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the pure observer

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

Do You Really Need to Triple Clean?

What it is, where it comes from, and when three passes are truly justified

The short version: A triple clean is a deliberate, three-pass cleaning and disinfection process used to establish or recover microbial control. It is not the same as the USP <797> monthly cleaning requirement, and it should not be the automatic response to every environmental monitoring excursion.

What exactly is a triple clean?

In sterile compounding, a triple clean means treating the same target surfaces three separate times. Each pass must be complete, methodical, and performed with fresh, appropriate supplies. A practical sequence is:

1. Pass 1: Apply an EPA-registered one-step bactericidal disinfectant cleaner to remove soil and reduce vegetative microorganisms.
2. Pass 2: Repeat with the bactericidal disinfectant cleaner or transition to an EPA-registered one-step sporicidal disinfectant cleaner, based on the reason for the cleaning and the facility procedure.
3. Pass 3: Apply an EPA-registered one-step sporicidal disinfectant cleaner.

Three applications do not mean three quick sprays. Each application must cover the entire surface, use the product exactly as labeled, maintain the required wet contact time, and avoid recontamination. The SOP should define the agents, order, surfaces, tools, wiping pattern, contact times, residue-removal step, and documentation expectations.

Where did the triple clean come from?

The triple clean did not originate with USP <797>, and it is not a procedure defined by the chapter. Its roots are in pharmaceutical and biopharmaceutical cleanroom practices, where multiple cleaning and disinfection passes have long been used as part of contamination-control and remediation activities. Today, triple-cleaning protocols are commonly described in the context of CGMP cleanrooms, including post-construction cleaning, facility start-up, and recovery from microbial contamination.

That distinction matters. USP <797> requires surfaces in sterile compounding areas to be cleaned, disinfected, and treated with a sporicidal disinfectant at specified frequencies. It does not say that the entire suite must be cleaned three times after every recovery or every action-level result. A monthly clean is the scheduled cleaning and sporicidal application required by the facility's program. A triple clean is an escalated recovery measure.

When a triple clean makes sense

- After new construction, renovation, or major repair work that introduces dust, debris, or uncontrolled traffic into the compounding area
- After an extended shutdown or loss of environmental control when the facility cannot rely on the prior state of control
- Following water intrusion, visible contamination, or another event that broadly compromises the cleanroom suite
- During remediation of a significant or persistent microbial problem, especially when results show widespread contamination, repeated recovery of concerning organisms, or evidence that routine cleaning has failed
- When required by a state board of pharmacy, accreditation body, approved remediation plan, or facility SOP

When it should not be the default

A triple clean should not replace investigation. One isolated environmental recovery does not automatically mean the entire space has lost microbial control. Before escalating, look at the full picture:

microorganism identity, recovery location, colony count, historical trends, personnel and compounding activity, cleaning records, facility conditions, and whether the result is isolated or recurring.

- Do not use it as an automatic response to every single action-level excursion.
- Do not substitute it for targeted cleaning when the source and affected area are limited and well understood.
- Do not use it to compensate for weak routine practices, poor technique, inadequate training, damaged surfaces, airflow problems, or an ineffective cleaning program.
- Do not assume that “more cleaning” is always better. Repeated sporicidal use can increase residue, material-compatibility concerns, staff exposure, downtime, and supply costs.
- Do not perform three passes without allowing the label contact time for each product. Incomplete applications create extra work without delivering the intended result.

Use a risk-based approach

The decision to triple clean should be intentional and documented. A useful trigger is evidence that the microbial state of control has been broadly compromised or cannot be confidently demonstrated. If the problem is localized, the response should usually be localized too. If the problem is systemic, persistent, construction-related, or associated with a major facility event, a cleanroom suite-wide triple clean may be appropriate as one part of the remediation plan.

Before you triple clean, ask:

- What evidence shows that routine or targeted cleaning is not enough?
- Is the issue localized, widespread, persistent, or tied to a major facility event?
- What agents, sequence, contact times, and residue-removal steps are appropriate for the affected surfaces?
- How will we verify recovery before resuming normal operations?

