Maintenance Improvement Process for Control Emission System in a Pharmaceutical Plant

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Abstract *— The Scrubber system SC-25 A/B is an emission control system that supports a manufacturing process of oral solid dosage in a pharmaceutical plant located in Barceloneta, Puerto Rico. Although the scrubber in subject is not an actual manufacturing system, it is responsible of removing 99% of volatile organic compound from the air exhausted from manufacturing process. While scrubber operations are highly regulated by the Environmental Protection Agency, several concerns were raised in the pharmaceutical plant due to consistent operational failures due to low flow rate alarms. Performing voice of the customer analysis, data gathering and field visit, the issue was assessed and addressed to provide a solution of improvement. Low flow rates in the scrubber are triggered by the following drivers: effluent water quality, pipe size capacity, and strainer capacity. As a result, short- and long-term improvement proposals were presented to the system owner which includes Preventive Maintenance Revision, Piping and Strainer resizing increase and propose the implementation of local water treatment using biocide for the scrubber.*

Key Terms *— Emission Control System, Maintenance, Reliability, Scrubbers.*

INTRODUCTION

A pharmaceutical plant located in Barceloneta, Puerto Rico is a multiproduct manufacturing plant that manufactures oral solid dosage (OSD) medicines to treat several conditions from different disease disciplines such as neuroscience, immunology, and oncology. As part of the manufacturing process of these OSDs, the solution preparation of the coating of the tablets requires solutions concentrations of ethanol and acetone in a liquid state. As the manufacturing process continuous, residual gaseous concentrations of these solvents are exhausted through the air stream towards the atmosphere becoming in a gaseous volatile compound (VOC). The emission of VOC for this industry and many other industries are highly regulated by the Environmental Protection Agency (EPA) under the Clean Air Act. To comply and control the emissions of VOC to the atmosphere, control emission systems are implemented as external auxiliar equipment to the manufacturing process.

To comply with the environmental regulations established by the EPA, the pharmaceutical plant in subject is responsible to implement controls within the operation to assure the emissions from manufacturing process are aligned with regulatory requirements. Systems designed to control environmental emissions of hazardous components such as VOCs are implemented and integrated into the manufacturing process cycle. The emission control equipment used by this pharmaceutical plant are dust collectors and wet scrubbers. The Dust collectors are designed to extract solid product residuals from the air stream exhausted from the process while wet scrubbers are designed to clean and extract the volatile organic compounds from the exhausted air, prior of being release to the atmosphere.

Given the regulatory importance and liability of the pharmaceutical plant, dust collectors and wet scrubbers are integrated in the manufacturing process cycle as external auxiliary components. This means that although the control emission systems are not a direct product contact system, it conforms a critical process step of the production cycle. Since this equipment is part of the production process cycle, a failure on this equipment will imply the interruption of the process resulting in

downtime and consequently, lead to impact manufacturing operations performance.

The scope of this project was focused directly to the wet scrubber named SC-25. This scrubber system consists of two scrubber housings identified as Scrubber 25A and Scrubber 25B, connected in a serial configuration. The scrubber system is integrated to the manufacturing process as an external auxiliar component and is in the last phase of the air stream exhausted from the process. Figure 1 shows the streamline of air in the process towards the Scrubbers System SC-25 A/B. The Scrubbers SC-25A and SC-25B operates in a serial configuration maintaining an effluent water flow rate of 104gpm that is injected to the scrubber SC-25B and then recirculated to the SC-25A.

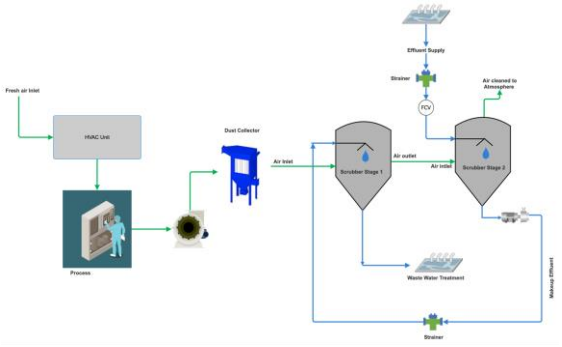

Figure 1
Airflow stream from the process phase to the Scrubbers

Recently, the pharmaceutical plant was experiencing several downtimes due to several situations with the scrubber operation. Besides a maintenance schedule existing for this system, several consistent unplanned interventions were reported. Consequently, maintenance costs provided by labor and material has increased. This in addition to the operational costs related to downtime.

