Cost Reduction in a Pharmaceutical Industry: Application of DMAIC Tools to Improve the Preventive Maintenance Process for Effective Job Plans and Maintenance Frequencies

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Abstract —Pharmaceutical Company LCPR is committed to achieve their vision through a cultural adoption of continuous improvement. An opportunity has been identified and is aligned with the company continuous improvement strategy. With the increased emphasis within the pharmaceutical industry on business productivity through the application of Lean Six Sigma (DMAIC Tool – Define, Measure, Analyze, Improve, Control), there is a need to provide a harmonized project for maintenance productivity improvement. Currently, facility technicians in this pharmaceutical industry are highly involved in non-value added activities such as; PMs (preventive maintenances) cancelation, unnecessary tasks within the job plans and there is no proper measurement of the effectiveness of their preventive maintenances (monthly average). There is a significant cost reflected in the direct labor, lower response to manufacturing needs, proactive use of technician labor time and current job plans. *The implementation of DMAIC tool will have impact on labor cost avoidance, cancelled preventive maintenances, current maintenance frequencies and job plans executions.*

Key Terms *– Cost Avoidance, DMAIC, Improvement, Maintenance.*

INTRODUCTION

Pharmaceutical Company LCPR has been in operation in Puerto Rico since the 1960s and has seen many products over the years. As these products have moved in and out of the plant the manufacturing area and equipment maintenance programs has changed. In addition, the plant mission has transitioned to a form/fill/finish site with packaging being moved elsewhere. Regulatory and cGMP (Current Good Manufacturing Practices) expectations have changed and the plant needs to be upgraded in order to continue to meet them.

The company is investing more than $150 million into a major expansion of its manufacturing operations in Puerto Rico including the addition of new equipment.

Although site expansion and new equipment are seen as an opportunity to grow the business worldwide, there are some maintenance concerns related to the effectiveness of equipment preventive maintenances and technicians labor time.

RESEARCH OBJECTIVES

The main objective of this design project is to create a strategy to avoid (cost avoidance) hiring additional resources to support the site preventive maintenance program and improve the job plan executions in order to fulfill the manufacturing demands for the company future growth.

RESEARCH CONTRIBUTIONS

This project supports the Company's goal of operational and continuous excellence by optimizing preventative maintenance measures that can drastically reduce faults in day-to-day operations, as well as increase the overall readiness of the site in case of unexpected levels of processing requirements. Not only does regular maintenance improve and extend the life of the plant by preventing excess impairment, maintenance includes and is not limited to adjustments, cleaning, lubrication, repairs and the replacement of parts. Moreover, having the ability to prevent possible issues from arising in the future and causing downtime will also avoid interference with your ability to deliver a quality product. Through this research paper it is estimated to avoid a $90k annual labor cost related to new resources hiring.

RESEARCH BACKGROUND

Pharmaceutical manufacturers have to ensure that their manufacturing equipment are properly designed, installed, tested, operated and maintained throughout their service lifetime.

During these service lifetimes manufacturing equipment will require preventive and corrective maintenance activities which may involve the replacement of parts within the systems. Equipment parts replacement must be performed under the appropriate change controls to ensure that manufacturing equipment remains in a validated state with respect to installation, operation and performance.

The main focus of Maintenance Department is to provide reliable manufacturing equipment with cost-effective and targeted maintenance.

Therefore, Preventive maintenance (PM) has the following meanings [1]:

- The care and servicing by personnel for the purpose of maintaining equipment and facilities in satisfactory operating condition by providing for systematic inspection, detection, and correction of incipient failures either before they occur or before they develop into major defects.
- Maintenance, including tests, measurements, adjustments, and parts replacement, performed specifically to prevent faults from occurring.

The primary goal of maintenance is to avoid or mitigate the consequences of failure of equipment [2]. This may be by preventing the failure before it actually occur which *Planned Maintenance and Condition Based Maintenance* help to achieve. It is designed to preserve and restore equipment reliability by replacing worn components before they actually fail. Preventive maintenance activities include partial or complete overhauls at specified periods, oil changes, lubrication and so on. In addition, workers can record equipment deterioration so they know to replace or repair worn parts before they cause system failure. The ideal preventive maintenance program would prevent all equipment failure before it occurs.

Figure 1
Preventive Maintenance

An extensive and detailed preventive maintenance program is integral in ensuring facilities operate at peak efficiency. Preventive maintenance not only helps managers reduce the frequency of equipment replacement and expensive repairs. It also minimizes occupant complaints and increases building efficiency.

