VALSOURCE

Growth in the Workplace: Enhancing Standards for Complete Mold Remediation in Pharmaceutical Cleanrooms

Introduction

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Agenda

- Mold Remediation in the Pharmaceutical Industry
- Mold Remediation in the Cleaning and Restoration Industry
- Moving Forward with Mold Remediation
- References

Mold Remediation in the Pharmaceutical Industry

Scope

Small, Isolated Mold Recoveries

- One-off recoveries
- Low CFU recoveries
- No adverse trend

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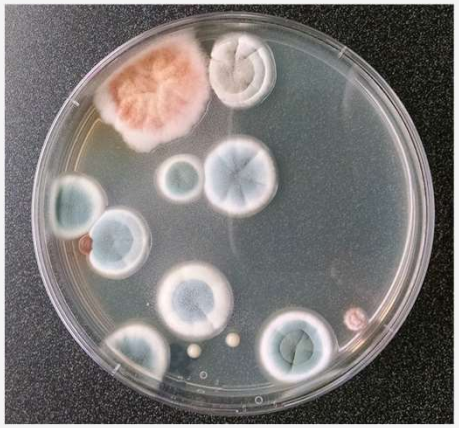

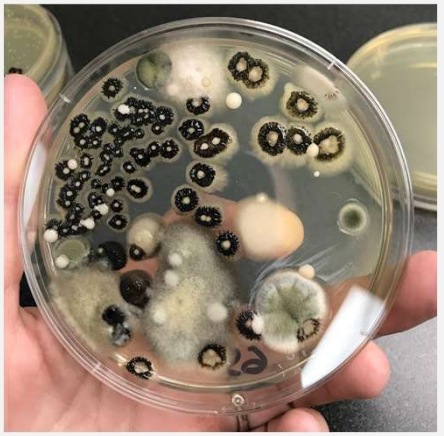

Warehouse Settle Plates

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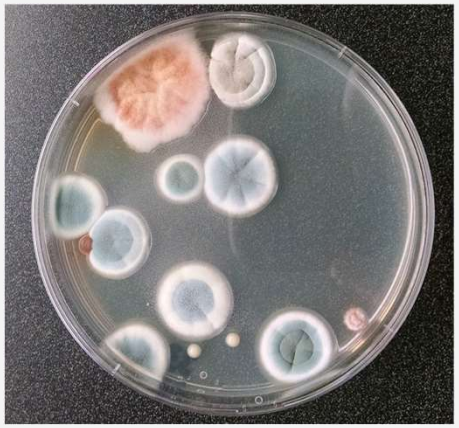
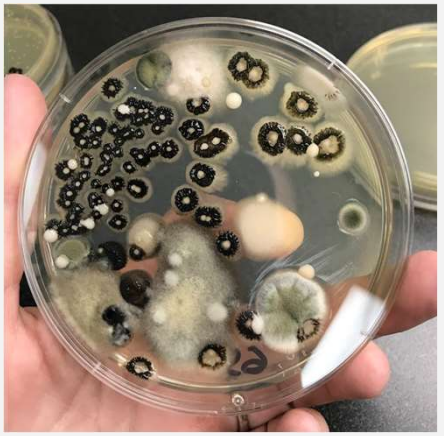
Easy to remediate!
Area cleaning/disinfection
Procedural changes





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- High CFU recoveries
- Adverse trends
- Don't respond to standard remediation efforts

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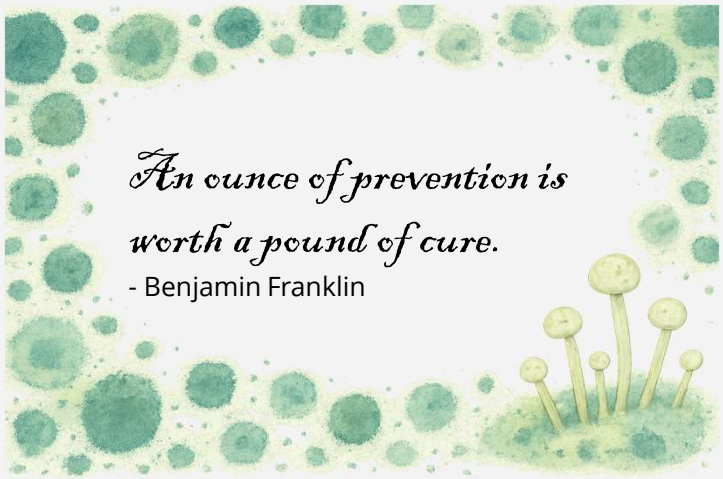
Mold Investigation and Remediation Guidance

"The most common cause of fungal spore…contamination in the cleanrooms are items that enter the cleanroom." Examples include tools, equipment, boxes, carts, etc.[1]



SO MUCH GUIDANCE on:

- Sources of mold and environmental control to prevent mold[2,3,4,9]
- Monitoring of mold[2,8,10]
- Investigation of mold events[1,3,4]
- Cleaning and disinfection programs that are effective against mold[3,4,9]

Case Study 1: Large, Isolated Contamination

Background: Warehouse employees identified visible mold on cardboard boxes, wire shelves, and wall material in the warehouse**.**

Root Cause: Not investigated. Assumed to be due to high humidity due to geographical location.

