Optimization of Filters Changes in Dust Collector CPO-1005 for Coating Machine Number 1

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Abstract *— The pharmaceutical industry has dust collectors to remove particulate generated by the coating machines. Actually a pharmaceutical presents a problem in one of the Accela-Cota machines because obstruction on filters in the dust collector and they have to turn off the coating machine many times in a batch. The company needs to optimize the functionality of the coating machine to improve the production. This project is focus in the optimization in filters changes in dust collector CPO-1005 and wants to reduce the frequency from every 3 months to every 12 months. The importance for the changes of these filters is because the vacuum in the coating machine. If there not vacuum in the Accela-Cota, the machine sends an alarm and turn off the system because had an increase in pressure.*

Key Terms *— Accela-Cota, Dust Collector, Coating Machine, Vacuum.*

INTRODUCTION

The functionality in the coating machine is essential in a pharmaceutical environment. Actually a pharmaceutical presents a problem in one of the Accela-Cota machines because obstruction on filters in the dust collector. This dust collector has 12 filters and its change involve turn off the coating machine. The time for do this change is approximately 4 hours with 4 employees and with the machine turned off. The company needs to optimize the functionality of the coating machine to improve the production. This project is focus in the optimization in filters changes in dust collector CPO-1005 and wants to reduce the frequency from every 2 to 4 months to every 11 to 12 months.

This project is focus in the optimization in filters changes in dust collector CPO-1005. The main objective of this project is reducing the changes of filters from every 3 months to every 12 months. There are 3 more coating machines in the room 171 that has the same problem and the plant should apply this project to these other machines.

LITERATURE REVIEW

A dust collector is a system used to increase the quality of air released from industrial and commercial processes by collecting dust and other impurities from air. A dust collector system consists of a blower, dust filter, a filter-cleaning system, and a dust receptacle or dust removal system.

The pharmaceutical industry generates a variety of products that can become a nuisance dust during production and packaging. Depending on the application, there may be concern with cross contamination of other products, Good Manufacturing Practices (GMP) issues, as well as occupational exposure limits to limit plant worker exposure to active pharmaceutical ingredients. The dust collectors companies has a wide variety of dust collectors for the pharmaceutical industry ranging from small down flow oval's for point of source collection at a packaging line to large specialized containment dust collectors customized to meet the needs for a specific product.

The design and construction of dust collectors, containment devices may need to address a range of potential issues; including configuration decisions to minimize material build-up, seam sealing of collectors and ducts, duct attachment and sealing techniques, and potential use of secondary monitoring filter such as High –Efficiency Particulate Arresting (HEPA) filters [1]. The pharmaceutical factory for this project use HEPA filters for accomplish near zero emissions to the environment.

In some instances, devices with special seals are required to reduce or eliminate the discharge of dust from the dust collector when transferring material to storage containers for disposal. In other situations, custom sealed filter change-out procedures may become necessary during filter servicing to reduce exposure when the dust in the collector has potentially adverse health impacts.

Some of the pharmaceutical processes that may generate dust are; crushing, milling, screening, mixing, pelletizing, dispensing, sampling, granulating, drying, coating, batching, blending, compressing, weighing and packaging [2]. The process for this project is coating and there specifically the coating machines number 1. That machine has a dust collector that is independently from others coating machines. The plant has many others dust collectors for janitorial and for others process such mixing and granulation. The coating machine is some of the processes that make dust in pharmaceutical factories, for this reasons any coating machine has it dust collector [3].

For this project case the dust collector that the pharmaceutical has is a Donaldson Torit Downflo II (Figure 1). This dust collector is design for pharmaceutical processes such coating [4].

Figure 1

Downflo II Dust Collector

Pharmaceutical dusts may also have identified adverse health impacts, and special mitigation strategies may be required to limit occupational exposure below levels Occupational Safety and Health Administration (OSHA) or other health organizations have established for these materials.

Some of the equipments have stainless steel contact surfaces or Food and Drug Administration (FDA) approved paint to accomplish the pharmaceutical requirements. National Emissions Standards for Hazardous Air Pollutants includes specific amendments related to the pharmaceutical production industry.

The design in this dust collector was enhanced with a valve diaphragm to maintenance the dust in the bottom of the equipment (Figure 2).

