Medical Device Quality Control Testing Process Time Reduction

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Abstract *— A Medical Device Company has paid, in overtime labor hours for processing raw materials and 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 which is expecting to have a positive impact on productivity and will reduce Quality Notifications, Out of Specification and human errors.*

Key Terms *— Certificate of Analysis (CoA), Out Of Specifications (OOS), Quality Control (QC), Quality Notification (QN).*

PROBLEM STATEMENT

The testing process at the Medical Device Company begins with the incoming process of reagents and antibiotic raw materials. This process consists in 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 such as appearance, potency, and specific attributes of the raw material. Since there are 211 catalogs of raw materials bought by family, the QC testing steps have an impact on the time spent on each raw material in the Main QC Laboratory. Due to these requirements, the raw materials are not released for use on time to meet customer requirements, thus incrementing the backorders of the products in Product Department. 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. With these process improvements, we expect to create a standard work to prevent and reduce QN and OOS on Finished Product.

DESCRIPTION

The Quality Department process requires the raw materials to be released in order to use them for products manufacture. All the raw materials have to pass the quality control test in order to be released for use in manufacturing. These raw materials are supplied by the Vendor with either CoA or specific tests results that ensure that the material met the specifications during its manufacturing. Once the raw materials are received in the Medical Device Company, these raw materials undergo a full quality control testing that may include tests already performed by the Vendor. These materials also have the COA and/or specific tests certificate when arrive at the Medical Device Company. The materials testing also required a lot of documentation, which is based on the quantity of

tests that are required, are prone to errors, thus impacting negatively the OOS and QN metrics. Process improvement project was put into action to implement a new quality control test requirement by eliminating non-value-added activities and redundant tests in order to optimize the QC Testing process and all the documentation that it involved.

Objectives

The *Medical Device Quality Control Testing Process Time Reduction Project* targets the optimization of the QC Testing process and documentation that lead to the elimination of non-value-added testing that will reflect in the reduction of approximately 839 hours on the overall QC testing process time for raw materials of this specific product, a reduction on QN and OOS reports on Finished Product and also have an impact in the total costs incurred at Main QC Lab.
Expectations: reduce workload, no compromise of quality, challenge everything, risk-based changes, material testing, relay on CoA and scale lot sizes.

Contributions

Quality: The quality of the raw material will not be affected by the reduction on incoming tests. The raw materials are already tested at vendor site, who provides documented evidence on the tests results. 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. Also, since the tests are to be streamlined, an optimized process and a standardized work will be implemented to document revised process, reduce overtime, and optimize sampling.

LITERATURE REVIEW

Medical Device Company use a specific amount of raw materials in the manufacturing and assembly of the finished product. 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].

Raw materials are verified with incoming inspections plan performed in-house. These inspections are performed to corroborate if the raw material comply with the quality specifications and requirements to begin the manufacturing process. Specifications are intended to define and communicate what is needed for all parties involved [2].

Usually, the testing process time vary depending on the tests required for each raw material. The tests should be those that can quickly and accurately detect deficiencies in the materials specified physical or chemical properties or differences from lot to lot [2]. Some of the incoming testing are indispensable as: pH, Appearance, Potency, and Infrared Spectrum, among others. It was found that some of testing process like Alkali Metal test, Halide Test, Solubility, Melting Point among others, are not required to be performed in-house if the CoA is provided by the supplier. Once the CoA for raw-materials are accepted and those testing duplications are eliminated, QC Technician could apply their time on other important activities and increase the efficiency on Main QC laboratory. The process improvements identified, once implemented, will have an impact in the total costs of QC Testing at Main QC Laboratory and will allow the work standardization and prevent any QN's and OOS.

At this moment the Main QC Laboratory spend approximately 752 hours per year to satisfy the Antibiotics and Reagents testing demand.

The overtime is a result from diverse reasons as:

- Incoming Testing of each purchased raw material lost. Company used to purchase many small lots instead of bigger lots of the same raw material.
- Testing performed on raw material purchased from Sister Plants (Duplication of testing).
- Performing tests that have been already performed by the supplier.
- Time on handling raw materials on manufacturing process.
- Performing tests to reliable characteristics that have never failed for the past 10 years.

