Material Qualification Process Improvement to Reduce the Cycle Time

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Abstract — *This project was focused in improving the material qualification process, reducing the cycle time. A Documentation Checklist and Tracking Sheet System were created as part of the improvements. The Documentation Checklist is a checklist to request all the information required from the vendor and the company to complete all the material qualification documentation. The Tracking Sheet System is to know the status of the material qualification activities. The improvements were made using a combination of DMAIC and Kaizen methodologies. DMAIC is an acronym for a series of step used to measure defects in business process and improve profitability. DMAIC stands for Define, Measure, Analyze, Improve, and Control. DMAIC is a data-driven quality strategy used to improve process. In the other hand, Kaizen means continuous improvement. There are five fundamental Kaizen principles: know your customer, let it flow, go to Gemba, Empower People, and be transparent [1].*

Key words — *DMAIC, Improvement, Kaizen, Material Qualification.*

INTRODUCTION

Biopharmaceutical companies are regulated by agencies such as the Food and Drug Administration (FDA), ANVISA, etc. They need to focus on cost reduction, customer satisfaction, and revenue increase to maintain the quality of their products for the customers. These companies manufacture products in vials and/or syringes for different cancer, cholesterol, and kidney transplant treatments, among others. The manufacturing process of these products requires aseptic techniques and validation of each one of the processes according to their corresponding Standard Operation Procedures (SOPs). The manufacturing process is comprised of the formulation, filling, and packaging. Materials used in each phase of the manufacturing process require to be qualified prior to its intended use.

Figure 1
Flip Off Seal and Syringe

PROBLEM STATEMENT

Analytical Technical Services (ATS) of a Biopharmaceutical company supports the Quality Control (QC) Incoming and Analytical laboratories. One of the responsibilities of this area is to qualify each material, direct and indirect product contact, to be used in the manufacturing process according to their respective SOP and specifications. These materials are received in QC Incoming laboratory. Some opportunities were identified during the material qualification activities, which include too much time to complete the material qualification, no schedule plan nor structure, no references of the appropriate activities and documentation required to complete the impact assessment, corrections to approved material qualification documentation packages to add missing information, etc. After evaluation, a Kaizen was performed in order to reduce the cycle time of the material qualification process.

PROJECT DESCRIPTION

The project proposal was to improve the material qualification process reducing the cycle time. As part of the improvements, it was used a

combination of the DMAIC and Kaizen methodologies.

Research Objectives

The main objective of this project is to structure a new material qualification process in the ATS area. This increases the quantity of the materials to be qualified in the company in less time and reducing the costs.

Research Contributions

This project seeks to maintain a material qualification structure, in which any new employee can be integrated in the function in a fast pace. Also, a visual tracking management for the Material Qualification can be followed minimizing any delays.

General Concepts of DMAIC and Kaizen Methodologies

DMAIC is an acronym for Define, Measure, Analyze, Improve, and Control. It is a quality strategy and rigorous approach to improve a process as part of the Six Sigma. It can be implemented as a standalone quality improvement or as a process improvement initiative. It represents the aforementioned five phases [2].

- **Define**: is where you determine the project goals and the improvement activities based on the customer requirements and the company needs.
- **Measure**: gathering information of the current issue and record the activities performed.
- **Analyze**: determine the root causes or variation and poor performance.
- **Improve**: implement the solutions by addressing and eliminating the root causes.
- **Control**: maintain the improved process in a state of control.

Kaizen means continuous improvement that involves breaking down a process and removing waste. DMAIC methodology was integrated with the Kaizen. The Kaizen was based on the eight steps and the DMAIC in five steps as described on Table 1 [3].

Table 1
Integrating DMAIC with Kaizen

DMAIC	Kaizen Event
Define	Step 1: Problem Settings
Measure	Step 2: Goal Settings
Analyze	Step 3: Situational Survey
	Step 4: Root Cause Investigation
Improve	Step 5: Kaizen Action implementation
	Step 6: Confirm Effect
Control	Step 7: Standard Maintain
	Step 8: Future plan

Project Methodology

The Biopharmaceutical companies are in continuous improvements to be a competitive organization. The material qualification structure provided to the company a robust and reliable process. The DMAIC methodology along with the Kaizen methodology were used to obtain it.

In the Define steps (Problem Solving), it was determined the problem of the material qualification process.

In the Measure step (Goal Setting), it was evaluated the material qualification process, which information is required, how long take to complete the activity, and how is the structure in order to improve and reduce the cycle time.

In the Analyze step (Situational Survey and Root Cause Investigation), it was evaluated how the originally the materials were qualified, and the issues found were described.