One of the major issues reported upon Scrubber SC-25 failed to maintain the setting flowrate setpoint of 104gpm. The process startup requires the scrubber to operate at a flowrate of 104gpm. This flowrate is measured in two points, the first flow meter is before it enters to the scrubber SC-25B and the second point is in the effluent makeup transition prior entering into the Scrubber SC-25A. The scrubber system was having issues maintaining the flow rate of 104gpm specifically in the makeup point. Consequently, the system triggered alarms of low flow rate keeping the manufacturing process from start or continue.

The low flow rate is commonly related to clogs in the pipeline due to water sludge. Hence, maintenance program schedule is in place to periodically clean Scrubber components that includes pipeline, packing bed camera, sump camera, and basket strainers. However, sustaining the required flow rate is still a challenge that is significantly impacting system reliability and manufacturing process performance.

OBJECTIVES

Given the issues mentioned previously, the reliability and current maintenance condition were evaluated to identify and define improvements opportunities to the Scrubber systems SC-25. For this the following objectives were established:

- Reduce unplanned troubleshooting of the equipment.
- Reduce maintenance costs.
- Reduce process downtime and operational cost due to downtime.

LITERATURE REVIEW

EPA Regulations

Packed wet scrubber are emission control systems that are used to clean pollutant components from an air stream emission. These pollutant emissions are known as volatile organic components (VOC) and can be harmful to the human and air quality. Hence, the emissions of VOC emissions and particulates are controlled and regulated by the EPA. Due to the regulation requirements enacted over many industries, scrubbers' systems are introduced to many applications from different industrial sectors, including the pharmaceutical industry.

The design and operation of the scrubbers are provided based on the permit requirements

established by the Title V of the Clean Act [1]. The Title V permits provides the enforceable conditions, monitoring program, reporting, sources, and other provisions to assure that the operation of the scrubber system is in full compliance [2].

Scrubbers

Scrubbers' mechanisms are designed to remove VOC suspended along the exhausted airstream before is released to the environment. To remove the pollutant component, the scrubbers use electrostatic ionization, mirror force image attraction, effect through different mechanisms to trap the water droplets and VOC particulate. The wet scrubbers will require an injection of water spray that will serve as solution media to ionize the VOC particulate and trap the pollutant component by means of impaction mechanism [3]. The wet scrubber will also require a surface with a pack of helix design telleretes that is designed to trap the water droplet creating a surface tension that will trap the VOC particles through absorption. This packing surface of telleretes may come in different sizes that will depend on the particle size designed to capture. After the droplets of water capture the VOC particles, the wastewater is disposed from the scrubber housing to be treated or as in many cases the water is recirculated to the other connected scrubber [4].

The design of packed wet scrubber system and operation will rely on different characteristics such as waterflow injection rate, airflow rate, particulate density and size, differential pressure and among others to acquire the removal efficiency percent defined and accepted by the regulatory agency. Regularly, removal efficiency percent may range between 40% to 99%. Commonly, during the operational process of the scrubber, the effluent water that remains into the surface bed and sump will create a concentration of sludge. In the case, the scrubber system uses water makeup, an auxiliary component must be used to segregate solid sludge material from the water liquid. For this, strainers from several designs are placed into the water pipeline to collect the solidification components from the effluent water. The strainers play an important role within the scrubber's operation because it will prevent clogging in the pipeline, pump, and nozzles [4].

Failures of these equipment are mainly driven by recirculation pipeline clogging issue, inadequate design of pump capacity, inadequate size or volume of packaging bed, certain biological growth inside the scrubber housing, and among others. An effective troubleshooting, preventive maintenance and an effective monitoring system will provide the necessary tools to maintain a reliability standard of the system performance.

A maintenance program schedule for scrubber system is in place to maintain proper operation of the scrubber. The current program schedule for the scrubber system SC-25A consist in the following:

- Weekly: Cleaning of Strainers
- Monthly: Minor cleaning and inspection of Scrubber
- Quarterly: Cleaning and inspection including scrubber sump, packing and pipeline
- 3 Years: Replacement of packing telleretes

METHODOLOGY

The sigma tool DMAIC (Define, Measure, Analyze, Improve, and Control) was the methodology used to design the improvement for scrubber maintenance and reliability.

Define

According to the issues reported toward the Scrubber SC-25 system impacting maintenance performance and manufacturing process continuity, the project was defined to address the improvement of Scrubber SC-25 system reliability.

Measure and Analyze

Tools such as voice of the customer were used to gather information related to issues and need from impacted areas such as manufacturing, maintenance, reliability, and Environmental department.

