponsor (Manufacturing Manager) start by refining what will be the project charter for the Belt assigned to it. The project charter is a live document that was signed by the departments involved in the project. It contain the problem statement, goal statement, business impact, project scope & project plan/ team selection. Figure 2 presents the project charter that was developed and approved by the team members and the champion.

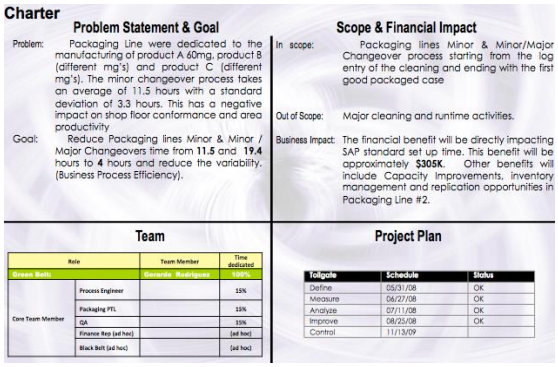

Figure 2
Project Charter

Once the project charter was developed, you start the team launch were you begin to validate it by using different tools. The tools used on this phase were: SIPOC, Voice of the Customer Collection Plan, Risk Analysis & Communication Plan.

SIPOC diagram is a high-level picture process that depicts how the giving process is servicing the customer. It is an acronym for Suppliers- Inputs- Process- Outputs- Customers. The team developed it during our team lunch.

Suppliers - provide inputs to the process. (Manufacturing water, Mechanical operator, Process Assistant, Quality Department, Material Handler & Operators).

Inputs - define the material, service and /or information that are to be used by the process to produce the outputs.
(Work Instructions, Lot Tickets, Sequential Log, Materials, Filler Change parts, Lot entry, Cleaning approvals, Equipment setups, Setup sheets, Miscellaneous, water tanks & Procedures)

Process - is a defined sequence of activities, usually adds value to inputs to produce outputs for the customer.

Outputs - are the products, services, and/or information that are valuable to the customers.
(Documentation completion, Cleaning approval, Setup completion & Lot start up).

Customers - are the users of the outputs produced by the process. (Patients, Operators & Process assistant).

The SIPOC diagram of actual process is defined in Figure 3.

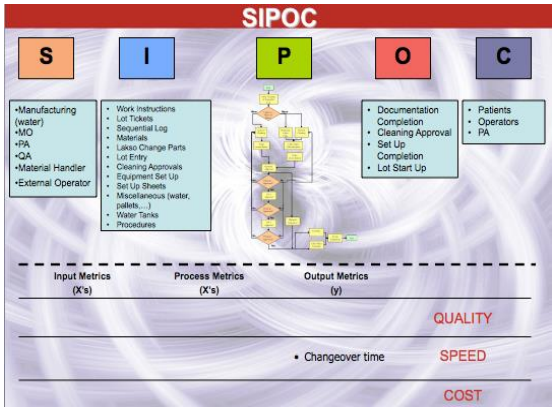

Figure 3
SIPOC

Measure Phase

Once Define is completed; Measure phase is where the team continue, starting by defining a Value Stream Map for deeper understanding and focus. The process flowchart on Figure 4 is the current Minor & Minor/Major changeover process on Packaging Line.

