Medical Device Quality Control Testing Process Time Reduction

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Abstract

A Medical Device Company has paid on overtime labor hours the processing of raw materials quality control testing due to inefficient process requirements thus impacting costs on product. The raw material purchasing is performed in small batches due to Supplier Company limitations, nevertheless Medical Device Company have a larger demand on these raw materials and must purchase those small lots more frequently per month. Improvements on QC testing process will be possible with the purchase of bigger lot sizes of each raw materials, elimination of non-value-added activities that will result in a decrease in the total hours of labor and reduce incoming testing for raw materials that will decrease the total labor cost incurred at Main QC Laboratory. These improvements will allow a work standardization on Main QC laboratory that is expected to have a positive impact on productivity and will reduce Quality Notifications, Out of Specification and human errors.

Introduction

The testing process begins with the incoming process of reagents and antibiotic raw materials. Raw material entrance confirmation in the SAP System by the Warehouse associate. Then, QC Technicians perform the required testing to assure that the raw materials meet its specifications. These testing include the verification of specific characteristics. These testing requirements have been met with overtime hours of labor that can reach up to 752 hours per year to meet demand. Also, due to the rigorous testing and processing, seventy-two (72) cases of OOS investigations were generated. Some of those testing processes are not necessary and clearly can be eliminated in order to reduce the time invested. Reducing the Testing time would directly translate to an optimization QC Testing process and documentation. The elimination of a non-value-added testing would result in a reduction of Main QC Laboratory total hours. Would also have an impact on the total costs incurred in the Medical Device Company.

The basic properties of the raw materials are guaranteed by material vendors who provide certificate of analysis, compliance and test results. Nevertheless, it is still necessary to conduct incoming inspections by manufacturer to assure the quality was not affected during transportation or handling of the material [1]. QC encompasses all of the processes and activities that ensure adequate quality in the finished product from receipt of materials through joint manufacture to final product test [2]. Some of the incoming testing are indispensable and it was found that some of testing process are not required to be performed in-house if the CoA is provided by the supplier. Improvements will affect as follows:

Quality: The quality of the raw material will not be affected by the reduction on incoming tests. Reduce Risk of human errors.

Cost: The procurement of Purchase of bigger lot sizes for each raw material batch each month will allow the reduction in testing and a reduction on cost related to overtime.

Time: The reduction in the number of tests will decrease the time required to process the tests and the time required to document tests results.

Table 1. Project Charter.

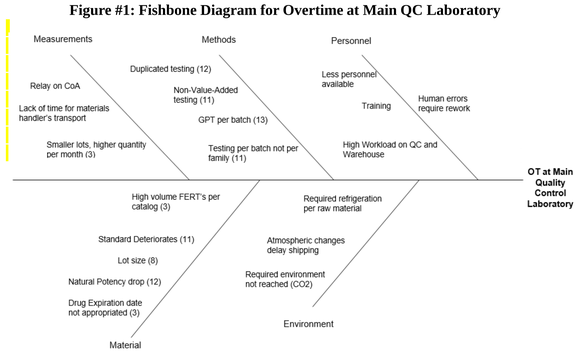
Problem Statement		
Currently at Medical Device company, the QC Testing is inefficient and use a large percentage of testing hours. Those QC Testing process imply on an overtime of 752 hours per year to meet demand and has 72 Out of Specifications.		
Project Scope		
In Scope: Incoming Antibiotics and/or Reagents in process and stability.	**Out of Scope:** Other QC Testing processes.	
Goal Statement	**Actual**	**Project Goals**
Reducing the Testing time would directly translate to an optimization QC Testing process and documentation. The elimination of a non-value-added testing and a reduction of Main QC Laboratory total hours. Would also have an impact in the total costs incurred in of this Department. With these process improvements, we expect to create a standard work to prevent/reduce Quality Notifications and OOS on Finished Product.	Raw Material = 104 lots per year. Non Value Testing = 144 hours #FERTS lots = 800 per year Bauer-Kirby = 202 hours	Raw Material = 63 lots per year. Non Value Testing = none #FERTS lots = 100 per year Bauer-Kirby = none
	Estimated labor hour savings short term could be up to 839 hours vs target savings of 375 overtime hours.	