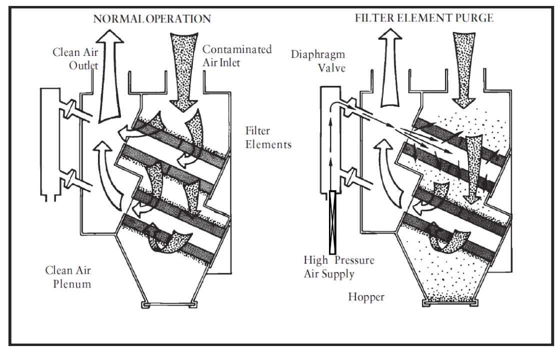

Figure 2

Dust Collector Diaphragm

The installation of this kind of equipment vary from equipment, for this case the arrangement of the valves is one valve per filter (Figure 3).

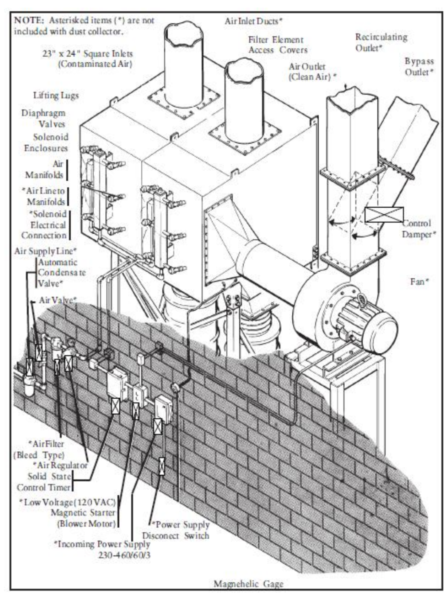

Figure 3

Dust Collector Installation

Twenty-five states, Puerto Rico and the Virgin Islands have OSHA-approved State Plans and have adopted their own standards and enforcement policies. For the most part, these States adopt standards that are identical to Federal OSHA.

The Pulse Cleaning Technology is an enhance for the dust collectors systems using proprietary, computer-modeled pulse cleaning technology to easily ñpulse offò dust from the surface of the filter, improving filtration efficiency and prolonging filter life [5]. Our pharmaceutical plant has this system as well an HEPA filters for assurance the environmental emissions.

The dust collectors systems are very useful in pharmaceutical industries because the environmental emissions [6]. For this project the pharmaceutical located in Vega Baja has one dust collector with pulse cleaning for any coating machines as well HEPA filters. The focus of this project is the optimization of change the filters in this dust collector for the coating machine number 1.

PROBLEM STATEMENT

The pharmaceutical industry has dust collectors to remove particulate generated by the coating machines. For this case the dust collector is the CPO-1005 for the Accela-Cota number 1. This dust collector has 12 filters and the change range is usually every 11 to 12 months. In past months the filters changes were incremented by 2 to 4 months. The importance for the changes of these filters is because the vacuum in the coating machine. If there not vacuum in the Accela-Cota, the machine sends an alarm and turn off the system because had an increase in pressure.

This increment in filters change represents the cost of filters, working employees, but even more by machine stops to change the filters.

What is achieved is reduce the change of filter to optimize the coating machine time operation. It is important to reduce these changes in filter to guarantee the constant functionality of the coating machine.

There is a gage to measure the quantity of dust that has a scale from 1 to 10 and the level to change is 6. When the dust collectorês gage is more than 6, the Accela-Cota presents positive pressure and the operator have to turn off the machine for change the filters.

This optimization in filters changes represent more hours of production and less unexpected stops by changes in pressure. The contributions of this project will be the reduction in coating machine stops and extend the shelf life of dust collector filters. With these contributions we are expecting an optimization, at least of 25% that represents the reduction of changes of filters from 1 to 4 months.

The cost of these filters is US $3,000, plus 4 hours of working employees that is approximately US $5,000 plus machine stops that is more. Once the project is done the expectation is at least do this changes every four months. With this range the plant can safe a total of US $32,000 every 4 months or US $96,000 annually, reducing the changes of filters from 1 month to 4 months. This optimization represents quality improvement in the product because the reduction in move the product from one machine to another.

METHODOLOGY

The methodology that will use for this project is the Six Sigma and the DMAIC model. That methodology will help this project finding the reasons that cause the increment in filters changes. Sig Sigma is a great methodology to apply for this kind of project because we can identify true causes of problems, find solutions that evidence how are linked to the causes, establish procedures for maintaining the solution after the finish of the project and confirm the nature of the problem.

