

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.

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.

Methodology

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 its 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]. As detailed in Figure 1, the cyclical phases of the project were from understanding the process, to implementing the effectiveness check.

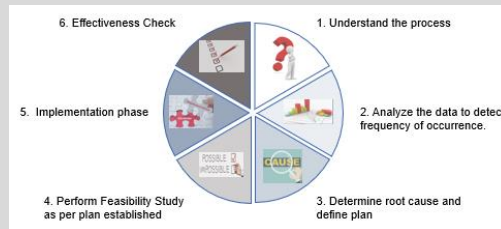


Figure 1 – Cyclical phases of the project

Analysis

As detailed in Figure 2, 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.

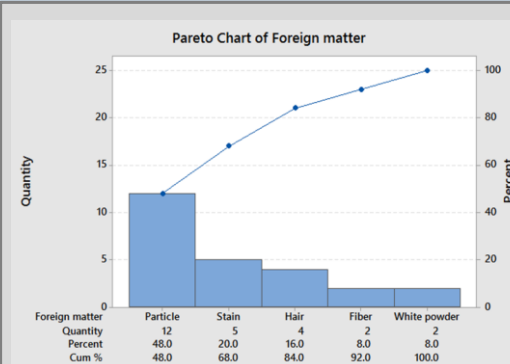


Figure 2: Pareto Chart of Foreign Matter Frequency

As a mean to visualize and understand how these subgroups were related to one another, a Relationship Matrix was performed based on it. 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

	Output (↑)	Input (↓)
5M + E		
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.

Results

Based on the investigation of the root cause, a plan was defined to execute the feasibility study performed as a mean to analyze if suggestions to be implemented were feasible. Samples were subjected to the plan established under the feasibility study. As discussed in Table 2 and 3 there was a reduction on the static charge of the components by 98% and a reduction of particles of 100%.

Table 2: Static Charge Results

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

Table 3: Particle Assessment Results

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

Conclusion

The plan established aids in reducing and mitigating the foreign matter in product ABC and as a result reduce the complaints for this product. The objectives of were achieved by adequately utilizing the steps of the Plan-Do-Check-Act cycle and it has been demonstrated that by going through its cyclical phases, it can be of great help to organizations to mitigate the defects in their processes.

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/>.