Remediation: Opened the warehouse roll-up doors to the outside for ventilation and used a sporicidal agent on all impacted surfaces. Discarded impacted cardboard.

Case Study 2: Large, Pervasive Contamination

Background: Firm had mold in one of their Grade B cleanrooms coming from the humidified incubators. CAPAs included enhancing the PM procedures for the incubators and using an antimicrobial agent in the water pans.

By this time, however, the incubators were contaminated throughout and were continuing to exhaust spores into the cleanroom. New incubators were sourced, purchased, validated, and implemented.

Now though, mold is still being recovered from the original cleanroom and a cleanroom on the same AHU.

Case Study 2: Large, Pervasive Contamination

Root Cause: Assumed that mold originated in the incubators and had found subsequent reservoirs within the cleanroom.

Remediation: Company brought in a third party to fog the impacted cleanrooms with vaporized hydrogen peroxide (VHP). Cleanrooms were fogged at least 4 times in a 1-month timespan, with continuing mold recoveries from air EM samples.

Takeaway Lesson: Mold remediation must occur quickly. The source of the mold, as well as the water and nutrient source it's using, must be identified in order to remediate it.

What's Wrong Here?

Incomplete remediation can lead to:

- Recurrence
- EM excursions, adverse trend investigations, deviations
  - Delayed batch release
- Ineffective CAPAs, leading to wasted time/effort/money
- Contaminated product

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WXYZ Channel 7

Ex-NECC owner pleads no contest to manslaughter charges in Michigan connected to 2012 meningitis outbreak

Barry Cadden, the former owner of New England Compounding Center (NECC), pled no contest to in connection to the 2012 fungal meningitis...

Mar 5, 2024

Law360

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A Michigan judge sentenced former New England Compounding Center founder and president Barry Cadden to at least 10 years in prison on May 10...

May 14, 2024

Mold Remediation in the Restoration Industry

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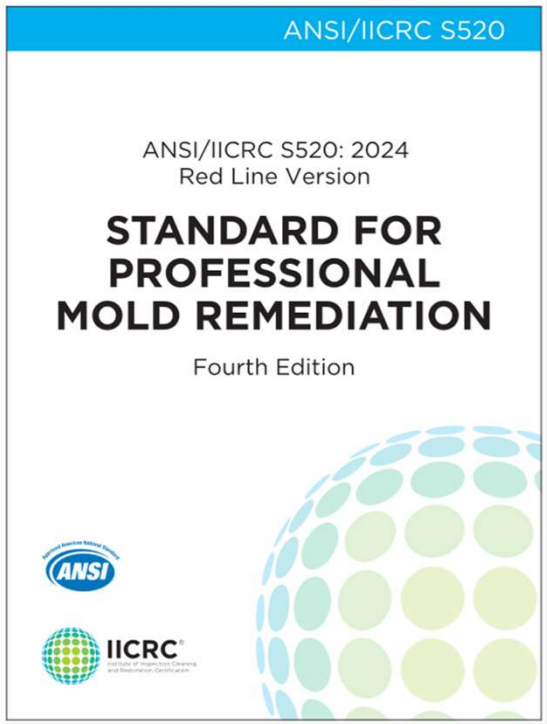
IICRC (Institute of Inspection Cleaning and Restoration Certification): Global organization that provides industry standards, credentials, and certifications

- Each state will have its own set of standards and license requirements.

Illinois amends Mold Remediation Registration Act to include IICRC certifications; Gov. Pritzker signs SB 1087 into law following unanimous legislative approval

Aug 15, 2024 • Press Release • 2 min read



Major Themes of Mold Remediation[5]

Primary mold remediation technique: Physical removal of contaminated items.

- Disinfection/fogging/etc. with antimicrobial chemicals is **not** to be used in place of physical removal.

1.4 Contamination Removal

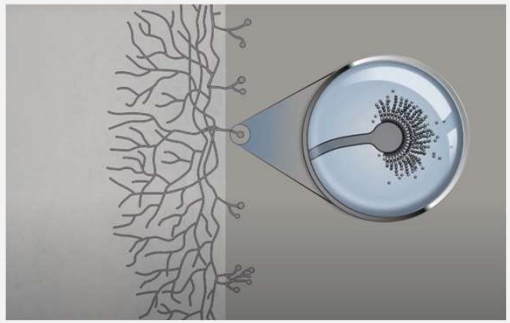
Physically removing mold contamination is the primary means of remediation. Mold contamination *should* be physically removed from the structure, systems, and contents.

Attempts to kill, encapsulate, or inhibit mold instead of proper source removal generally are not adequate. The Standard emphasizes source removal by physical methods, therefore utilizing spray, fog, foam, gas, or other remediation approaches, without physical removal, is a deviation from this standard of care. Refer to Sections *2.1.2 Cleaner, Stain-Remover and Antimicrobial Application Considerations* and *9.3.9 Deviation from Removal Processes* for additional information.

