ON THE CONTAMINATION HUNT: INVESTIGATING OOS RESULTS

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BACKGROUND

When sterile compounding quality assurance parameters result in deviations, the out of specification (OOS) results must be investigated and corrected.

Viable sampling is one quality assurance activity to help maintain control in a sterile compounding clean room. In July 2021, sampling results for the Royal Alexandra Hospital (RAH) Main Pharmacy clean room demonstrated CFU counts exceeding action levels and higher than normal fungal growth. An investigation, including trending and root cause analysis, was completed in response.

VIABLE SAMPLING FACTS

- Counts of colony forming units (CFU) are used to identify the number of microbes growing on an agar plate.
- Investigations must be completed when greater than 10 CFU / 1000 L of air are collected from a clean room.
- Colony morphology refers to the visual appearance of bacterial or fungal colonies on an agar plate.
- Personnel, equipment, the environment, materials and processes can all be sources of contamination.

REFERENCE: NAPRA. Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. 2016. Available from: Mdl_Stnds_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Nov2016_Revised_b.pdf (napra.ca)

METHODS

Collection of viable samples from the air was conducted by trained pharmacy technician aseptic leads according to a consistent site sampling plan. The plan outlines the number of agar plates, sample locations and volume of air collected by impaction sampling.

The agar plates were incubated at 30° to 35° Celsius for 3 days and 20° to 25° Celsius for 3 days. When visual observation of recovered microbes suggested fungal growth, some plates were incubated for an additional 2- 3 days to improve potential for identification by colony morphology characteristics.

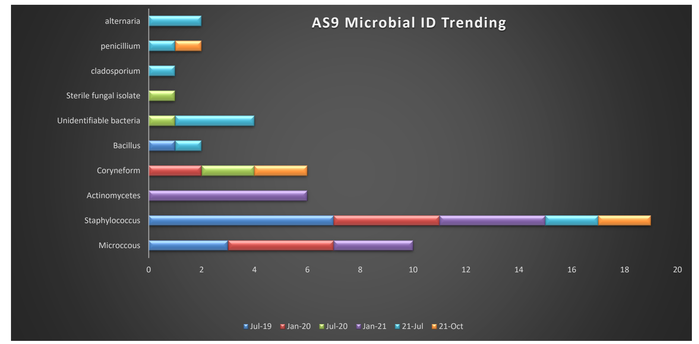
As a standard initial action for all viable sample OOS investigations, a deep clean of the clean room and re-sampling was completed. Viable air sample CFU counts continued to exceed actions levels.

An investigation plan was initiated which included:

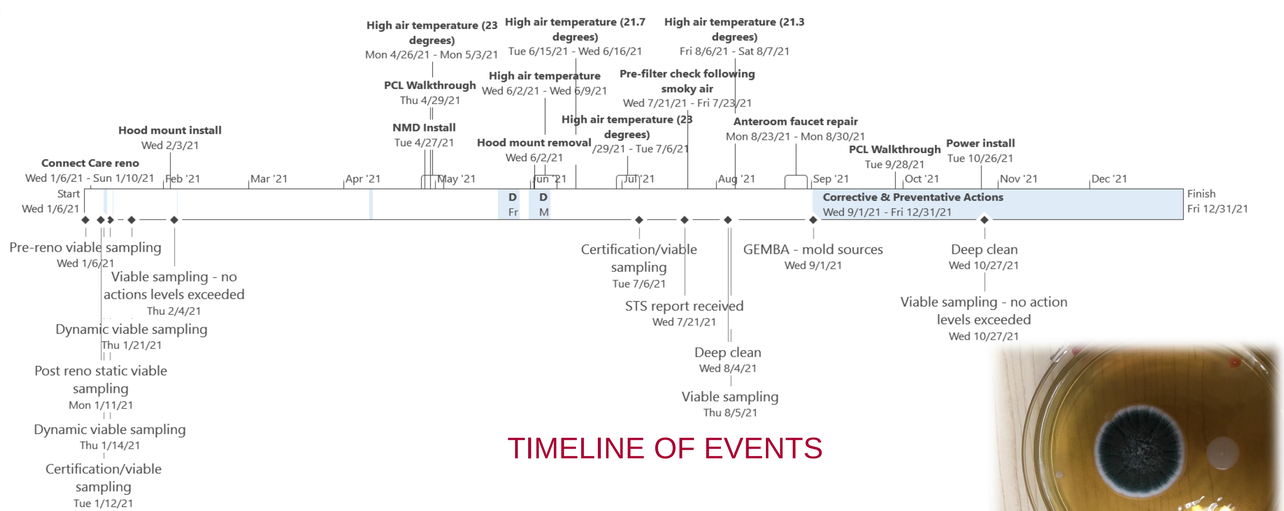
- Review of temperature, cleaning and personnel assessment documentation
- Observation of current conditions in the clean room to identify potential sources of contamination (GEMBA walk)
- Evaluation of cleaning solutions and practices
- Review of heating, ventilation and air conditioning (HVAC) maintenance
- Timeline creation of all maintenance and outside provider activity in the clean room
- Root cause analysis using a 5 Whys tool

RESULTS

A historical review for the period of January 1 2021 to October 31 2021 was completed. Trending of viable sampling results, especially one sample location (AS9) prone to excursions, showed reoccurring OOS and fungal growth.



Over the course of the review period there was increased activity in the clean room due to the install of power and equipment. The timeline of maintenance requests confirmed that there were repeatedly high temperatures caused by seasonal heat waves and inefficient cooling. These conditions were contributing factors for the OOS results and were the basis for corrective actions.



TIMELINE OF EVENTS

Photo of air sampling agar plate growing penicillium and other microbes recovered from RAH pharmacy

CONCLUSION

Actions related to decreasing the transference of contamination by personnel and cleaning practices have helped improve current state. Viable sampling completed October 27 2021 did not exceed action levels of 10 CFU/1000 L of air but there was still fungal growth (1 CFU each on 2 agar plates) recovered from the clean room.

Further actions are needed to remediate the presence of mold and prevent repeat OOS sampling results. The benefit of more frequent viable sampling (at least quarterly) has been demonstrated.