Case Study of Environmental Mold Isolation in a Controlled Manufacturing Facility

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BACKGROUND

Problem Statement:

Atypical levels of mold recovered from an environmental monitoring test session in a Grade D environment.

Introduction

At Pfizer Sanford we manufacture:

1. Drug substance intermediates
2. Carrier protein used in vaccines
3. Clinical trial materials

We are not a Fill/ Finish site; however, we have a sterility requirement on our intermediates.

Disclaimer:

This presentation is a case study of a system evaluation and implementation, it is not intended to advertise or endorse any vendor's technology.

OUTLINE:

- Right level of awareness
- Right level of response
- Right level of resources

Laboratory Personnel

- What is atypical?
  - Amount of mold recovered?
  - Number of sites that recovered mold?
- When to escalate?

Trend Analysis

- Real-time trending performed by the laboratory
- Monthly trending of EM results for informational use and communication to the manufacturing floor
- Quarterly and annual trend reports

Is response required?

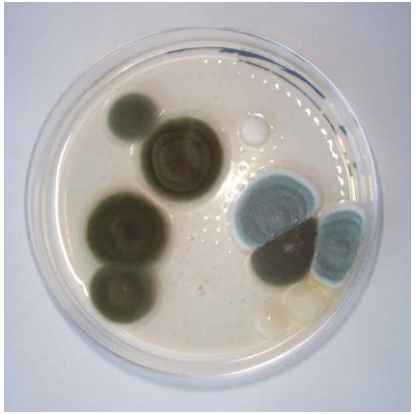
- What is the grade/classification of the area?
  - Does a higher classification require a different response?
- What are previous trends in the area?
- How to document the remediation?

What process occurs in the area?

- Is the process open or closed?
  - Does the process manage the risk?
  - In-process sample results?

What are the risks?

- Identification of the organism?
  - What risk does the organism present?
    - Quantity
    - Toxin production
    - Disinfectant effectiveness
    - Unique characteristics



Cross-functional team!

- Who should be the team?
  - QC Microbiology, Microbial Control, QA, Manufacturing, Engineering
  - How often should the team meet?
    - Meet at the appropriate frequency for response and remediation

RESOURCES

Risk assessment performed with cross functional team to assess continued processing in the area

Identify Potential Sources

- Areas of penetration
- Pressure differentials, temperature and humidity
- Non-invasive examination of HEPA filters
- Non-routine activities in the facility (internal and external)
- Seasonal variation
- Training and aseptic practices of personnel

2 Potential Sources were Identified

- Room B – access room to decon autoclave
  - MoldGuardian™, a mold prevention solution was applied to adjacent, non-classified areas
  - Additional routine air viable sample location added to the EM sample plan
- Eyewash Station
  - Closed up any penetrations
  - EM sample locations already in the EM sample plan

Additional Sampling

- Weekly sampling of routine sites until 3 weeks of acceptable results
- BioTrak® - Rapid technology utilized to determine potential root cause
  - Performed routine sites
  - Used the “sniffer” to verify sources. All sources remediated.

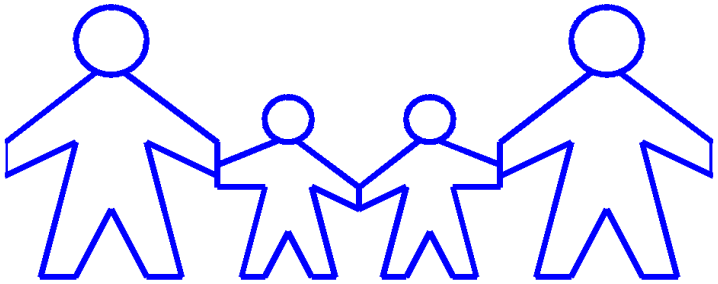
PROCESS IMPROVEMENTS

- Awareness –report outs to manufacturing colleagues, including level of growth and types of growth and monthly trends
- Response –report outs ensure quicker responses to atypical results
- Resources – Environmental Review Committee meets to discuss trends and organisms. Mold prevention solution application on a defined frequency (PM).

IS IT WORKING?

- Manufacturing colleagues are now contacting Microbial Control to push out information that may be impactful to the environment.
- Atypical levels of mold have not been recovered in the manufacturing facility post changes.

Microbial Control is the Priority!



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THANK YOU