Some of the testing mentioned previously are not necessary based on redundancy, and can be eliminated to reduce the time, cost and release cycle time to manufacturing department. If the purchase process changes from small lot of raw material to larger lot size, incoming testing time could be reduced to approximately 301 hours out of 752 total hours. Some of the testing that could be eliminated are those performed to the raw materials that come from Sister Plant and have the CoA available. It is also possible to reduce time with the elimination of all non-value-added testing performed by the vendor which also contains a CoA. The historical data showed that some raw materials testing have never failed in the last 10 years, concluding that the material purchased is reliable and comply with the quality specifications. For this project to be implemented successfully, there is other data that need to be assessed in deep such as number of complaints that may be related to raw materials, amount of OOS's and QN's that have raw material as a root cause. This data has not been analyzed at the time this document is released but is in schedule prior to implementation of these initiatives.

Testing reduction directly translates to a process optimization of the Main QC Laboratory and will have an impact on the total costs incurred at the Quality department. By the implementation and maintenance of DMAIC methodology, potential waste related with not necessary testing could be eliminated and reduced to a minimum. This process will generate an estimated labor hour savings pursued short term could be up to 839 hours vs. target savings of 375 overtime hours.

PROJECT METHODOLOGY

In order to achieve project expectations, a systematic method as DMAIC will be implemented to carry out the improvement efforts. The DMAIC methodology is a powerful five-phase approach to addressing a process that needs improvement and this approach allows flexibility in the structure [3]. This approach which stands for Define, Measure, Analyze, Improve and Control will provide the guidance to identify inefficiencies and waste in all testing processes, addressing speed and quality with an accuracy method. Each phase has certain techniques that will help to determine each feature to improve and will comply with the objectives of the project as follow:

Define Phase will study and identify each topics to be evaluated in order to define 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. Define phase use some techniques as Project Charter that helps the organization to avoid projects that deal with unimportant issues, overlap or conflict with other project objectives, target soon-to-be-obsolete processes or products, have poorly defined or overwhelming scope, study symptoms instead of root causes, provide poorly defined deliverables, and lack management authority and responsibility [4].

Measure Phase will determine key steps to proceed with meetings that will create Change Control with spreadsheets and time measure in order to track the changes throughout the implementation of changes. Techniques that would help are: Critical to Quality Identification (CTQ Metrics), process map and statistical process control (SPC). The personnel responsible for

implementing the process on a daily basis should be enlisted to develop the detailed process map [4].

Analyze Phase: Once the problem or the element to be improve has been identified, the Analyze Phase will evaluate those spreadsheets and time process for the raw materials, possible cause and effect related to QN and OOS reported and all those testing that could be eliminated without affecting product quality. It could be use techniques like: Value Stream Analysis, Quality function deployment (QFD), Cause and Effect Diagram, Pareto Analysis and reducing or eliminating Non-Value-Added cycle times that often provides the clearest and easiest methods to reduce cycle time and achieve better time [4].

Improve Phase implement all the changes determined in the previous phase in order to have a significant improvement in the time invested on QC Testing process. Defining and redefine the new process and practices to replace the current one, standardize and remove unnecessary testing process. Improve phase will compare techniques from the measure stage as CTQ metrics.

Control Phase will maintain those changes implemented in order to comply with new requirements and control the results expected. Techniques to implement are: work instructions, flowcharts, and process maps that will be used to document process procedures and responsibilities. [4].

RESULTS AND DISCUSSION

Each topic has been evaluated through a fishbone diagram in order to determine the problem and goals effectively **(Figure 1)** 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.

Incoming inspections of raw materials of Antibiotics and Reagents are performed to corroborate the characteristics and specifications of the materials to be use on manufacturing of Product, even though are not requirements that affect final product specifications. Actual Incoming testing hours invested on each raw material are creating an excess cost on Main QC Laboratory Department. The majority of the test are included in the CoA, we analyzed those testing that are critical and those that can be improve without affecting product quality to reduce workload. The critical testing identified on **Table 1** as: Appearance, CoA verification, InfraRed spectrum (IR) or Optical Rotation (OR or specific rotation) and Potency calculation (if applicable). It was determined to maintain these critical tests only for routine incoming testing. All the testing identified and shown on **Table 2** were determined to be removed as part of the evaluation of historical QN data for the past three years that shown no QN's related to Antibiotics and Reagent.