In the Improvement step (Kaizen Action Implementation and Confirm Effect), a Kaizen was performed using different tools like the flow chart, voice of customer, and waste-time in order to make improvements in the material qualification process. The new process was implemented reducing the cycle time.

In the Control Phase (Standard Maintain and Future Plans), the material qualification new process

is maintain using the Documentation Checklist and the Tracking Sheet system when a new material requires the qualification.

RESULTS AND DISCUSSION

The following were the results obtained using the DMAIC phases integrated with the Kaizen.

Define Phase

As part of the define phase the problem was determined based on the company needs and the voice of customer. Also, the strategy of material qualification improvement was discussed with the ATS team. The goal was to reduce the cycle time of the material qualification process.

Measure Phase

Data was gathered of the materials to be qualified as described in Table 2. A brainstorming of the material qualification process was made in order to determine what documents are required to reduce the cycle time of the material qualification process (Table 2).

Table 2
Material Qualification Documentation Checklist

Actions	Check
Company Purchasing or Component Specification (PS or CS) and/or Artwork Specification	☐Yes ☐No ☐ N/A
Company Testing Standard (TS)	☐Yes ☐No ☐ N/A
Company Test Methods	☐Yes ☐No ☐ N/A
Company Work Instruction (WI)	☐Yes ☐No ☐ N/A
Company Other SOP	☐Yes ☐No ☐ N/A
Company Documentation Control Form (DCF)	☐Yes ☐No ☐ N/A
LIMS Structure	☐Yes ☐No ☐ N/A
Vendor's Specification **Note: If no, a formal memo from the vendor with the details is required. It should include the AQL criteria, the defects, and the dimensions requirements.**	☐Yes ☐No
Does the vendor evaluate defects? **Note: If yes and no detail is specified in the vendor's specification, a formal memo from the vendor with the details is required.**	☐Yes ☐No
Vendor's Sampling **Note: If no and no detail is specified in the vendor's specification, a formal memo from the vendor is required describing the sampling.**	☐Yes ☐No
Vendor's methodology for the visual inspection and the dimensions.	☐Yes ☐No
Vendor's equipment for the Dimensions and Visual Inspection **Note. If the equipment used is not described in the method, a formal memo from the vendor is required with this information**.	☐Yes ☐No
Vendor's Method Validation **Note: If the vendor is not able to provide the validation information, a formal memo from the vendor is required with the document number, title, and version.**	☐Yes ☐No
Vendor's Certificate of Conformance (CoC) or Certificate of Analysis (CoA)	☐Yes ☐No
List of form to update Form QCA-F-408 Form QCA-F-334	 ☐Yes ☐No ☐ N/A ☐Yes ☐No ☐ N/A
Other forms impacted	☐Yes ☐No
Changes in PS, TS, Test Method, WI, SOP, DCF or other forms	☐Yes ☐No
Are external labs qualified, where is documented?	☐Yes ☐No
Company method validation	☐Yes ☐No

Analyze Phase

After the analysis the following issues were identified in the original material qualification process:

Corrections to Material Qualification documentation packages already submitted for Compliance Area evaluation was needed to include missing or additional information. This impacts the Material Qualification cycle time.

Lack references to identify the appropriate activities and necessary documentation for the completion of material qualification. As a result, delays in the delivery of the Material Qualification package occurred, which trigger delays in the Compliance Area evaluation timeline.

No structure or schedule defined for the material qualifications activities needed for current year.

No tracking system was available to measure the progress of the Material Qualification activities towards the due date.

- Lack of the Material Qualification Checklist structure and tracking tool for the status of the material qualification process.

Improve Phase

A Kaizen was performed, creating a new Material Qualification Structure for the ATS area. As part of the Kaizen, the original Material Qualification process was evaluated using different improvement actions such as brainstorming and discussing the new material qualification with the team. The original process took a total of 115 working days using two resources. The improvement included the creation of a Tracking Sheet System (Table 3) and Material Qualification Checklist Documentation. The continuous improvement tools used were flow chart, voice of customer, and waste time. After the implementation of the new structure, the material qualification process was reduced to a total of 50 working days with two resources. The cycle time reduction was 57% (Table 4).

Control Phase

The main goal of this phase is to establish and implement effective control. This ensures that the identified problems improvements were properly implemented and maintain the process in a state of control. As part of the control phase, the material qualification Checklist Documentation is verified once a new material is required to be qualified and the Tracking Sheet System updated once each task is performed in order to comply with the cycle time implemented.

CONCLUSION

As a result, a new Material Qualification structure was created consisting of a Material Qualification Checklist Documentation and a Material Tracking System for the qualification process. Both tools were placed in the company SharePoint folder for visibility and to be accessible for all the ATS team.