Typically, departments should maintain building systems on a seasonal, monthly, or annual basis, depending on the type of equipment.

Managers should develop schedules designating the number of hours technicians need to perform maintenance tasks, the individual assigned to each task, the frequency of maintenance, and steps technicians can take to properly complete each task.

Managers can use a spreadsheet to develop these schedules for technicians, or they can use a computerized maintenance management system (such as Maximo) that issues maintenance requests at set frequencies, provides the equipment's maintenance history, and holds the staff accountable for completing assigned tasks.

Establishing a preventive maintenance program can ensure equipment is more efficient, which will reduce utility costs and extend the equipment's performance life.

Many people see the maintenance function as an expense and it is often one of the first departments to suffer from cuts when times become difficult, however this is very much false economy as the money spent on preventing problems from occurring will almost always be far less than the costs you will incur due to actual failures. However it is often difficult to justify "just in case" expenditure and it is all too easy to hide the costs of failure in a multitude of places within the budget.

Preventive maintenance can be divided into three subgroups:

- Planned maintenance,
- Condition-based maintenance and
- Predictive Maintenance

The main difference of subgroups is determination of maintenance time, or determination of moment when maintenance should be performed.

While preventive maintenance is generally considered to be worthwhile, there are risks such as equipment failure or human error involved when performing preventive maintenance, just as in any maintenance operation.

Subgroups can be explained as follows:

Table 1
Maintenance Classifications

Planned maintenance
Variety of scheduled maintenance to an object or item of equipment. Specifically, Planned Maintenance is a scheduled service visit carried out by a competent and suitable agent, to ensure that an item of equipment is operating correctly and to therefore avoid any unscheduled breakdown and downtime. Planned maintenance comprises preventive maintenance, in which the maintenance event is preplanned, and all future maintenance is preprogrammed. It is created for every item separately according to manufacturer's recommendation or legislation.
Condition-based maintenance (CBM)
It is maintenance when need arises. This maintenance is performed after one or more indicators show that equipment is going to fail or that equipment performance is deteriorating. This concept is applicable to mission critical systems that incorporate active redundancy and fault reporting. It is also applicable to non-mission critical systems that lack redundancy and fault reporting. Condition-based maintenance was introduced to try to maintain the correct equipment at the right time. CBM is based on using real-time data to prioritize and optimize maintenance resources. Observing the state of the system is known as condition monitoring.
Predictive Maintenance
Uses various predictive maintenance tools such as thermal imaging and vibration analysis to predict when a breakdown is going to occur by identifying wear. This can lead to components being used for far longer periods rather than just being replaced at each service whether they need to be replaced or not.

PROJECT DESCRIPTION

The main focus of this project is to systematically improve the preventive maintenance process including effective job plan assignment and maintenance frequencies.

Lean Six Sigma DMAIC methodology [3] may be used as an approach to achieve the improvement goal. DMAIC is used for projects aimed at improving an existing business process. The DMAIC project methodology has five phases:

1. <u>Define</u> the system, the voice of the customer and their requirements, and the project goals, specifically. Establish the objectives of the department and identify the critical-for-quality processes. In this phase, leaders, planners, maintenance staff, Black Belts, and Green Belts need to work together to set departments goals.
2. <u>Measure</u> key aspects of the current process and collect relevant data. The indexes, data collection plan, and analysis method can be chosen. Some common indexes include frequency of preventive maintenance,

frequency of predictive maintenance, productivity, number of corrective occurrences, maintenance costs, downtime, pulse survey, overall equipment effectiveness (OEE), etc

3. Analyze the data to investigate and verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered. Seek out root cause of the defect under investigation. Teams will use analysis graphs (Pareto, scatter, run chart, box plots, etc.) to visualize trends and to search for root causes.
4. Improve or optimize the current process based upon data analysis using techniques such as design of experiments, poka yoke or mistake proofing, and standard work to create a new, future state process. An action plan and failure mode and effects analysis (FMEA) can help in the action definition to improve the performance of the chosen indexes.
5. Control the future state process to ensure that any deviations from the target are corrected before they result in defects. Implement control systems such as maintenance boards, visual workplaces, and continuously monitor the process. Teams will outline a plan to retain the gains after the conclusion of the project. The finance department can assist in investment calculations, profits, Return on investment, etc.