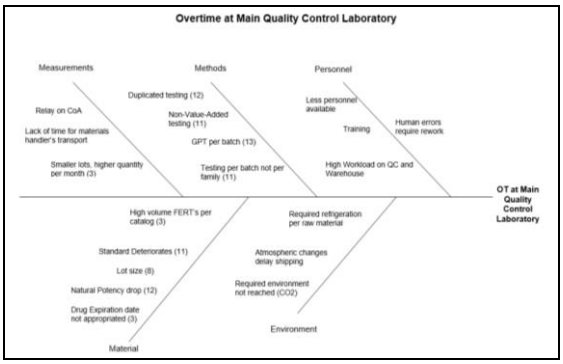

Figure 1
Fishbone Diagram for Overtime at Main QC Laboratory

Table 1
Critical Tests Characteristics

Test	Description
Appearance	Condition and the visual characteristics that identify the material.
Certificate of Analysis (CoA)	Provided by supplier per batch. Shows their results certifying the physical and/or chemical characteristics of the material.
InfraRed Spectrum (IR) or Optical Rotation (OR)	Identification test to verify the material compares to the approved as per established standard for the material.
Potency	Assay provided by the supplier in CoA. Potency is calculated as needed and verified for each Antibiotic/Reagent received.

Implementation of these changes will be specified on the current Antibiotics and Reagents QC Handling documents and each Inspection plans on system. The individual incoming testing procedures of each raw materials will remain with all the characteristics in order to be used as reference for any Change Control or additional testing required for further purposes. The inspection plans on system will show all the removed testing as alternative test for reference on testing required for further purposes and if changes on supplier occurs.

To accomplish a significant reduction on working hours by the elimination of the non-critical testing or non-value-added testing, was determined by the Team analyzing CoA, QN's, OOS and human errors reported for the past three years (see **Table 2)**. Working with Control Quality Technician, each Incoming testing to be removed was identified and report their testing process time **(See Figure 2)**. Each raw material of Antibiotic/Reagent has their unique characteristic thus, the testing reported on **Table 2** will not represent specifications of each raw materials, it reports those testing that will be eliminated from Main QC Laboratory as per each raw, as applicable. The elimination of the incoming testing will contribute to a reduction of approximately 31.9 hours of the QC technician on the performance of the incoming test per each raw material that required them.

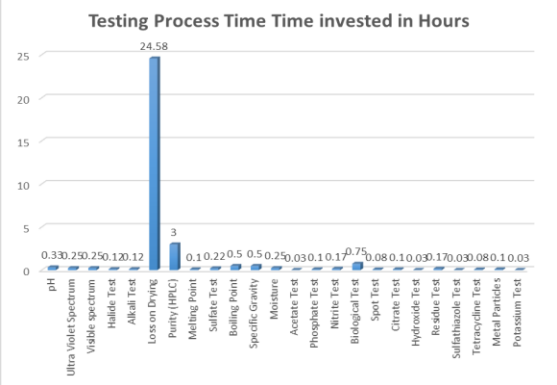

Figure 2
Graph of Testing Process Time Invested in Hours

These testing only apply to those raw materials that has those characteristics and were performed every time that raw material was purchased during the month. Previously, depends on the circumstances, raw materials were purchased 9 times during the month. Each time the raw material was received by Warehouse Department, QC Technician performed the incoming testing that the Inspection plan on system required for each raw material. With the implementation of the elimination on testing, this Incoming Testing process will be reduced.

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**

** Sampling is dried under oven for 24 hours before process the weighing measurements and reach results.*

In addition to the tests to be removed reported on **Table 2**, was decided to remove the Growth Promotion Test. This test is performed to verify the

capability of Dried Culture Media against selected microorganisms. It was implemented 10 years ago and have shown no failures to date. This test is performed on all batches of Dried Culture Media received from Sisters Plant sites with their respective CoA. The test takes a total of 36 hours to results and requires 1 to 3 organisms per lot. Its elimination will contribute to an overall 251 hours for Product Potency testing.