Term Six Sigma originated from terminology associated with manufacturing, specifically terms associated with statistical modeling of manufacturing processes. This is the main idea to be found in this project. DMAIC is divided in Define, Measure, Analyze, Improve and Control. The voice of the customer and the project goals will be used to identify the problem in the define aspect. Critical to quality tool is very helpful to this project since shows what the operator want. The phases of this project are required to start a project charter. The project charter helps to keep in focus as well clear expectation. The information include in the project charter will be the description of the project, the background, goals, assumptions, and who will work in this project.

The research schedule is one step of the project charter. The research schedule includes the expected dates to complete each step in the methodology of DMAIC for this project as follow:

- Define (2 wks)
- Measure (3 wks)
- Analyze (4 wks)
- Improvement (3 wks)
- Control (4 wks)

The measure key aspects of the current process and collect relevant data is very useful for this kind of project since the data is there and is use. The histograms and flow charts will be some of the measures tools that will be used in this project.

The analyze data is to investigate and verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered. Seek out root cause of the defect under investigation. Also the failure modes and effects analysis we will be very helpful in this project because we have to know what the mistakes in the process are.

In the improve, the current process based upon data analysis using techniques such as design of experiments, poka yoke or mistake proofing, and standard work to create a new, future state process. Set up pilot runs to establish process capability.

And finally for control the future state process to ensure that any deviations from target are corrected before they result in defects. Implement control systems such as visual workplaces, redesigning SOP and continuously monitor the process.

RESULTS AND DISCUSSION

The data shows that the filters changes before the change in the diaphragms were every 12 months average. After the change in diaphragms the filters changes increments to every 2 to 4 months. There was a graph that show the point when the filters change was increment (Figure 4). It in very notable that before the diaphragms change the filter changes were less. The red line denote the diaphragm change, the left side is before and the right side is after the diaphragms change.

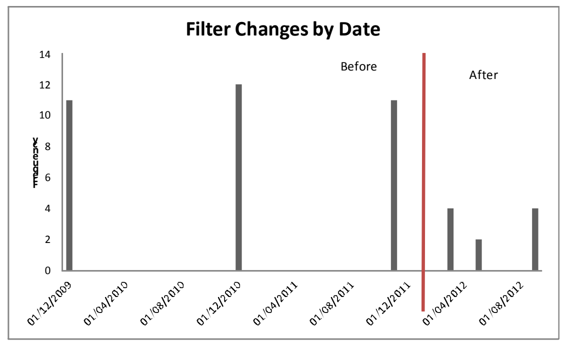

Figure 4

Graph of Filter Changes by Date

The fish bone diagram (Figure 5) show that the machine stops should be one problem, but was found that in many cases the measure in the scale change going up and down. The water and humidity in the system was not a problem neither because was found that this equipment has not holes and corrosion. When the operators clean the machine there is not tap water in the room. The filters also were founded that are the correct ones. In the other hand, looking the data, was observed for almost two years shows that the problem comes with the diaphragm change. Before the diaphragm change the filter changes has a range in changes of 12 months and for these months this range was increment to 3 months in average.

Other tool that helped in this project was the Failure Mode and Effect Analysis (Figure 6) where was observed that the installation of diaphragm was the root cause of the increment of filter changes due to the bad adjusted done by the technician.

