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Top 3 “People Bugs” Found in Sterile Compounding Pharmacies

In sterile compounding pharmacies, the goal is simple: keep the compounded medications sterile—especially from the people working in the cleanroom. Even in the most tightly controlled cleanroom environments, viable air and surface monitoring often reveal a familiar microbial cast of characters: organisms that hitch a ride on skin, hair, and clothing. These “people bugs” are common contaminants in sterile compounding pharmacies, and while often considered low-risk, their presence can signal breaks in aseptic technique or garbing compliance.

Here are the **top three microorganisms that are** most frequently recovered—and what they mean for your facility.

1. *Staphylococcus epidermidis* – Gram-positive cocci

Pathogenicity Concerns

While often dismissed as a harmless skin commensal, *S. epidermidis* can be a serious, opportunistic pathogen, especially in immunocompromised patients or when it contaminates parenteral products. It forms biofilms on medical devices and resists many antibiotics, making it a notable risk in sterile compounding.

Why It Shows Up

- Originates from skin and mucous membranes.
- Poor aseptic technique, inadequate glove sanitization, or improper garbing can lead to recovery on surfaces or air samples.



Remediation Considerations

- Retrain on garbing protocols and glove sanitization.
- Reinforce hand hygiene.
- Conduct root cause analysis (RCA) for repeated detections.
- Increase cleaning frequency of high-touch surfaces.

2. *Micrococcus luteus* – Gram-positive cocci

Pathogenicity Concerns

Typically **non-pathogenic**, *M. luteus* is a low-virulence environmental and skin microbe, but its presence is an indicator of human contamination. Rarely, it can cause infections in immunocompromised hosts.

Why It Shows Up

- Commonly found on skin, hair, and clothing
- Often recovered on contact plates (e.g., work surfaces, gloves, sleeves)
- Survives in low-nutrient environments, including cleanrooms

Remediation Considerations

- Emphasize garb inspection and glove sanitization.
- Review facility airflow and surface cleaning protocols.
- Consider personnel monitoring frequency or retraining.

3. *Corynebacterium spp.* – Gram-positive rods

Pathogenicity Concerns

Corynebacterium species are part of the normal skin flora but include strains (like *C. striatum*) that are emerging as **nosocomial pathogens** capable of causing bloodstream infections.

Why It Shows Up

- Associated with **skin shedding**, particularly from poorly garbed personnel
- Can indicate underlying HVAC issues or compromised air cleanliness

Remediation Considerations

- Audit HVAC performance and differential pressure.



- Retrain on aseptic movement and garbing practices.
- Investigate cleaning effectiveness.

Key References and Resources

1. USP <797> (2024) – *Pharmaceutical Compounding–Sterile Preparations, United States Pharmacopeia.*
2. CDC – Opportunistic Pathogens and Environmental Monitoring <https://www.cdc.gov>
3. PDA Technical Report No. 70 – *Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing*
4. FDA Guidance for Industry – *Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice*

Final Thoughts

These microbes aren't breaking into your cleanroom—they're *walking in with you*. Recovering *S. epidermidis*, *M. luteus*, or *Corynebacterium* doesn't always spell doom, but it's a flashing warning light that people are the primary contamination risk in sterile compounding. Just wearing a gown? It might be time to move to a full coverall. With robust training and contamination control strategies, you can keep these bugs out—and your compounded preparations safe.

best practice makes perfect

Read USP <1163> Quality Assurance in Pharmaceutical Compounding. It's available through the Compounding Compendium and is a great companion document to USP <797>.





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The only chapter requirements for non-HD gowns are that they fit snugly around the wrists and an enclosed neck. Back closing gowns are not recommended because staff often do not properly pull them all the way around the body to cover their back, resulting in more particles being released into the cleanroom.



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Instructors include:

Abby Roth, CMQ/OE

Patricia Kienle, RPh, MPA, BCSCP, FASHP

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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.