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Abstract

Safety relief devices in a pharmaceutical manufacturing start-up were found to be occluded by rainwater. The number of times these vent lines were found to be occluded varied greatly and depended on weather conditions in the area. After analyzing all the available options, it was found that shifting the responsibility of maintaining these vent lines free of occlusion from the maintenance team to the operations team would decrease completely the chance of using these skids with occluded safety relief devices.

Introduction

As part of a vaccine manufacturing facility start-up, different processing tanks/skids were designed and installed, as shown in Figure 1. Two of the processing suites in the building are a purification room and a solvent charging room. During processing, these tanks contain hazardous chemicals like ethanol and isopropyl alcohol. In case of a safety incident, it is preferable for the safety relief devices on these skids to vent to the roof instead of venting inside the room, like in other processing suites.



Figure 1: Purification skid [1]

Problem

Since these safety relief devices vent to the roof, the issue that operations management was facing was that rainwater was observed in the sight glass of these skids, meaning the vent lines were occluded with rainwater. Figure 2 illustrates a standard sight glass that is attached to a vent line to show the contents inside this line. Since rainwater level can vary depending on weather conditions, if the sight glass at any point was filled with rainwater and a safety incident occurred, there was a great possibility that the safety relief device for the skid would not operate as it was intended to. There was not easy way to drain the rainwater that was going into the sight glass because it was a closed end. There was also not a procedure in place to look at these sight glass regularly or to check if the sight glass was clear and free of any water, other than a preventative maintenance (PM) that the maintenance team scheduled on these skids for every three months.

Since the amount of rainwater that can get into these vent lines can vary on the weather, going by the preventative maintenance alone was deemed to not be enough to prevent these safety relief devices from getting occluded.



Figure 2: Sight glass [2]

The main objective of this project was to eliminate the risk of failure of safety relief devices because of vent-to-roof occlusion in a vaccine manufacturing facility. To accomplish this, different options to monitor and drain vent to roof lines based on rainwater level were assessed.

Methodology

Two different options were assessed along with the cost and time it would take to implement each option. The first option was to assess the possibility of re-designing or modifying the vent line in a way that it will prohibit rainwater from entering the line without changing its desired use. The second option was to add a part to each vent line that will enable personnel to manually drain the sight glass if it gets visually filled with rainwater. To be able to decide which option was more viable for operations, research into vendors and parts were conducted and quotes were obtained. After assessing these options, the next step was to implement the change selected and ensure that the optimal path forward worked and can be maintained.

Results and Discussion

The two options mentioned before were considered by the team in charge of this project, composed of a representative from the maintenance, operations, technical operations, and quality department. After going over the downtime of re-designing the vent lines along with the costs and effort needed, the first option was rejected by the team, and it was decided that maintaining these lines free of occlusion as part of day-to-day operations was the optimal solution to ensuring all operations are performed safely.

The safety relief devices that vent to the roof were observed from Monday through Friday for two weeks for the team to understand how frequently these occlusions occurred. The data gathered can be found in Table 1.

It was found that the instances where these lines got occluded with rainwater varied greatly with weather conditions in the area. The first day of inspection, the lines were filled with water and the maintenance team scheduled the work to drain these lines. Thursday of week 1, three days after the lines were drained, the vent lines were observed to be occluded with rainwater again. During that following weekend, the maintenance team scheduled for the lines to be drained. During week 2, the vent lines were observed to be free of occlusion. After December 15th, the manufacturing plant started their winter shutdown, and all employees went away on vacation. During the first week of January, once the shutdown was over and the team went back to work, these vent lines were occluded. This proved that these lines were getting occluded frequently and the preventative maintenance on the skids scheduled for every three months was not enough to ensure the safety relief devices will work as intended in any unforeseen circumstance.

Table 1: Two-week inspection of vent-to-roof lines

| | Week 1 (Dec 4-Dec 8) | Week 2 (Dec 11-Dec 15) |
|-----------|----------------------|------------------------|
| Monday | Occlusion found | No occlusion |
| Tuesday | No occlusion | No occlusion |
| Wednesday | No occlusion | No occlusion |
| Thursday | Occlusion found | No occlusion |
| Friday | Occlusion found | No occlusion |

To be able to manage the maintenance of these lines, the sight glasses on the vent lines where the water was observed were changed from being a closed end to an open end that closed with an endcap and a tri-clamp. This way, during processing activities, a technician is instructed by a standard operating procedure to look at the sight glass for occlusion and, if occlusion is found, to drain according to the procedure.

To continue with the optimal solution selected, a quote was requested to one of the company's external vendors for the endcaps and tri-clamps needed. The work for these sight glass to be changed from closed end to an open end was scheduled and completed during the first week of January. After the work was completed, the standard operating procedures applicable for all skids that vent to the roof were requested and pulled for updates. All necessary updates were made to ensure instructions were added for the draining of these lines and the procedures were reviewed and approved by operations and quality representatives.

Conclusions

The change that was made by the team to these processing skids will ensure the effective management of these occlusions. By managing the draining of these vent lines before any processing activity begins will ensure that in case of any unforeseen circumstances these safety relief devices will work as designed and personnel, equipment, and facility will not be affected. The goal of all manufacturing facilities is to be able to work with a safety-first mindset and avoid any reportable injury caused at work. The goal is to ensure all employees can go back to their families with their health intact. Finding a possible unsafe situation and fixing it before an incident can occur is a great win and a good catch for the team and it is something that is promoted every day, for employees to tap in and speak up about unsafe situations they witness in their work areas.

Future Work

These vent lines will be continuously monitored to ensure the solution implemented can be maintained. If any changes are needed in procedures, it will be tracked and updated to continue to uphold the safety-first mindset in all parts of the process.

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Team members:

- Operations manager: Michael Loff Moreira
- Maintenance manager: Jacob Cropley
- Technical operations representative: Alyssa Brown
- Quality representative: Amber Sechrist

References

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