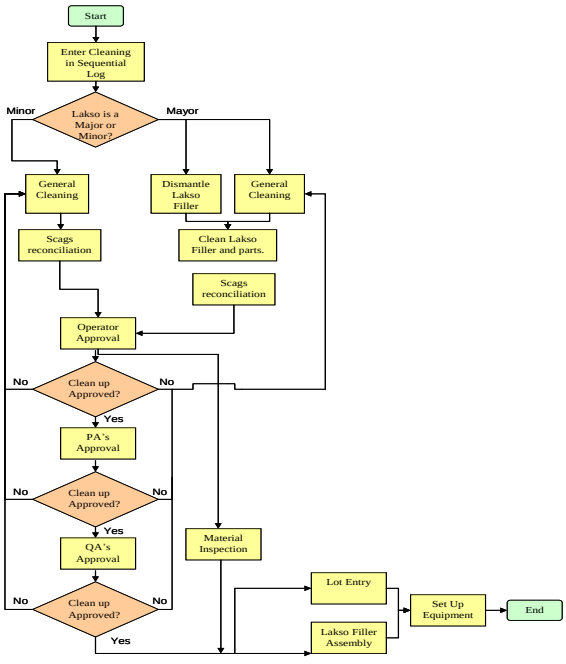

Figure 4
Minor & Minor/Major changeover process on Packaging Line Flowchart

For complete gathering of the data the team had to complete this high-level process map to understand where it begins and where it finishes. This process start when the operator enters on the sequential log the cleaning process and finish first 10 good packages of the next lot. Then operational definitions are develops, defining each metric, for which information will be gathered, to provide clarity. Figure 5 is the Operational Definition/ Data Collection Plan.

Operational Definitions/Data Collection Plan

Measure	Definition	Source	Sample/ date	Stratification factor
Room Cleaning Cycle Time	Elapsed time from removal surpluses from packaging line until the room is verified.	Sequential log, Work Sampling	Jun 2- Jun 13 2008	Cycle time by step and overall
Equipment Cleaning Cycle Time	Elapsed time consisting in the cleaning of each one of the equipments according Work Instructions.	Work Sampling	Jun 2- Jun 13 2008	Cycle time by step and overall
Equipment Set-up Cycle Time	Elapsed time between materials check-in and when corrugated box #10 is completed	Work Sampling	Jun 30- Jul 08 2008	Cycle time by step and overall
Lot entering Cycle Time	Time where materials are entered to the line	Work Sampling	Jun 30- Jul 08 2008	Cycle time by step and overall
Changeover Cycle Time	Sum of Cleaning, start up, and lot entering cycle times.	Sequential log, Work Sampling	All Line 1 packaged lots from March 2008 to April 2008	Cycle time by step and overall

Figure 5
Operational Definition / Data Collection

Once these two tools are completed, the team wanted to understand how the process was behaving; and decided to create a Histogram and Control Charts (Figure 6) for these two types of cleaning processes for the period of time of two months.

It was decided to develop a data collection plan including stratification factors to assist us in the Analyze phase. The time study was developed on each step of the cleaning process. Is very important that clearly you gather each data correctly, because it will help you understanding what types of waste you have on your currently process, what Quick wins or opportunities you saw during the sampling. For completing the study, we decided to divide on 3 groups (Minor Cleaning, Minor/Major Cleaning & Lot entry and Setup Time). The results show us that in Minor Changeover the total time was 7.99 hours & on the Minor/ Major 10.8 hours; Figure 7 shows you the Time Study for the whole processes.

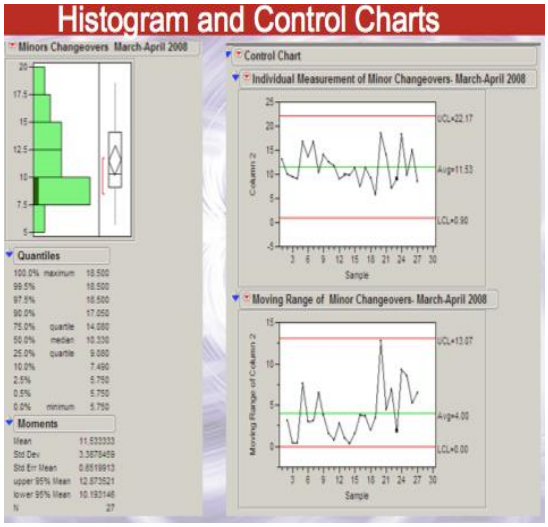

Figure 6
Histogram/ Control Charts

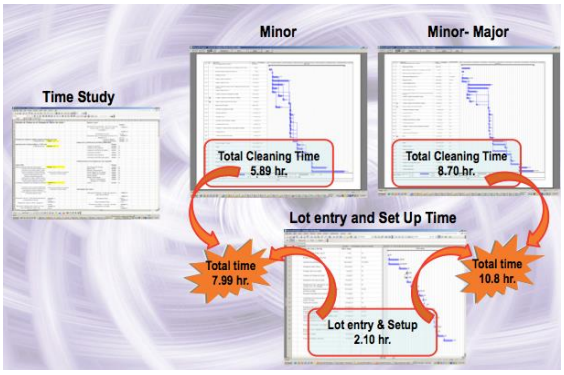

Figure 7
Time Study- Minor & Minor/Major Changeover Process.