Project Team	Project Milestones Schedule		
	Milestones	**Scheduled**	**Actual**
Champion	Define	1/19/18-3/21/18	1/19/18-3/21/18
Blitz Team Leader Facilitator			
Quality System Specialist at QC Lab	Measure	3/23/18-4/30/18	3/23/18-4/30/18
Staff Quality System Specialist QA			
Quality Technicians	Analyze	4/30/18-6/1/18	4/30/18-7/17/18
Quality Specialist			
Scientist II	Improve	7/31/18-8/1/18	7/30/18 – 8/13/18
Continuous Improvement Manager			
Planner/Buyer	Control	9/30/18-10/01/18	8/14/18---
Coord 3 Quality Document Systems			

Methodology

In order to achieve project expectations, a systematic method as DMAIC will be implementing to carry out the improvement efforts. Each topic has been evaluated through a fishbone diagram in order to determine the problem and goals effectively as: the actual testing hours invested for each QC test of each raw material, the identification of those non-added value tests, tasks that could be standardize, process to be optimized and all those important points that could be improved the Main QC laboratory.

Figure #1: Fishbone Diagram for Overtime at Main QC Laboratory



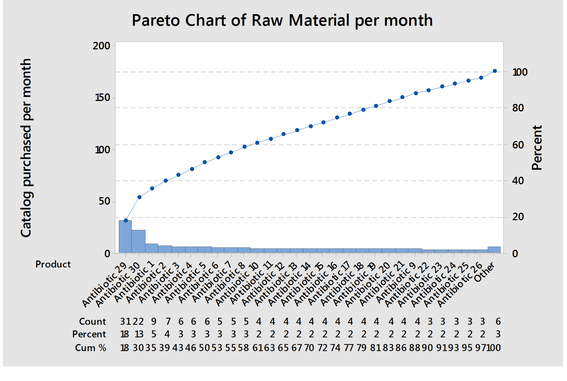
Working with Control Quality Technician, each Incoming testing to be removed was identified and report their testing process time.

Table 2.
Testing Process to be Removed from Routine Incoming Inspections with Their Respective Time

Testing process	Time invested in hours
pH	0.33
Ultra Violet Spectrum	0.25
Visible spectrum	0.25
Halide Test	0.12
Alkali Test	0.12
Loss on Drying	24.58
Purity (HPLC)	3.00
Melting Point	0.10
Sulfate Test	0.22
Boiling Point	0.50
Specific Gravity	0.50
Moisture	0.25
Acetate Test	0.03
Phosphate Test	0.10
Nitrite Test	0.17
Biological Test	0.75
Spot Test	0.08
Citrate Test	0.10
Hydroxide Test	0.03
Residues Test	0.17
Sulfathiazole Test	0.03
Tetracycline Test	0.08
Metal Particles	0.10
Potassium Test	0.03
Total hours	**31.89 hours**

The most requested raw materials shown in Figure #2 reports the frequency of purchasing for each raw material per month of the 30 Antibiotics most purchased on the Medical Device Company.

Figure #2: Pareto Chart of Raw Material purchased per month



Results and Discussion

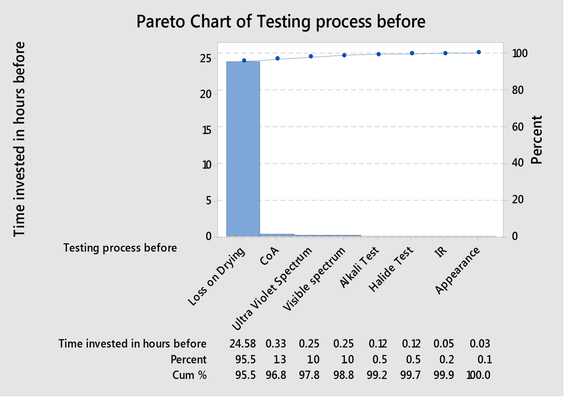
Overall results for time reduction from the improvement implementation are Shown on Table: 3. Results were divided per topic: Incoming testing shows 426.88 hours reduced, with each non-value-added testing removed, acceptance of CoA and the testing reduction per lot size. Elimination of the Growth Promotion test were evaluated of 10 years ago and have shown no failures to date and contribute to 251 hours reduction. Evaluation of QN's, OOS and Human Errors results in a reduction of 202hours.

