Reducing Particle Matter in Medical Devices Product

Anthony González Ortiz
Master of Engineering Management
Dr. Héctor J. Cruzado
Graduate School
Polytechnic University of Puerto Rico

Abstract *— In the medical device industry, particle matter in products is a problem. Recently, a medical device company noticed that, for the last three months, rejection of product due to particle matter was in an increasing trend. The problem was analyzed by evaluation of manufacturing process, storage area, personnel training and inspections performed on product. Additionally, to boost employee engagement and moral, a rewards system was implemented. Evaluation identified areas of improvement in manufacturing process, storage area cleaning, implementation of new inspections for product as well as new inspection equipment. Data collection after improvements demonstrated a better control for particulate matter. Rejection quantity was reduced from 25% to 14%, there was a profit increase of $165,000 and the rewards system implemented improved employee engagement to target the particulate matter problem.*

Key Terms *— Generation of particle matter, increase employee engagement, medical device problems, manufacturing evaluation, surgery complications*

INTRODUCTION

In the medical device industry, having particulate matter in products is a risk companies don't have the luxury to take. Particulate matter can create problems such as product recall, negative financial impact and, in a worst-case scenario, be the cause of death of a patient.

A manufacturer of medical devices performed internal audit on one of the manufacturing lines and identified a high defect scrap rate related to particle matter inside a tube which is part of the product. As explained before, having particle matter inside the tube of the product is very critical for patient safety. The product provides suction and irrigation via the different tubes attached to it. Particle matter can be a cause for infection in patients if it is introduced to the inside of the body, so it is important that medical device products manufactured by medical device companies are free of particle matter.

This project was executed at the manufacturing line for the suction and irrigation product, where the particle matter is generated and introduced to the products. With this project, it was intended to mitigate, as much as possible, the particle matter inside tube defect from the manufacturing line. The particle matter inside the tubing defect has an increasing trend from 15% of total produced products to 25% in the past three months. An increase in this defect is translated to $375,000 lost in sales which represents a 10% of the gross profit of the medical device company.

The project objective is to reduce the particle matter inside tubbing defect and increase gross profit for the medical device company.

LITERATURE REVIEW

For all major medical device companies there is one common problem: particulate matter. To avoid recalls, first it is critical to understand the requirements set forth by the regulating agencies (FDA) and industry standards for medical device companies [1]. There are different recall situations that range from the designing of the product to the validation activities perform for that product. For each of these situations, different actions must be executed to prevent the dreaded product recall, which for any company it represents a loss of millions of dollars. In addition, to avoid recalls it

is important to perform a risk assessment and have an effective risk management structure implemented. Finally, for all this actions to have a positive impact, it is required the engagement from management. They must be engaged in all aspects that range from the basics of establishing the right company policies to implementing good design and good manufacturing practices [1].

All particle matter is not the same and each situation must be evaluated to determine the risks associated to the presence of particle matter in a product. There are various sources of possible particle matter contamination, such as: particles from glass containers, plastic containers, infusion sets, and undissolved solids in drugs [2]. Additionally, it must be considered that a reaction between the drug and delivery fluid utilized to deliver the drug can occur. This interaction of their chemical properties when expose to each other can generate a precipitate, thus creating unwanted particle matter in the product. It is important to evaluate the risk associated with the particulate and the different variables that can affect the level of risks, such as: patient characteristics, route of administration, number and characteristics of particles, electric charge, size and shape of particles [2].

For a company to start gaining control for the particle matter situation in their manufacturing line, it must implement inspections and the periodic sanitization and cleaning of that manufacturing line. There are different ways for removing particle matter (cleaning) that a company can implement to help assure all product that is sent to the customer it complies with the highest quality standard [3]. The method of interest is the ultrasonic cleaning since this is a technology readily available, easy and fast to implement in any manufacturing line. The ultrasonic cleaning helps to eliminate static of the product and particle matter allowing it to be removed with ease. Cleaning the manufacturing area is not enough to resolve the particulate matter issue, it is required to also evaluate the different inspections that are performed on the product. The visual inspection by human operators to a product; it has been proven statistically that 100% inspection by human represents approximately an 85% efficient inspection [4]. Evaluating variables such as how one operator is related to another performing the same inspection and the time factor it can confirm the most efficient way of performing the visual inspection. This is performed utilizing statistics, to demonstrate if the different variables utilized for the evaluation have a significant difference between them or not (ANOVA test) [4]. To help further upgrade the inspections perform on the product, all companies must start to move to the automation of inspections. A robot vision system to inspect the different defects during blister packaging of products can be the alternative. The implementation of the automated (robot) vision system targets the reduction of human errors during inspections and to perform 100% inspection with 100% detection that which is not possible due to the human factor [5].

METHODOLOGY

Here is presented the methodology followed for this project:

- Interview of Operators - All operators were interviewed for their inputs about where the particle matter could be generating from. This gives them participation and creates engagement with the issue at hand.
- Implementation of Rewards System - To help motivate the operators further, a rewards system was implemented to provide incentive to those that participate, and a group reward was also presented to promote team unity.
- Manufacturing Process Evaluation - The engineering team was tasked with performing evaluation of the entire manufacturing process to help determine where in the process particulate matter was being generated (input from operators help guide engineering team).