The bottom line

A triple clean is worth the effort when you need to bring a new cleanroom into a state of control, get it back under control after a shutdown or major facility event, or recover from a significant contamination problem. But it is not a universal remedy, and it should never become a reflexive substitute for root-cause investigation. Reserve it for the situations that justify the labor, chemistry, downtime, and documentation. The goal is not to clean more often than necessary. The goal is to use the right response for the actual risk.



best practice makes perfect

Don't save garbing observations for the competency assessments. Watch a few staff members garb on a regular day. It's one of the easiest ways to find contamination risks.



QUESTION of the MONTH

Our certifier mentioned that CETA is rolling out a new accreditation for technicians who certify biological safety cabinets. Is this something we should require of the certifier?

If your BSCs meet NSF/ANSI 49 requirements, anyone testing them should hold an accreditation that shows they are skilled in certifying those cabinets, such as NSF accreditation. The new CETA credential will be another way to demonstrate that skill, so ask your certifier which credentials they hold and verify them before your next certification.

Bringing USP <797> Microbiology to Life: A New Collaboration with University of North Carolina

Sterile compounding demands precision, consistency, and a deep understanding of risk. But for many teams, the microbiology tied to sterile compounding can feel abstract—something reviewed after the fact instead of used as a real-time decision-making tool.

That's about to change.

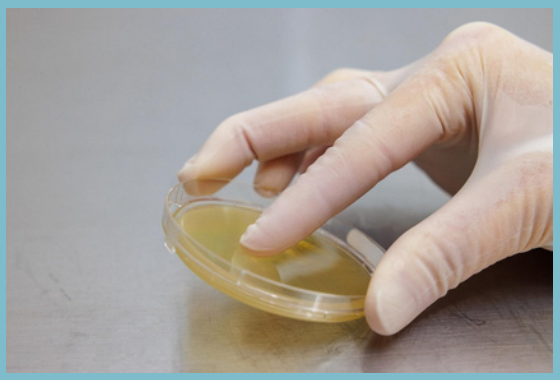


Through a new collaboration with UNC, this advanced microbiology micro-credential is designed to bridge the gap between knowledge and practice, equipping sterile compounders and leaders with the skills needed to confidently collect, interpret, and act on viable environmental monitoring data.

This program moves beyond checklists and requirements. Instead, it builds a practical, end-to-end understanding of how microbiology supports a true state of control. Participants will explore how sampling, incubation, enumeration, and investigation work together—not as isolated steps, but as a connected system that informs performance and drives continuous improvement.

What makes this program different is its focus on application. Learners will not just review what USP <797> requires; they will develop the ability to evaluate data, recognize patterns, and make informed decisions rooted in microbiological principles. From designing a viable sampling program to analyzing media-fill results and managing excursions, each component is built to reflect real-world workflow and risk.

To further support competency development, the program includes three optional competency assessments designed to help organizations verify readiness and reinforce practical skill application. These assessments give teams a structured way to evaluate both technique and interpretation—critical elements often overlooked in traditional training.





This focus is especially timely. Accrediting organizations such as The Joint Commission (TJC) and ACHC are increasingly focused on not just whether programs exist, but whether personnel involved in viable sampling and media analysis are appropriately trained and competent. This program is designed with that expectation in mind: helping organizations move beyond compliance toward defensible, consistent practice.

Just as important, the program emphasizes consistency across teams. In environments where variation in technique or interpretation can impact results, this training provides a shared foundation—helping organizations align practices, strengthen competency, and improve overall microbial control.

For those performing sampling, counting colonies, overseeing cleanrooms, or responsible for compliance, the value is clear: a stronger understanding of microbiology leads to clearer insights, more defensible decisions, and ultimately, safer patient outcomes.

Because collecting samples and interpreting results isn't just a requirement; it's one of the most powerful tools you have.

For more details on how to participate in this UNC collaboration, click HERE.

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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.