Analyze & Improve Phase

In Measure phase the team decided to create all the Value stream mappings on papers; helping us understanding better the process by making more visually to the team members what was the activities that add value to the process and the ones that not add value. In the Analyze phase the Value stream mappings was used to identify what were the problem root causes (Figure 8) and solutions (Figure 9) to fix each situation. This phase combines the actual team members of the project with a group of operators that work daily on the packaging lines.

These processes came up with the problems or waste of each activities for a total of 145 root causes; the root causes where prioritized on the ones that had the major impact on time duration and then on high-58, medium-11 or low- 12 for a total 81 causes that need immediate action.

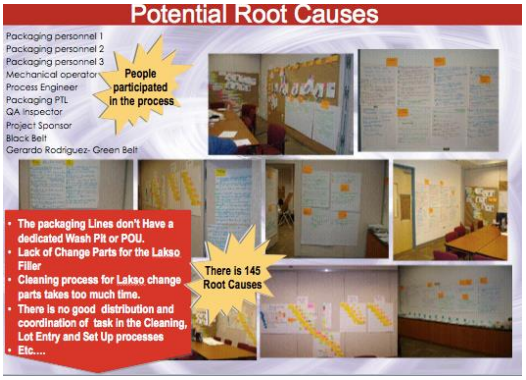

Figure 8
Potential Root Causes

Figure 9
Potential Root Causes

The major offenders on downtime or waste for the changeover process were the lack of availability on wash pits for the packaging lines. This creates a lot of waste for the operators that had to look for water or a place the clean the Filler machine parts. Also it was found that the filler machine need more spare parts availability, because it was taking too much time to wait for the cleaning process of the parts and the approval of the QA Inspector.

Other major problems was the use of mop during minor cleanings, indirect tasks performed by the operator because of lack of knowledge on the work instructions and on overall they had bad distribution and coordination of task in the cleaning, lot entry and setup process.

The Improve phase came up with a great brainstorming of ideas that results on more than 200 possible solutions. The team concentrated on 137

ideas that were prioritized on High- 87, Medium- 15, Low- 16 and Quick Wins- 19. The team completed 96% of all the solution and completed all the ones categorized on high; that was one of the great achieving's on the reduction of the changeover.

The solutions with the major impact on time reduction were the creation of Guidelines Task for the changeover. They were created base on the quantity of operators available between 5-3 operators, the type of cleaning (minor or minor/major) and one guideline for the Process Assistant. That last one was a guideline for preparation before, during & after changeover that will help the Process Assistant be on the expected time duration of the changeover. Each guideline was created like a card that the Process Assistant will distribute between the operators on every shift before the start of the changeover. Figure 10 shows the Guidelines Task.

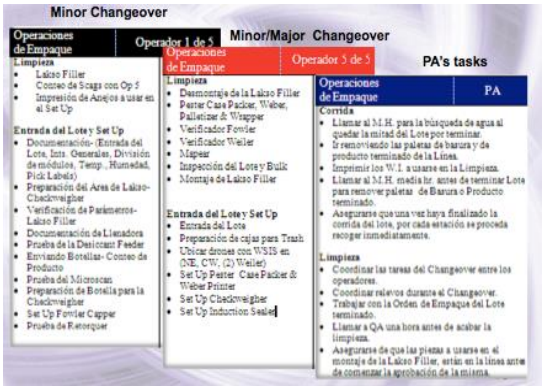

Figure 10
Guidelines Tasks

The Time Study observed some problems that the operators had followings the Work Instructions (WI), for that reason we clarify all the tasks on WI's during the qualification process and made a new revision on some of them. WI's revision on some of them includes: addition of photos of rejects station, equipment's and areas where you have to clean or inspect, removal of instructions related to pick up line side materials, modify cleaning sections in sequential order, among others.