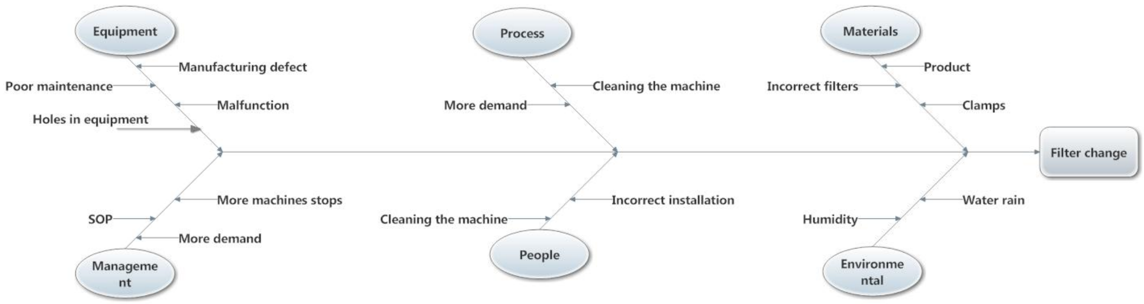

Figure 5

Fish Bone Diagram

Item / Function	Potential Failure mode	Potential Effects of Failure	S (severity rating)	Potential Cause(s)	O (occurrence rating)	Current controls	D (detection rating)	CRIT (critical characteristic)	RPN (risk priority number)	Recommended actions
Filters shape	Manufacturing defect	Do not came with the correct shape	8	Factory error	1	No	2	Y	16	Inspect the filters when arrives
				Bad purchased	1	No	2	Y	16	
Maintenance in equipment	Not in good conditions	Malfunction	8	Poor maintenance	3	No	5	Y	120	Inspection
Operation in accela-cota	Drop in pressure	Machine operation	7	Poor trainning to operators	5	SOP	7	Y	245	Training
Operation in dust collector	Cleaning	Operator us the dust collector to collect the cleaning water	6	Bad used	1	SOP	3	Y	18	Training
	Cleaning pulse	Waiting time between intervals pulse	3	Bad adjusted	1	SOP	3	Y	9	Training
Production	More demand	More time with machine running	1	Equipment design	7	Engineering department	2	N	14	Inspect the equipment design
	More machines stop	More changes in batch and cleaning	1		7		7	N	49	
Installation of clamps	Incorrect installation of clamps	Clamps out of position	7	Bad adjusted	1	Engineering department	8	Y	56	Inspect the installation of clamps
Installation of filters	Incorrect installation of filters	Filters out of position	7	Bad adjusted	1	Engineering department	8	Y	56	Verify the installation of filters
Installation of diaphragms	Incorrect installation of diapragms	Diapragms out of position	8	Bad adjusted	10	Engineering department	9	Y	720	Inspection, test before the machine starts and training
	Manufacturing defect	Do not came with the correct shape	8	Bad purchased	1		9	Y	72	
Enviromental	Too much humidity in dust collector	Holes in equipment	7	Poor maintenance	3	Maintenance	9	Y	189	Inspection
	Rain water inside dust collector		7		1		1	Y	7	

Figure 6

Failure Mode and Effect Analysis

The improvement we are recommending for this project is the inspection in the installation, re-training to employees performing this installation and test the equipment before the start up.

The contribution in the control part that makes this project to the pharmaceutical industries is to include a visual management with plans of how this equipment is installed.

The optimization of this filters changes was very helpful to the pharmaceutical because reduce the cost by machines stops, cost of filters and cost of installation. The sum of cost of filters and installation is US$ 5,000 by change. From 2009, 2010 and 2011 the costs remained in US$ 5,000 per year, but in 2012 this cost grow up to US$ 15,000 until September because the increment in the filters changes (Figure 7). This cost have been US$ 20,000 if the data have been collected until December. So the cost reduction in this project is 75% or US$ 15,000 that was expected in the problem statement.

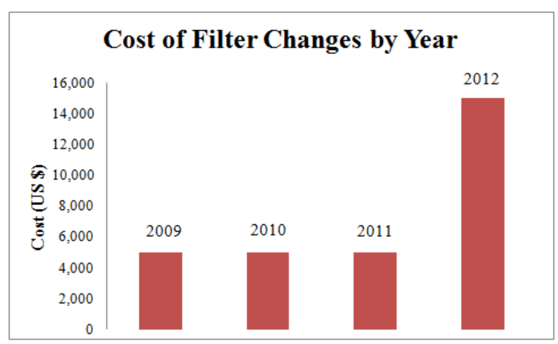

Figure 7

Graph of Filter Changes by Date

CONCLUSIONS

During this project was it analyzing different things that thought that are the cause of the increment of filters in the dust collector. Many limiting were present to define the result in the project because the many possible causes that would produce the problem with the increment in the filter changes such the humidity and temperature, the equipment operation, bad installation of filters, between other ones.

In conclusion, that what caused this increase filter change is that when in a preventative maintenance the diaphragms of the equipment were changed and not mounted correctly. It is now recommended that a certified technician from Donaldson realize the change of these diaphragms and train all number of technicians in this filters change.

With this research was founded that the plant needs to improve the review of their equipments when come to the stock room and improve the installation of diaphragms.

The contributions for this project is a format revision of this equipment in the stock room with photos and a brochure for the equipment.

Also the technician must make sure that he is installing correctly the equipment with the actualized drawings of equipment.

By these findings can be verified if the other two dust collectors were made the diaphragm for this same time or if it was the same person as these two equipment have the same problem of increased filter change.

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