Some of the improvements to be made, imply on communication and negotiations between the Medical Device Company and the Antibiotic/ Reagent Supplier Company. In the past years, the Supplier Company manufactured small batches of Antibiotic/ Reagents catalogs because they have only two buyers for that products. That's why, on a month, some raw materials were purchased more than 9 times. This represent a problem for the Medical Device Company as the Antibiotic/Reagents demand increased. Team determined to reduce the purchased frequency of raw materials and negotiate with the Supplier to purchase bigger size lot. Pharmacy agrees with new purchasing needs to supply the amount per material per month. It was defined that raw materials classified as high runner for the Medical Device Company, will be modified on lot size. Medical Device catalog as high runners those Antibiotic/Reagents that have greater demand. Were identified the following High Runners: Antibiotic 29, Antibiotic 30, Antibiotic 1, Antibiotic 2, Antibiotic 3, Antibiotic 4 and Antibiotic 5 as depicted in **Figure 3**. For this confidentiality and security purposes, each raw material name was replaced for "Antibiotic Number". The most requested raw materials shown in **Figure 3** reports the frequency of purchasing for each raw material per month of the 30 Antibiotics most purchased on the Medical Device Company. Improvement implemented demonstrate a reduction on the frequency of purchasing per year and a cost reduction. Supplier Company agreed to manufacture those High Runners Antibiotic/ Reagents on lots with bigger size with a minimum increment of the price. On the past purchasing the cost per month of 9 small lots, results on approximately the same price of one bigger size lot per month.

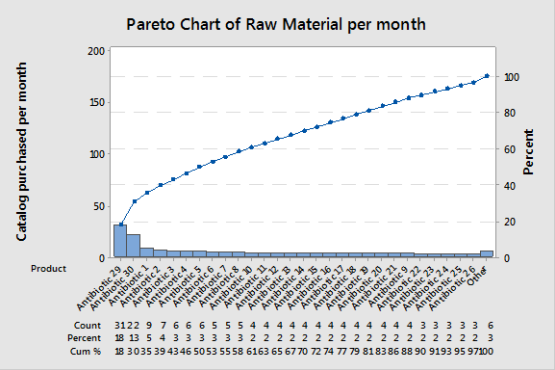

Figure 3
Pareto Chart of Raw Material Purchased per Month

Lot size increase with a reduction of purchasing contribute on savings for the Medical Device Company. Implementing lot size reduction not necessarily resulted on monetary savings. The majority saving will be reflected on the incoming testing that only be performed once a month instead of nine times a month also all the waste that imply for each incoming test. Analyzing reduction testing process of one family of **Antibiotic #1** that required testing as: Ultraviolet Spectrum = 0.25hours, 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.

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.	In the past, per month was ordered 104 lots, in the present are ordered 42 lots per month was reduced= **175 hours.**
Sister Plant CoA	Stop testing Sister Plants receipts due to a duplication and CoA. Hours reduced = **24 hours**.
Testing removed	Supplier/ vendor performed test on CoA. Hours reduced = **227.88 hours**
Potency Total reduced hours = **251 hours.**	
Elimination of GPT	Shown 10 years of non-failure to date. Test require 36 hours for results per batch for a total reduced hour of **101 hours.** The reduction of the duplicate testing of Sister Plants and minimizing the purchased of catalog. Total hours reduced are **150 hours**.
QN's / OOS and Human Errors = **202 hours**	
QN's	Were reviewed 2 years and only 1 OOS of stability with complaint but not on same batch, no other QN's or complaints were found. Change the stability protocol per Antibiotic family, result 1 per year based on QN's, OOS, Complaints. Include reflex procedure if a product fails to run a small product panel to show it was product and not drug related. Total of **202 hours** saved per year
OOS	
Human Errors	
Total hours reduced = 879.88 hours	

One of the topics that where considered during the implementation of these changes was the effect on sampling. With a bigger size lot, the sampling must be proportional. On Antibiotic/Reagent raw material, incoming testing will only require 200miligrams. No matter the lot size, sampling will be 200 milligrams. This sampling is used to perform all the required incoming testing to determine if that drug have the characteristics for the manufacturing of the final product on manufacturing area. The sampling milligrams that was not used during the testing process, must be saved with all the raw materials required conditions until the expiration date for further testing purposes if needs. In the manufacturing department for the final product could present problems, the sampling on the incoming testing serve to discard that the Antibiotic/Reagent represent the cause of that issue.

CONCLUSION

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.

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