The benefits obtained with these improvements were:

Visual tracking management process for the Material Qualification status

Material Qualification Checklist helps the clients to be mindful of the information needed to begin the material qualification process prior to be delivered to ATS team. In addition, a robust impact assessment can be performed during the Change Control generation.

A flexible and accessible Tracking Sheet System for all the ATS personnel to access in any computer across the company share point. This helps to track the cycle time process progress for the Qualification completion and will flag possible delays.

This helps new employees (trainee) to quickly integrate to this function.

No time invest in searching the documentation necessary for the Material Qualification Process.

Material Qualification process completion in a total of 50 working days with two resources, reducing the cycle time for the Material Qualification.

Table 3

Material Qualification Tracking Sheet

Project Lead:	**Updated Date:**	**Total Days:** 50

Current Status:

Green: = Project under control.
Yellow: = Project shows issues that require attention and deliverables could be affected if no action taken.
Red: = Project in trouble, needs intervention.

0%

Tasks		Due Date	Start Date	Completion Date	Responsible	Comments
T1	LIMS Structure Generation-Days 4					
m-1	Information Gathering (1Day)					
m-2	LIMS Memo Generation, FORM QCA-F-172 and Authorization (1Day)					
m-3	Create in SAP No. LIMS (1Day)					
m-4	Review LIMS Structures					
m-5	QA Approval (1Day)					
m-6	Activation of Material in LIMS					
T2	Technical Document to provide instructions Generation-Days 9					
m-1	Information Gathering (1 Day), **if available**					
m-2	Draft Word (3 Days)					
m-3	Review and address comments (3 Days)					
m-4	Approval and upload in Child Action (2 Days)					
m-5	Training					
T3	FORM QCA-F-396 Generation-Days 8					
m-1	Information Gathering (1Day), if available					
m-2	Draft Word (3 Days)					
m-3	Review and address comments (3 Days)					
m-4	Approval and upload in Child Action (2 Days)					
T4	FORM QCA-F-395 Generation-Days 7					
m-1	Information Gathering, **once LAB provides the Raw Data**					
m-2	Draft Word (2 Days)					
m-3	Review and address comments (3 Days)					
m-4	Approval and upload in Child Action (2 Days)					
T5	FORM QCA-F-408 Update-Days 5 (TS only), if applicable					
m-1	Draft Word (1 Days)					
m-2	Review and address comments (2 Days)					
m-3	Approval and upload in Child Action (2 Days)					
T6	Work Instruction Generation or Review-Days 7, if applicable					
m-1	Draft Word (2 Days)					
m-2	Review and address comments (3 Days)					
m-3	Approval and upload in Child Action (2 Days)					
m-4	Training and Implementation					
T7	SOP or Control Form Update, if Applicable-Days 5, without training and implementation					
m-1	Draft Word (1 Days), if available					
m-2	Review and address comments (2 Days)					
m-3	Approval and upload in Child Action (2 Days)					
m-4	Training and Implementation					
T8	SOP or Control Form Generation, if Applicable-Days 10, without training and implementation					
m-1	Draft Word (4 Days), if available					
m-2	Review and address comments (3 Days)					
m-3	Approval and upload in Child Action (3 Days)					

Comments	
1	Costumer must provide all the information required to start the material qualification, such as (but not limit to) Tech Doc Justification for incoming sampling, testing and disposition, Purchase Specification, COA, any document from vendor that will necessary etc. **If documents are not available, commitment delivery date cannot be achieved.**
2	Once Lab provides the raw data.
3	If form is not attached to any change control.

Table 4

Kaizen

Kaizen Idea

Title: **Reducing Cycle Time with the New Material Qualification Structure in ATS**

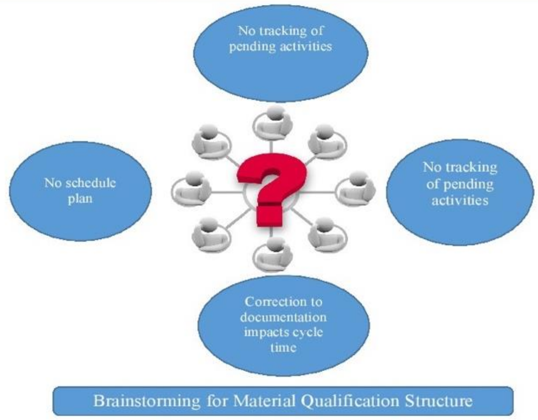
Problem Description

Currently, Analytical Technical Services (ATS) group provides support to Material Qualification activities, following site procedures. Evaluating the ATS currently Material Qualification process, the following opportunities were identified:

• Corrections to Material Qualification documentation packages already submitted for Compliance Area evaluation wasin instance to add required information. This impacts the Material Qualification cycle time.
• Lack of references to identify the appropriate activities and necessary documentation for the completion of material qualification impact assessment. As a result, delays in the delivery of the Material Qualification package occurred, which trigger delays in the Compliance Area evaluation timeline.
• No structure or scheduled plan defined for the material qualifications activities needed for a year.
• No tracking system was available to measure the progress of the Material Qualification activities towards the due date.
-The material qualification process was completed in a total of approximately 115 working days with two resources.

