Reduction and mitigation of foreign matter observed in product ABC

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Abstract *— During the past three years, a manufacturing company for medical devices on the west side of Puerto Rico has been in the need of evaluating and mitigating the causes behind an increase in complaint incidents reported due to foreign matter in product ABC. A PDCA (Plan, Do, Check, Act) methodology cycle was used to accurately develop the plan for each phase of the project. Following root cause analysis techniques, it was found the possible root causes behind the defects were Method and Materials. A plan to mitigate this was sought out, and after feasibility analysis it was found that by implementing an ionizing air gun plus a particle trap system, the components were cleaned of foreign matter and its static charge was reduced mitigating the ability of the foreign material of returning to the components. With the effectiveness check a surveillance system will be determined to monitor complaints for a determined timeframe.*

Key Terms *— Effectiveness Check, Feasibility Study, Relationship Matrix, Root Cause Analysis,*

INTRODUCTION

In a manufacturing company for medical devices on the west side of Puerto Rico, there is a need of evaluating and mitigating the causes behind an increase over the last three years in complaint incidents reported due to foreign matter observed in product ABC. This product is manufactured and packaged in a clean room categorized as ISO Class 8. Preliminarily, since these are complaints from the customer, it leads to assess that this defect is not being captured neither mitigated during the lifecycle of the process. The timeframe of complaints was spread out from 2017 to 2019. These products are manufactured in a Class 100,000 clean room (ISO Class 8). This Clean Room is cleaned and disinfected on a routing basis as per applicable procedure. This cleaning is made as a mean to remove contaminants to acceptable levels from surfaces and equipment. Disinfection is the process of removal, destruction, or deactivation of microorganism on objects and surfaces.

In terms of gowning, personnel use applicable procedure to go through the process of gowning and de-gowning in sequential steps. The gowning is comprised of shoe covers, surgical gloves, open face hood, face mask and taffeta (Dacron) Lab Coat. Workstation is cleaned as per applicable procedures and are wiped out with 70% isopropyl alcohol at the beginning of the shift, at lunch break, at the end of the shift, and/or when deemed necessary. Every cleaning performed is documented in its applicable procedure. This product is distributed globally on the market; thus, this could impact its distribution and the revenue it creates, which has been consistent through the pandemic. The quality system flagged up a trend due to its increase, thus the need to first understand the root cause of the situation during the timeframe, understand why current practices are not helping to avoid this situation, implement corrective/preventive methods to avoid re-occurrence, correct the situation and to reduce the complaints due to this defect.

OBJECTIVES

As a mean to declare this project as successful, two objectives were the goal. These were:

- Minimize the foreign matter material being detected at customer level in product ABC.
- Reduce, in reaction, the number of complaints for product ABC.

LITERATURE REVIEW

There are ten critical steps to handle a complaint [1], but three that stand-out for the objectives being pursued are the complaint evaluation to determine is validity, the complaint investigation where a root cause analysis must be performed as a mean to tackle the non-conformance, and the implementation of corrections and corrective actions, which may sound equal, but are different in their intention and timeframe of implementation. The PDCA Cycle (Plan-Check-Do-Act) is a good methodology to follow since it allows to properly identify which are those causes that are generating this effect and correcting them through cyclical phases [2].

The root cause analysis falls into the phases of that cycle. What the root cause analysis intends to do is find that triggering cause that is being done, or not done, that is spiraling into what is being deemed as a failure, reject or nonconformance. Two of the approaches of it that are needed to be follow are change analysis and barrier analysis. In combination, they will both focus on the changes that the process may have encountered that could lead to this situation and see what current mitigations are failing in preventing and/or detecting this non-conformance to be reached by a customer [3].

It is critical that in the complaint investigation, the nonconformances (rejects), be categorized to understand the level and weight of their impact through a Pareto Analysis. By performing this, a prioritization of the incidence with the highest impact will occur, and the focus shall be centered on implementing the corrective and/or preventive actions to mitigate it that will garner the highest level of benefit [4]. When the prioritization is set, the shift can be moved into analyzing those causes with highest level of impact. One of the techniques used for this is the Fishbone diagram. Through it, the problem statement is set at beginning of the "fish skeleton" and the "bones" of it are used to display the outmost probable causes, and from there, different factors that feed those causes are displayed. This technique is applicable since it aims to find the real root cause that is not clearly seen that it is not obvious [5]. Through the application of these methodologies in the process steps, a feasible action can be reached that would move forward the objective of reducing and mitigating the foreign matter detected in product ABC.