- Evaluation of Product Inspections - Inspections performed during manufacturing were evaluated to understand if there were deficiencies in the inspections performed or if additional inspections were required.
- Storage Evaluation - Since particulate matter can be generated from multiple sources storage area was evaluated.
- Operators Training - To ensure all operators manufacture the product in the same standard way as established, re-certification of all operators was performed.

RESULTS

The interview with all operators was a good technique to utilize since it is them who perform the manufacturing of the product day to day. This knowledge greatly helped the engineering and quality teams determine what areas on the manufacturing line they should be focusing on. This reduced time spent on evaluation and allowed for a faster implementation of solutions.

Implementation of a rewards system was well received by the operators and as expected, it boosted operator performance and engagement in the overall efficiency of the manufacturing line. Manufacturing re-training of all operators was achieved successfully and helped to eliminate the variability that can happen when different operators perform the same task differently. From the evaluation of the manufacturing line, inspections of the product and component storage performed, it was determined the following:

- New inspections were required.
- New equipment for inspections was required.
- Validation of new inspections and equipment was required.
- Additional cleaning was implemented during line clearance for component storage locations.

After completion of all validation activities and implementation of additional tasks, data collection was started. This data was evaluated at the end of each manufacturing shift in order to provide constant monitoring of the defect and help correct any deficiencies that could arise. The data is presented graphically on Figure 1. The graph presents a clear trend for particle matter reduction.

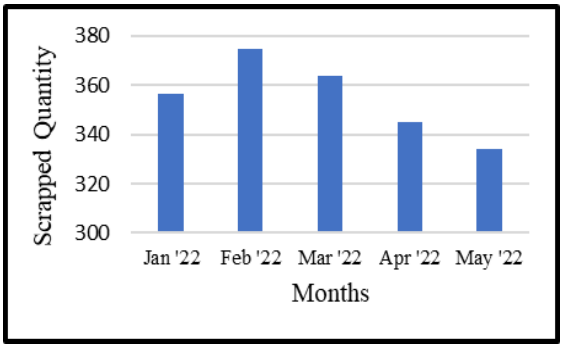

Figure 1
Scrapped Units for Particle Matter Inside Tubing

In addition to the defect monitoring as presented in Figure 1, a profit trend analysis was performed to translate the reduction in defect creation into a monetary value that management could easily understand the output of the project. The data reported is presented on Table1 and the profit trend analysis is shown on and Figure 2.

Table 1
Profit Increase Data Reporting

Month	Increase in Profit ($)
Feb '22	0
Mar '22	45,000.00
Apr '22	120,000.00
May '22	165,000.00

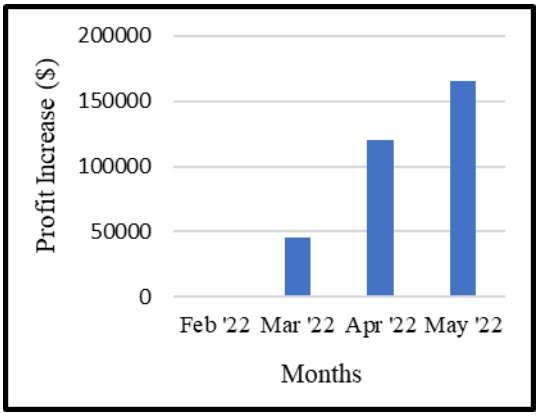

Figure 2
Profit Trend Analysis

CONCLUSION

With implementation of all activities and from the data collected, it was confirmed through objective evidence that control of particle matter defect can be made possible if a complete evaluation of the process is performed. The total reduction in particle matter scraped product contributes to a 11% of a total manufacturing yield of $1,500,000. This units which are now saved and can be sold to customers represent an increase in profit of $165,000. Therefore, it can be concluded that the project for reducing particle matter in tubing component from a medical device was completed satisfactorily.

REFERENCES

[1] Raheja, D. (2014). *Preventing Medical Device Recalls*. Taylor & Francis. https://doi.org/10.1201/b17210

[2] Perez, M., Maiguy-Foinard, A., Barthélémy, C., Décaudin, B., & Odou, P. (2016a). Particulate Matter in Injectable Drugs: Evaluation of Risks to Patients. *Pharmaceutical Technology in Hospital Pharmacy*, *1*(2). https://doi.org/10.1515/pthp-2016-0004

[3] Awad, S., & Nagarajan, R. (2010). Ultrasonic Cleaning. *Developments in Surface Contamination and Cleaning*, 225–280. https://doi.org/10.1016/b978-1-4377-7830-4.10006-4

[4] Morales, J. A. (2020, December 15). *Reliability of Operators performing the Visual Inspection of Parenteral Drug Products*. PRCR. http://prcrepository.org:8080/xmlui/handle/20.500.12475/988

[5] Torres, E. (2020, June 25). *APIS Automatic Packaging Inspection System*. Pupr.Edu Library. Retrieved April 3, 2022, from http://prcrepository.org:8080/xmlui/handle/20.500.12475/201