Figure 2
Understanding DMAIC Cycle

Implementation of the DMAIC methodology will also upgrade to the company's preventive maintenance program, which ultimately led to:

- Recurrent cancel WOs which results on non value added tasks spent by the mechanic to close the documentation.
- 2.5 hours spent by technicians during Cancel Work Orders,
- Excess of documentation and signatures to close work orders,
- Preventive maintenance frequencies has not been revised on the past 2 years and
- 2.23 hours spent by each mechanic on corrective maintenance activities.
- Incorrect job plan instructions

The following graph shows the schedule of the project.

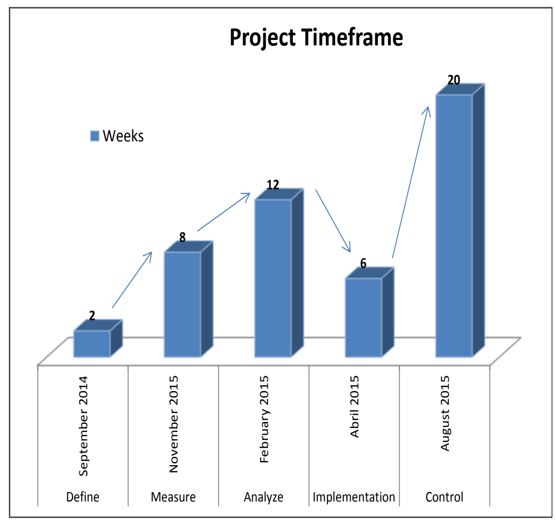

Figure 3
Project Scheduling

RESEARCH RESULTS

Pharmaceutical Company LCPR applied the DMAIC methodology as follows:

- DEFINE: Project Charter was submitted to establish project goal details, start/end dates and expected business results.

A SIPOC diagram (acronym SIPOC stands for suppliers, inputs, process, outputs, and customers) was used by the team to identify all relevant elements of the maintenance process improvement project before work begins.

A Critical to Quality (CTQ) Tree was created to give a visual layout of what a customer expects for a product, what their needs and interests are for that product. For this project our product is the maintenance process. Our customer is the manufacturing process.

PROJECT CHARTER

PROJECT DETAILS			
Project Leader: Edwin Nieves	Sponsor: Facilities Manager		
PROJECT DESCRIPTION/STATEMENT	**Description:** Preventive Maintenance Optimization **Statement:** This project is aimed to systematically improve the preventive maintenance process for effective job plans and maintenance frequencies.		
BUSINESS CASE	Currently, technical facilities are highly involved in non-value added activities such as 70 cancel PMs, unnecessary task within the 1,506 job plans and there is no proper measurement of the effectiveness of 872 preventive maintenances(monthly average). Based on the Pharmaceutical Company LCPR True North, we have committed to achieve our vision through a cultural adoption of continuous improvement. This opportunity is aligned with the company continuous improvement strategy.		
SCOPE	Start: 09/01/14 Stop: 08/2015	**Scope:** Job Plan Executions, Preventive Maintenances **Out of Scope:** Corrective Maintenances, Preventive Maintenances with frequencies > 1 yr, PM's for Equipments with High CM rates	
PROJECT GOALS	METRIC	BASELINE	GOAL
Labor Efficiency	Cancel PMs	182 cancel WOs from 2014	100% Reduction
	PMs Frequencies	9,682 PM's/yr	↓10%
	Cost Avoidance	12 Technicians	10 Technicians
EXPECTED BUSSINESS RESULTS	Labor Cost Avoidance of $90k, Faster Response to Manufacturing Needs, Proactive Use of Technician Labor Time, and Optimization of current PM job plans.		