Improve Actions:
• Brainstorming
• Generate a Material Qualification Checklist Structure
• Tracking Sheet to know the material qualification activities status
• Discuss new material qualification with the team

Original Schedule (Photos)



Improvement Results

Improvement Description

A new Material Qualification structure was created consisting of a Material Qualification Checklist Documentation and a Material Tracking System for the qualification process. Both tools were placed in the company SharePoint folder for visibility and to be accessible for all the ATS team.

The benefits obtained with this improvement are:
• Visual tracking management process for the Material Qualification status
• Material Qualification Checklist helps the clients to be mindful of the information needed to begin the material qualification process prior to be delivered to ATS team. In addition, a robust impact assessment can be performed during the Change Control generation.
• A flexible and accessible Tracking Sheet System for all the ATS personnel to access in any computer across the company share point. This helps to track the cycle time process progress for the Qualification completion and will flag possible delays.
• This helps new employees (trainee) to quickly integrate to this function.
• No time invest in searching the documentation necessary for the Material Qualification Process.
Material Qualification process completion in a total of 50 working days with two resources, reducing the cycle time for the Material Qualification.

Continuous Improvement Tools Used:
• Flow Chart
• Voice of Customer
• Waste Time

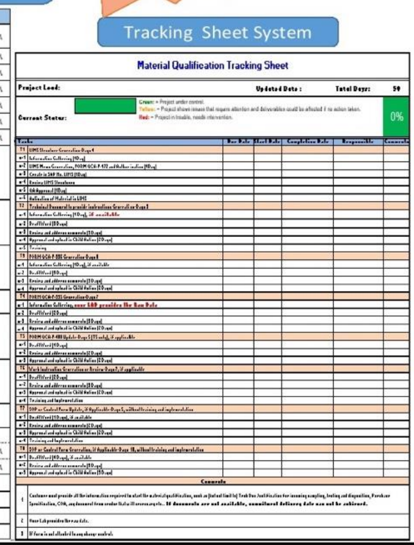
Follow Up Action/ Further Improvement Opportunities:
New Material Qualification Structure is already implemented. The area benefits from the improvement at this moment.

Improvement Support (Photos)

These two tables in greater detail on Tables 2 and 3, respectively.

Material Qualification Checklist Documentation

Actions	Check
1. Company Purchasing or Component Specification (PS or CS) and/or Artwork Specification	☐Yes ☐No ☐ N/A
2. Company Testing Standard (TS)	☐Yes ☐No ☐ N/A
3. Company Test Methods	☐Yes ☐No ☐ N/A
4. Company Work Instruction (WI)	☐Yes ☐No ☐ N/A
5. Company Other SOP	☐Yes ☐No ☐ N/A
6. Company Documentation Control Form (DCF)	☐Yes ☐No ☐ N/A
7. LIMS Structure	☐Yes ☐No ☐ N/A
8. Vendor's Specification **Note: If no, a formal memo from the vendor with the details is required. It should include the AQL criteria, the defects, and the dimensions requirements.**	☐Yes ☐No
9. Does the vendor evaluate defects? **Note: If yes and no detail is specified in the vendor's specification, a formal memo from the vendor with the details is required.**	☐Yes ☐No
10. Vendor's Sampling **Note: If no and no detail is specified in the vendor's specification, a formal memo from the vendor is required describing the sampling.**	☐Yes ☐No
11. Vendor's methodology for the visual inspection and the dimensions.	☐Yes ☐No
12. Vendor's equipment for the Dimensions and Visual Inspection **Note. If the equipment used is not described in the method, a formal memo from the vendor is required with this information.**	☐Yes ☐No
13. Vendor's Method Validation **Note: If the vendor is not able to provide the validation information, a formal memo from the vendor is required with the document number, title, and version.**	☐Yes ☐No
14. Vendor's Certificate of Conformance (CoC) or Certificate of Analysis (CoA)	☐Yes ☐No
15. List of form to update	
Form QCA-F-408	☐Yes ☐No ☐ N/A
Form QCA-F-334	☐Yes ☐No ☐ N/A
16. Other forms impacted	☐Yes ☐No
17. Changes in PS, TS, Test Method, WI, SOP, DCF or other forms	☐Yes ☐No
18. Are external labs qualified, where is documented?	☐Yes ☐No
19. Company method validation	☐Yes ☐No



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