As summary, Table 1 shows the feedback provided by the stakeholders that will be primarily impacted with the project. As a result of this tool, the feedback was linked together as appeared to have the same common denominator: pipeline clogging.

Table 1

Voice of the Customer Summary

Manufacturing	Scrubber constantly triggers low flow Alarm delaying process to start.
Maintenance	The scrubbers have been cleaned at least twice a day
Reliability	The scrubber has been one of the major offenders impacting equipment performance during recent months.
Environmental Manager	Water quality has decreased and several solids and bacteria growth has been observed inside the scrubber. Water must be treated.

Additionally, data from the maintenance system was retrieved to evidence the issues of the scrubbers by means of the work order demands generated for troubleshooting and repairs and other interventions performed through the preventive maintenance. In the year 2023, about 47% of the work order generated were demands service and troubleshooting while the other portion pertained to Preventive maintenance. In 2024, up to April 2024, the demands related to the Scrubber surpass 50% in comparison to the preventive maintenance. The results shown in Figure 2 imply an additional increase of labor and material costs.

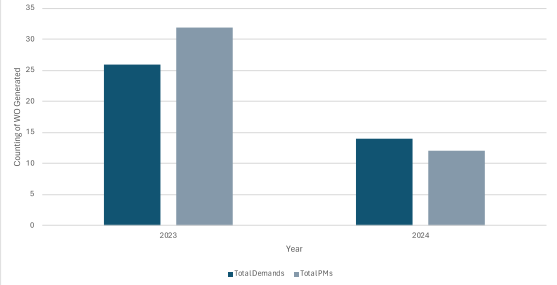

Figure 2

Comparison of Work orders Demand vs Preventive Maintenacne related to Scrubber SC-25 A/B.

Analyze

The fishbone analysis tool was used to organize and sort the data in terms of cause and effect. Figure 3 shows the fishbone analysis performed to understand the issues related to the scrubbers from the different cross functional areas that are impacted by the consistent required troubleshooting. Using this tool, the issues to address were defined in the aim to address the reliability improvement. Based on this information, short- and long-term enhancements proposals were designed to help the scrubber A/B system improve reliability operations.

Figure 3

Fishbone Analysis to Evaluate Scrubber SC-25 A/B Issues Rule Out

To complement this analysis phase, a visit to the Scrubber area was rendered during a preventive maintenance execution. During this visit, several factors and potential drivers of the issues brought were discussed and evaluated. One of these factors was the capacity of the pipe and strainer located toward the makeup phase.

Another major factor leading the scrubber to fail due to pipe clogging was the quality of the water treatment. Bacteria from the wastewater plant process is transferred with the effluent water distributed to the scrubber. These bacteria end up growing in the pipelines and scrubbers producing solidification and sludge consistency within the pipeline and scrubbers.

Improvement

Based on the analysis of the information gathered, data recollected and field visits, the following improvements proposal were developed for the short and long terms.

- Short Term: Preventive Maintenance job plan was modified focusing on the cleaning scope and schedule. In the case of the quarterly cleaning, some of the cleaning tasks such as sump cleaning and pipelines were included in the monthly preventive maintenance.
- Short Term: A project was proposed to increase pipeline and strainer capacity from 2in to 3in. The project was estimated and submitted to the management to approve the required funding.
- Long Term: A project was proposed to design an auxiliary system to treat water in-situ the scrubber system. The proposal consisted in connecting a fresh water supply into the scrubber and distribute the waterflow by a pump. The application of a specific caustic concentration into the auxiliary system of fresh water. The water will be drained and transported back to the wastewater treatment plant.

Control

The Scrubber performance is measured and monitored through the KPI's (Key Performance Index) and performance of the supporting manufacturing equipment. To measure the improvements, demands work order and production downtime related to the Scrubber SC-25 must be reduced.

CONCLUSION

The Scrubber SC-25 improvements were proposed for both short and long terms. Through the project and analysis, one important factor gathered was that the issues encountered within the scrubber SC-25 A/B were closely related and tailored to the main issue, the constant clogging. Understanding the history of the troubleshooting made on the scrubber, the analysis questioned the current capacity of the scrubber components.

While the current quality of the water fosters a faster bacteria growth inside the scrubber components, pipe sizing, strainers and pumps may not be able to manage such amount of solidification. The increase of the pipe sizing and strainer will help to handle better the solids growth due to bacteria.

The long-term proposal related to the local water treatment provides a suitable alternative to automize system cleaning by means of properly controlling bacteria growth by chemical treatment. However, the implementation of such a cleaning system my required further qualification.

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