

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

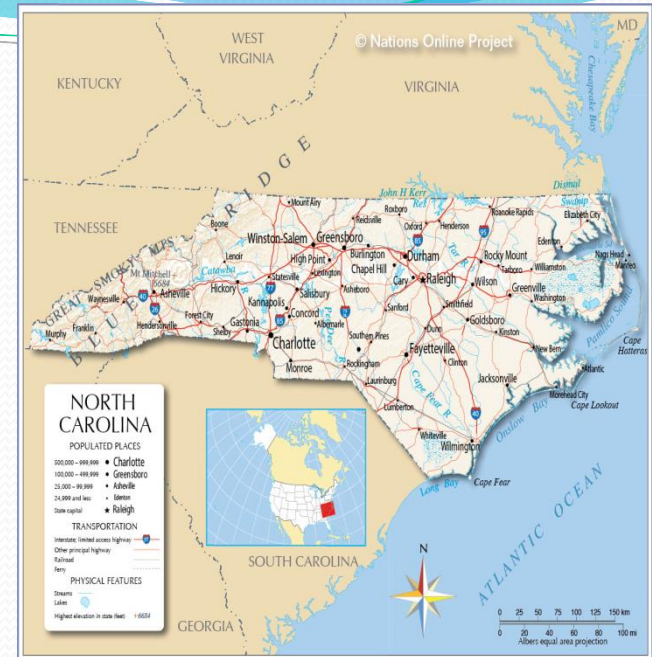
At Pfizer Sanford we manufacture:

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

We are not a Final 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

AWARENESS

Laboratory Personnel

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



AWARENESS

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



RESPONSE

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?

RESPONSE

What process occurs in the area?

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

RESPONSE

What are the risks?

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



RESOURCES

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



RESOURCES

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

POTENTIAL SOURCES

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

RESOURCES

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

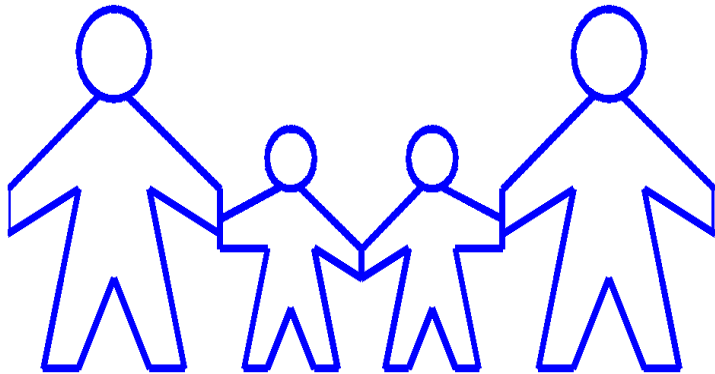
- Awareness –report outs to manufacturing colleagues, including level of growth and types of growth and monthly trends
- Response –report outs ensure quicker responses to atypical results
- Resources – Environmental Review Committee meets to discuss trends and organisms. Mold prevention solution application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

CONCLUSION

Microbial Control is the Priority!



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



THANK YOU