ANALYSIS

As a mean to reach the goal of completing the objectives of the project, the first step was mirrored towards understanding the process and facts captured in this portion were divided between known items and unknown items.

In terms of the known items, 25 complaints have been opened and span through three years, there are five different categories of foreign matter type, complaints came from the same country, catalogs affected have cleaning process implemented in their process, only two of the four catalogs in the product family have presented complaints, there is no harm to the patient that was informed through the complaints, and acceptance criteria in process of foreign matter should be less than $0.10mm^2$.

In terms of the unknown items, it was not necessarily confirmed through the complaints the specific location of all foreign matter, the customer acceptance criteria is unknown, and a genealogy tree could not be performed thus, the complaints cannot be tied to specific lots.

As detailed in Figure 1, there is a total of five different foreign matter conditions that have been documented in the complaints for the affected product family. It is found that the major contributors are particles, stain, and hair with an 84% of the cumulative weight of defects.

An Affinity Analysis was performed to consolidate and understand the facts and ideas into the subgroups "Man", "Method", "Machine", "Environment", "Materials" and "Measurement" that could lead to the root cause of the occurrence of this problem. These subgroups aided in determining why mistakes keep happening

throughout the timeframe from 2017-2019 and why current practices are not helping to avoid this situation.

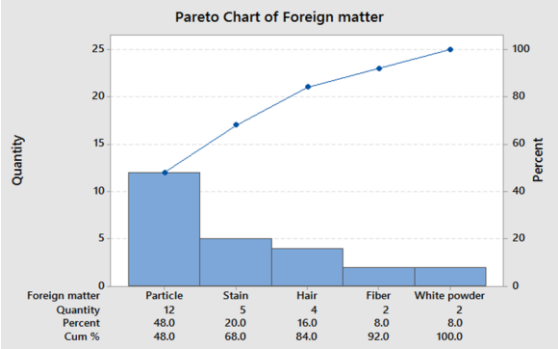

Figure 1
Pareto Chart of Foreign Matter Frequency

As a mean to visualize and understand how these subgroups were related to one another, a Relationship Matrix was performed based on it. This provided information regarding the strength between each subgroup and which subgroup affected the other or were a reaction of another subgroup which is established by the direction of arrows. If a relationship was not found between them this meant that the probability of them being the probable root cause was low.

As per Table 1, it can be assessed that the subgroup that was determined to be the highest source of cause based on that it provided the highest number of outputs was Method with five (5) outputs. Materials and Environment came second since both have 2 outputs and 2 inputs.

Table 1
Relationship Matrix Results

5M + E	Output (↑)	Input (↓)
Man	2	1
Method	5	0
Machine	0	4
Environment	2	2
Materials	2	2
Measurement	0	2

Nonetheless an investigation into the root cause was performed for all six categories under the 5M + E technique. Out of this, Man, Machine, Environment and Measurement were defined as not probable root causes. In terms of the probable root causes, the identified categories went hand-in-hand with the results from the Relationship Matrix.

For Method the issues found to mitigate were as follows:

- There is not minimum time to use the ionizing air gun to blow away the particles.
- There is no guidance on which area of the component to cover with the gun
- There is no distinction nor guidance into how to clean the individual components and once it is assembled.
- There is not a specific distance established.
- For inspection part, some use a magnifying lamp, some don't. The procedure does not establish when to use it, it just says "if necessary".

For Materials the issues found to mitigate were as follows:

- Although particles can be detected visually and removed, the static charge makes them return to the components, and become lodged in hidden places of the assembly.
- Components are made of silicone and PVC, their nature is making the blown-off particles to return to the components, which means that current use of alcohol lint free wipes and ionizing air gun are not enough to combat it.

Based on the investigation of the root cause, the plan defined to execute the feasibility study was to:

- Standardize the cleaning method (area covered, timeframe of air blow, distance) for the individual components and for the assembly.
- Introduce a Particle Trap that will allow to capture those blown-away particles, Particle Trap should be big enough to fit the worst case (largest) component to be cleaned for this product family.
- Include guidance as to for what type of contaminants/foreign matter/conditions to look

for when inspecting the components (e.g. hair, stains, particles)

- Include standardization of inspecting the assembly with the magnifying lamp at a QA In-Process level.

A feasibility study was performed as a mean to analyze if suggestions to be implemented were feasible (ionizing air gun plus particle trap system). Particle Trap used was an existing one for other products that fits the worst-case tray (bulkiest and largest) used in the affected products. Plan was defined by cleaning 30 trays with alcohol lint free wipes.