Figure 4
Project Charter

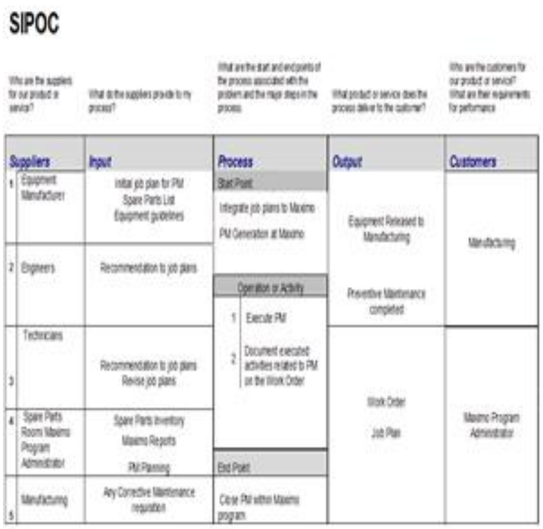

Figure 5
SIPOC

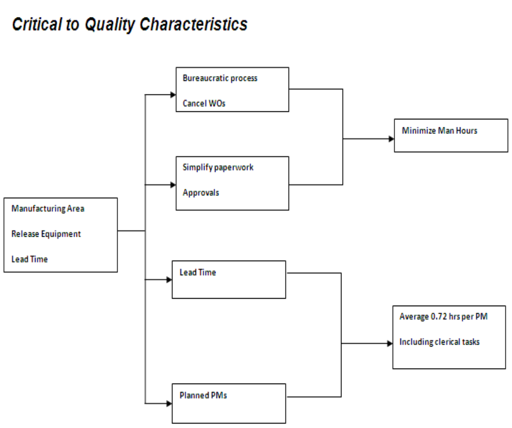

Figure 6
Critical-To-Quality Tree

- MEASURE: Establish current baselines as the basis for improvement. Data was collected to create a process baseline for the project metric.

Preventive maintenances breakdown was identified for each technician; a total of 1,506 PMs were identified excluding PM > 1 year frequency.

Process mapping was performed to understand the following steps within the maintenance process:

- Purchased Equipment entering to the company
- Job Plan generation for new equipment
- PM execution and closing

182 Cancel PMs were accounted for year 2014; root cause for these cancel PMs were identified as Equipment Pending Validation, Out of Service, Job plans not adequate and Obsolete Equipment. Due to the signature approvals (five approvers) for cancelling PMs it was measured that the technician is involve 21% of his productivity in this non-value task.

This means an average of 2.5 hours per cancel PM.

Note: This Company applies planned maintenances.

- ANALYZE: Preventive maintenance frequencies and job plan details (technician work instructions) are being analyzed.
  PM Frequencies Current State most significant data is as follows:

Table 2
Frequency Current Sate

PM Frequency	PM Quantity
7 days	45
14 days	11
30 days	400
60 days	61
90 days	216
180 days	389

172 preventive maintenances frequencies were identified for improvement based on low or zero corrective maintenance and equipment criticality during the past two (2) years. Some equipment will be included in a Conditioned-based maintenance (CBM) and were considered as part of this analysis.

Table 3
Annual Reduction

Quantity of Job Plan Frequencies Identified for Improvement	Annual % Reduction	Current Annual PMs	Proposed Annual PMs (including CBMs)
172	13 %	9682	8493

As part of this Analyze step, seventy (70) PMs with a frequency of 30 days can be change from planned maintenance to conditioned - based maintenance (CBM).

Therefore, maintain the correct equipment at the right time.

- IMPROVE
  Consider the following implementations as part of the improve phase:
  - Submit changes to modify the frequencies of 172 PMs.
  - Submit documentation evidence to update or remove the 182 cancelled PMs.
  - Revise Preventive Maintenance procedure to include the modifications related to technician work instructions.
  - Revise Engineering Procedures to modify the instructions to engineers when purchasing and evaluating new equipment.
  - Create a procedure to monitor the corrective maintenances quarterly and considering the usage of CBMs.
- CONTROL
  In the final phase of the project, the Pharmaceutical Company LCPR monitored all actions taken to ensure that the process put in place is fully implemented by all members of the Maintenance and Engineering Department. Continuous Improvement and Follow-up Maintenance meetings should be establish to keep track of work-order flow, preventive maintenance scheduling, asset histories, corrective maintenances, cancelled PMs, quality issues from equipment and budget control.

CONCLUSIONS

The DMAIC-based strategic plan would optimize the Pharmaceutical Company LCPR preventive maintenance process and assured high yields with minimal losses. Implementing Six Sigma in the pharmaceutical engineering field means more than simply delivering defect-free product. It also entails providing safe, effective and reliable medicines that is able to contribute to the overall improvement of quality patient care.

The DMAIC project consisted of improving operating processes while integrating current statistical control over input and output variables. These improvements enabled the company to maximize the equipment uptime and optimize the overall preventive maintenance schedule.

Base on the analysis we can concluded that the application of DMAIC methodology within the maintenance program would result in a 13% reduction of labor time for the maintenance personnel; therefore, avoid an estimated $90k annual labor cost related to new resources hiring.

ACKNOWLEDGEMENTS

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