Table 3
Reduction in Hours Results from the Improvement Implementation

Improvement	Hours of reduction
Incoming Test Total reduced hours = **426.88 hours.**	
Order less raw material lots with a bigger size.	**175 hours.**
Sister Plant CoA	**24 hours.**
Testing removed	**227.88 hours**
Potency Total reduced hours = **251 hours.**	
Elimination of GPT	**251 hours.**
QN's / OOS and Human Errors = **202 hours**	
QN's	Total of **202 hours** saved per year
OOS	
Human Errors	
Total hours reduced = 879.88 hours	

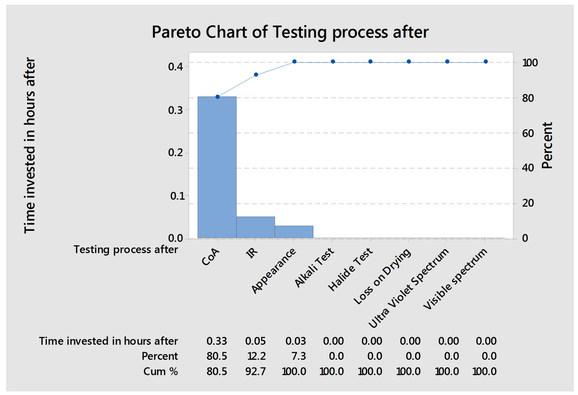
Analyzing reduction testing process of one family of Antibiotic #1 that required testing as: Ultraviolet Spectrum = 0.25 hours, Visible Spectrum = 0.25 hours, Halide Test = 0.12 hours, Alkali Test = 0.12 hours, and Loss on Drying = 24.58 hours the final test. Collaborates to 25.32 hours of reductions. This Antibiotic was tested 9 times a month resulting in a 227.88 hours of testing per month and an overtime of 67.88 hours for a regular hourly employee. Each raw material represents a different amount hour of testing reduction.

Figure #3: Time to process Antibiotic #1 before implementation of the project



Results and Discussion

Figure #4: Time to process Antibiotic #1 after implementation of the project



Conclusions

Based on all the data assessed, the implementation of a standardization process as well as the reduction in non-value-added activities starting with the incoming process, has reported great savings in man-hours, and increased productivity. Also, the results obtained lead to a better response of the analysts since they can apply their knowledge in other quality control projects for cost-saving, cost-avoidance, increase productivity even further, and supply the release materials to the Product Department on time, every time.

This project enters into the Control Phase. Lean manufacturing methodology will be used to monitor the implementation effectiveness and determine further actions to stream line even more. Also, job standards need to be implemented to ensure that the tests are performed as designed in this project. Learning curve have been established to monitor the results, obtain Voice of the Customer after implementation and assess process quality to assure its critical attributes do not change over time.

Future Work

- Monitoring purchasing frequency of Antibiotics and control orders per month.
- Communication and negotiations with supplier to reduce cost per raw material.
- Monitoring Quality Control Incoming testing to update Inspection plan in System according to the Change Control.
- Analyze each High Runner Antibiotic testing time, Before and after the implementation of changes.
- Monitoring Testing time reduction and analyze possible improvements.
- Monitoring Out Of Specifications and Quality Notifications numbers after the implementation.

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References

[1] C. F. C. J. Dominique K. Numakura, Quality Assurance of flexible circuits, Haverhill, Massachusetts: McGraw-Hill Professional, 2008.
[2] E. M. Petrie, Handbook of Adhesives and Sealants, Second Edition. Quality Control, Nondestructive Testing, and Failure Analysis, McGraw-Hill Professional, 2007.