Prior to cleaning them with ionizing air gun, the quantities of particles detected with the naked eye (worst-case scenario) was documented. Also, static charge was recorded with a calibrated electrostatic field meter for each tray to capture the ionizing air gun's ability to reduce the static charge thus reducing the attraction of the particles by neutralizing close to zero after tray exposure to cleaning area.

Then each tray was located inside the Particle Trap. The tray must fit completely inside the Particle Trap, this standardized the distance between the tray and the air gun. The operators were instructed to clean the trays 10 continuous seconds per side as minimum starting from the farthest place from the filter with respect to the tray. This is as to "push" the particulate into the HEPA filter of the Particle Trap, and into the suction motion of the equipment.

After the cleaning per tray, trays were inspected for remaining particles and information was documented. Also, the static charge was documented post cleaning to confirm of a reduction. The static charges are reducing if the value (either positive or negative) is closer to zero.

DISCUSSION OF RESULTS

Thirty trays were subjected to the plan established under the feasibility study. As discussed in Table 2, the static charge was documented and the maximum static charge was 16.5kV after spraying with ionizing air gun, the static charge was reduced to 0.25kV therefore the Static Charge was neutralized by 98%.

Table 2
Static Charge Results

Sample #	Maximum Pre-Cleaning Static Charge	Post-Cleaning Static Charge	Percent of Reduction (%)
21	16.5kV	0.25kV	98%

In terms of the quantity of particles detected in the tray, as discussed on Table 3 prior to spraying with ionizing air gun the maximum quantity of particles in the tray was 11, after spraying with ionizing air gun inside the Particle Trap there were zero particles in the packaging, therefore, a 100% of reduction of foreign matter was obtained.

Table 3
Particle Assessment Results

Sample #	Maximum Quantity of Particles	Quantity of Particles remaining	Percent of Reduction (%)
16	11	0	100%

Based on results obtained it can be established that particle trap was capable of trapping particles, the ionizing air gun was able to perform the static neutralization during the particle removing process, net particle quantity was reduced in its entirety and that when used in combination, the system aids in reducing foreign matter in product ABC.

The plan was deemed as feasible to be implemented. Appropriate procedures were updated to include the standardization and steps followed under this feasibility study to reduce foreign matter in product ABC.

CONCLUSION

The objectives of this project were achieved by adequately utilizing the steps of the Plan-Do-Check-Act cycle as a mean to detect the root causes and effectively aid in the reduction and mitigation of foreign matter observed in product ABC.

The complaints were analyzed to determine the different contributors of occurrence in the situation which provided with the highest contributors. After investigation, the planned improvement was implemented at a manufacturing and QA In-Process level focusing on the categories that were defined as the probable root causes.

Since existing equipment was utilized (e.g. ionizing air gun, particle trap, magnifying lamp), no additional cost was incurred in the implementation of this plan.

Operators were effectively trained on the standardized methodology to clean the packaging where the time, distance, and motion were standardized, and visual aids were provided in the current procedures to avoid discrepancies in methodology.

Two effectiveness plans were established. One for a short-term where the manufacturing process will be studied for the 15 lots after implementation by using 5 retain samples and open the product after a week to inspect for particles with the magnifying lamp. The quantity of particles will be recorded, if any, will be recorded and compared with existing device master records.

For the long-term effectives check plan, the complaints will be monitored for this category of defect six (6) months after implementation.

REFERENCES

[1] W. Imam, "13485 Academy," 21 March 2017. [Online]. Available: https://advisera.com/13485academy/blog/2017/03/21/how-to-comply-with-iso-134852016-requirements-for-handling-complaints/.

[2] L. Lopes, "Can practice lead to perfection in management? The PDCA cycle demonstrates that it can.," [Online]. Available: https://for-managers.com/pdca-cycle/.

[3] ASQ Quality Press, "What is Root Cause Analysis (RCA)?," [Online]. Available: https://asq.org/quality-resources/root-cause-analysis.

[4] Mind Tools Content Team, "Pareto Analysis, Choosing the Solution WIth the Most Impact," [Online]. Available: https://www.mindtools.com/pages/article/newTED_01.htm

[5] Six Sigma, "Root Cause Analysis Tool - The Fishbone," 3 March 2017. [Online]. Available: https://www.6sigma.us/etc/root-cause-analysis-rca-tool-fishbone/.