While finding viable growth in your cleanroom suite can be alarming, some types are not uncommon and can be controlled if you take the appropriate steps. Gram-positive cocci are typical because they are resident bacteria that live on everyone’s skin. Additionally, fungi such as mold and yeast release spores that personnel can easily carry on themselves or on the materials they bring into the room.

You should think of fungi as “atypical” and work persistently to keep it out of the cleanroom. Since it’s not feasible to sterilize personnel, you must control the amount of contamination brought in to reduce the amount of risk in sterile compounding and ensure you are delivering a safe and effective product to your patients.

Reducing Risk of Fungi in a Cleanroom:

1. **Change into laundered scrubs and dedicated footwear before donning cleanroom garb:** Before arriving at work, personnel might perform everyday tasks like walking the dog or taking out the trash that introduce bacteria or fungi onto their person. To minimize the transfer of these particles, require fresh clothes prior to garbing to keep outside contamination out of the cleanroom.

2. **Send items, not spores, into the cleanroom:** Before compounding, components must first be transferred into the cleanroom. Stock is often stored in bins or boxes that are under constant exposure to spores in the general environment. Treat items with an appropriate sporicidal just prior to transfer to ensure that you leave the spores behind.

3. **Confirm that sporicidal instructions are completely followed during cleaning:** Spores survive in harsh conditions and can only be effectively eliminated when exposed to specific agents over an adequate length of time. Whether disinfection is performed by environmental services or the pharmacy department, personnel must never take shortcuts and must always follow instructions thoroughly to avoid wasting both time and effort.

4. **Consider performing your own environmental sampling:** Your own personnel are already qualified in garbing, handwashing, and aseptic technique, so use their expertise to perform in-house environmental sampling to effectively confirm control.

5. ** Routinely sample cleanroom surfaces:** Carts, racks, bins, and pass-throughs are touched by the same gloved hands that enter the primary engineering control. Surface sampling is an objective indicator of your disinfecting effectiveness and can also warn you when microorganisms have a direct pathway into the compounding area.

6. **Stay in touch with your cleanroom:** If your daily routine does not include regular cleanroom time, stop in for unannounced visits to evaluate opportunities for improvement. Keep watch for things like gaps in the ceiling, blocked air returns, simultaneously opened doors, cardboard and other clutter, dusty storage bins, poor garbing practices, and other red flag items.

7. **Evaluate your air supply:** Sharing an HVAC system with the rest of the hospital can result in inefficient elimination of spores and fungus in the cleanroom. Other parts of the building can “steal” cool air that is needed by the HEPA filters to effectively remove all the particles and heat generated during garbing, compounding, and cleaning. If airborne viable results are a consistent problem, consider making a case for a dedicated HVAC system to avoid compromised air supply.

8. **Support your case for an HVAC upgrade with data:** To support a proposal for an upgraded HVAC system, share unfavorable test results with your administration. Highlight temperature, humidity, pressure differential, and viable test data that show a trend that supports your concerns about the air supply.
9. **Compare certification reports over time:** Review test results and reporting for trends over time. Each report is a snapshot in time, so changes that occur from report to report can be an early indicator of a drop in performance. Confirm leak tests on every HEPA filter and evaluate any reduced air velocities, declining pressure differentials, or losses in air changes per hour.

10. **Keep copies of maintenance records:** Copy and file all records of pre-filter changes and HVAC maintenance. Use other test results to evaluate whether pre-filters are being changed with adequate frequency.

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**USP <797> Revisions**

If the proposed <797> revisions are approved, the type of microorganism will no longer trigger an action limit. Instead, viable limits will only be based on the number of colony forming units (CFUs) recovered. In addition, the proposed revision will no longer require routine genus identification of CFUs. Only exceeded action limits will require identification. It is still too early to know the full impact of these changes, but they do pose some questions.

Will states change regulations to respond to the new requirements? Will third-party microbiology labs adjust their services? With less sample identification, will pharmacies only have limited knowledge of what’s a typical growth in their cleanroom? We are interested in your comments. Please write us at Eric.Bauer@CAPSPharmacy.com

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**Countdown to USP <800>**

In this issue, we have emphasized the importance of having a dedicated HVAC system for your cleanroom. This is even more critical for buffer rooms that are negative pressure. Primary engineering controls that are ventilated will remove a lot of air from the room, but the pressure differential cannot be greater than negative 0.03.

To avoid having too much negative pressure, a large amount of clean air must be put back into the room. If not provided exclusively from the HEPA filters, the buffer room will take air from any path of least resistance (e.g., gaps, leaks, and any other openings). Not only are these a source of unfiltered air, they can also be a route used by spores and other viable contamination to gain access into your cleanroom.

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