Why?

Major Themes of Mold Remediation[5]

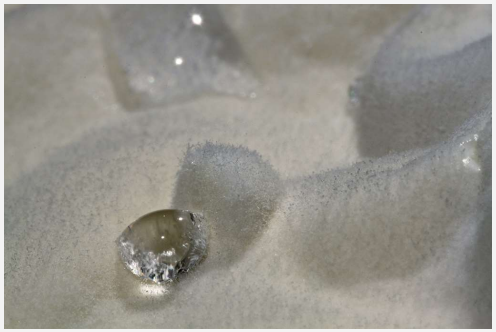
1. Only removes surface structures, not the hyphae ("roots")[5]



Inside material

Visible surface

2. Some molds are hydrophobic and repel water-based disinfectant droplets[6]



3. Nonviable spores can still cause health effects[7]

Major Themes of Mold Remediation[5]

Locate the mold, nutrient, and water source(s) and remediate them.

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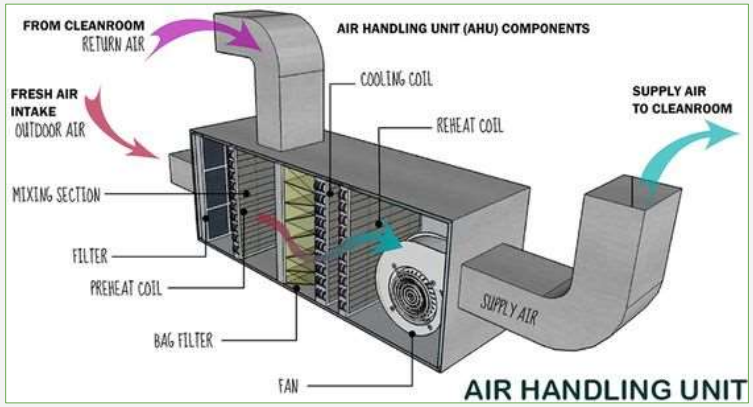
Ensure current HVAC system is able to maintain appropriate temperatures and relative humidities.



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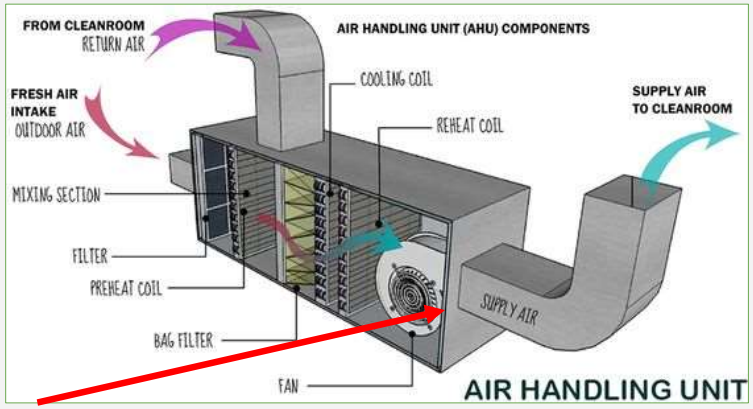

Sensors

Major Themes of Mold Remediation[5]

Containment with HEPA filtration under negative pressure is critical during remediation activities.

Containment ≠ painting over mold with mold-resistant or encapsulating paint.

Moving Forward with Mold Remediation

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Source of mold (including nutrients and water source) to be investigated before it can be remediated

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1. Personnel involved aren't trained or qualified, and do not have sufficient PPE to protect themselves or prevent spread throughout the facility
2. Impacted surfaces not physically removed = mold left in the space
3. Nonviable spores can still cause health problems
4. (Assumed) high humidity was not addressed

Case Study 2: Large, Pervasive Contamination

Summary: Company had mold that originated in their humidified incubators. Over several years, they investigated, implemented CAPAs, and eventually replaced the incubators. Now there is still mold in their air, and it is unknown where it's coming from. Room has been fogged with VHP an exorbitant number of times.

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1. Contain the room. Stop using it. Stop VHP fogging it.
2. Take investigational EM samples in strategic locations.
3. Take atmospheric readings (rH, temperature). Is the system functioning?
4. Look for other moisture sources.
5. Look for biofilms.

Conclusion

- The pharmaceutical industry is good at dealing with small, isolated mold recoveries.
- We can learn from the cleaning and restoration industry
  - Physical removal of contaminated materials must be primary
  - Mold, nutrient, and water sources must be identified and remediated
  - Current HVAC system must be evaluated
  - Impacted area must be properly contained

References

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6. Bayry J, Aimanianda V, Guijarro JI, Sunde M, Latgé JP. “Hydrophobins--unique fungal proteins.” PLoS Pathog. 2012;8(5).
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9. United States Pharmacopoeia. “<1072>: Disinfectants and Antiseptics.”
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Thank you!
Any questions?