Also the process of Improve achieved the elimination of the use of mops in minor cleanings. This was accomplished by doing an evaluation of different types of mops; considering: supplier, material, result of the cleaning evaluation on the samples, among others. Then the team developed a presentation to the Quality and Manufacturing departments on the results and finally we agreed to eliminate the use of mops and changed it for a Dust Mop that helps us on a reduction on time of 0.5 hr. in the Minor Cleanings.

For the problem of waiting and waste create by the whole changeover process of the Filler Machine, the team came up with good improvements like: having a 2nd set of change parts for the filler, the creation of a new position- Floater Operator: in charge of the cleaning of change parts and the housekeeping of its and finally the wash pit dedicated to the packaging lines. These improvements gave us a reduction of time in 3.5 hr.

Control Phase

As for the final stage of the DMAIC methodology, Control was took very serious because the team did not want that these problems to reaper again. The team started by ensuring that all the procedures involved in this project were corrected and all the personnel involved with it also be trained on them. The team makes sure to run some pilots changeover and documented it, to later explain to the operators how great the accomplishments of achieving the goal on the reduction of time was. So after the pilot runs we start plotting the time of duration on the changeover and share with everybody the result. On Figure 11 & 12 you will see how the results were improving during time.

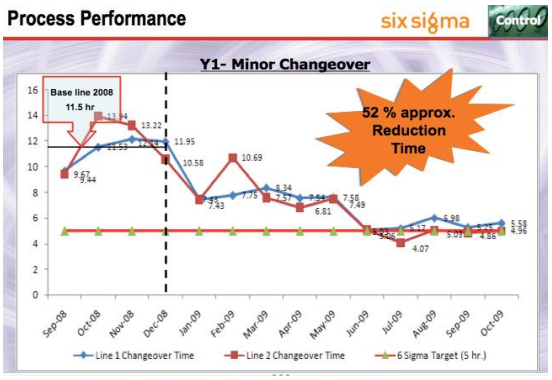

Figure 11
Minor Changeover Time

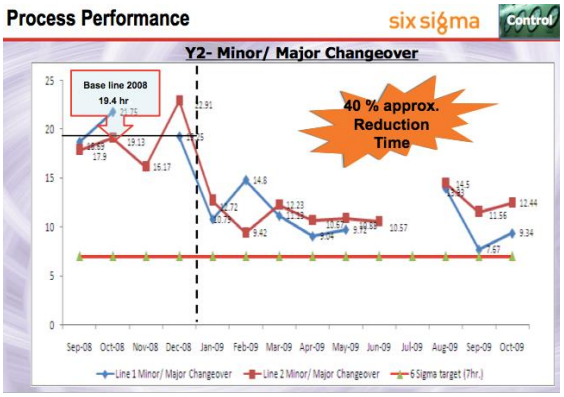

Figure 12
Minor/ Major Changeover Time

CONCLUSION

The result that team were looking did not go exactly as expected; but a reduce of 52% on Minor changeover and 40% on Minor/ Major changeover was achieved. The used of Lean Six Sigma and the DMAIC as systematic approach help us achieving great result on this project. The financial benefit will be directly impacting SAP standard set up time. This benefit will be approximately $305,000 per year (assuming 287 minor cleaning). Also after finished this project the team came up with a scorecard to monitored the process and help our leaders and managers view the behavior of their process on monthly basis. Figure 13 shows the scorecard for the packaging lines.

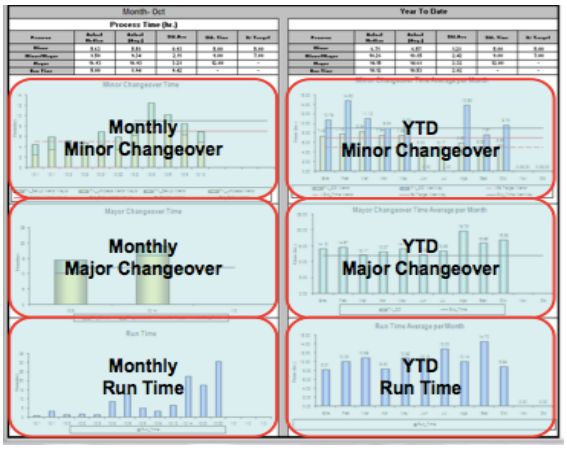

Figure 13
Scorecard Packaging Line Changeover

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