NEWSLETTER ISSUE: OCTOBER 2025

the pure observer

Stay current on compounding, contamination control, and compliance best practices with pure microbiology

We're Talking About Highly Pathogenic Organisms…Again

We received a question through The Aseptic Connection last month, and it made us say, "not again." Just when we thought we were past dealing with the misleading term "highly pathogenic organism," we discover we're not. But we're here to help, so let's take a look.

"Our board of pharmacy now requires cleanrooms to have corrective action plans if highly pathogenic organisms are found in environmental monitoring, but they don't define what organisms qualify, nor does the current USP <797>. We are working with our EM vendor and infection control. Do you know if there's a standard or accepted list of highly pathogenic organisms in environmental settings (e.g., similar to what's used in ORs)? Or any guidance on how we can approach developing a policy for this?"

The Term

The term "highly pathogenic organism" is a dangerous one, which is why we believe it was removed from USP <797>. Our June 2024 newsletter discussed this term in detail. If you haven't read that issue, we encourage you to take a look. A more appropriate term for the sterile compounding industry is "organism of concern." This broader term not only focuses on pathogenicity, but any risk that its presence could bring to the sterile compounding environment. That's really what we need to consider.

The List

It's frustrating that a board of pharmacy requires action plans for "highly pathogenic organisms" but doesn't provide guidance as to what it considers those organisms to be. There are a few lists out

there, such as WHO Bacterial Priority Pathogens List, 2024, FDA's Bad Bug Book, and FDA's rule titled, "Establishing a List of Qualifying Pathogens Under the Food and Drug Administration Safety and Innovation Act," but they are more applicable to public health concerns and not specific to the pharmaceutical/compounding industries.

The Reality

This lack of a list (which is a good thing) leaves the aseptic manufacturers and sterile compounders on their own to evaluate the microorganisms recovered. Now, the aseptic manufacturers have microbiologists on staff to assist with this. For the sterile compounders, it is critical that they partner with a microbiologist or infection preventionist. The pharmacy can't do this on its own. Some labs provide organism monographs that may be helpful, but that shouldn't be the sole source of determining risk.

The Guide

We can give you a general guide to follow, but each recovery will need to be evaluated based on the microorganism, the number of colony forming units (CFU) recovered, where the growth was recovered (way less concerned about anteroom recovery than buffer room recovery), and frequency of recovery. It will also be easier to determine risk if you have a species-level identification. Remember, this is not an all-encompassing list.

Spore-forming bacteria (e.g., *Bacillus*): Endospores resist drying, heat, and many disinfectants and can survive routine cleaning. Their recovery often means gaps in sporicidal disinfection, dirty/porous materials, or dust/dirt intrusions.

Gram-negative, water-associated rods (e.g., *Pseudomonas, Burkholderia cepacia* complex, *Ralstonia*): These are strong biofilm formers, intrinsically more disinfectant-tolerant. Many produce endotoxin, which is a patient safety risk, even if cells are later killed.

Molds and yeasts (e.g., *Aspergillus*, *Penicillium*, *Cladosporium*, *Mucor, Candida*): Airborne spores can travel far, seed surfaces and HEPA

housings, and be difficult to kill on damp or damaged materials. Some are opportunistic pathogens.

Some human-associated gram-positive cocci (e.g., *Staphylococcus aureus*, *Enterococcus*): Direct link to operator shedding. *S. aureus* is a notable pathogen.

Wrap-Up

A list isn't the answer; build a risk-based framework. Define "organisms of concern" in your SOP. Partner with a microbiologist or infection preventionist to interpret recoveries, document the rationale for every action, and use data to verify that controls are working. This approach aligns with USP <797> intent, satisfies board expectations for corrective action plans, and—most importantly—keeps patients safe without overreacting to labels.

QUESTION of the MONTH

If a viable air or surface sample has an exceeded action level, can we stop counting the colony forming units (CFUs) once the action level is reached?

No. You need to keep counting. The number of CFUs recovered is critical to properly trend data. Additionally, stopping the count at a random number and documenting that number would be considered falsification of data.

Only a few seats remaining in our November Pure Primer: Sterile Compounding and Handling Hazardous Drugs live training.

November 10-13, 2025

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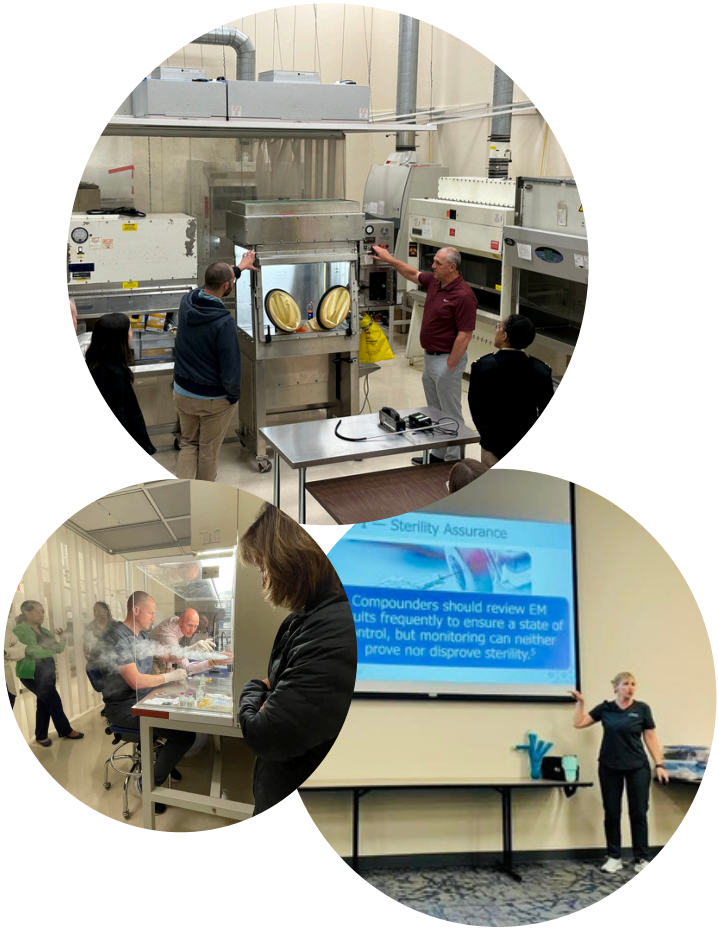

best practice makes perfect

USP Chapters 〈1113〉 Microbial Characterization, Identification, and Strain Typing and 〈1117〉 Microbiological Best Laboratory Practices are out for public comment! Take some time to check out the proposed changes to see how they might affect the microbiology aspects for your sterile compounding practice.

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Abby Roth, founder of Pure Microbiology, has been supporting the testing and consulting needs of the pharmaceutical, medical device, and compounding industries since 2004. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring. Abby also has participated in multiple microbial excursion investigations, providing guidance on contamination sources and remediation options.