NEWSLETTER ISSUE: JANUARY 2026

the pure observer

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

Happy New Year!

ASHP Midyear was absolutely incredible- seeing so many friends and colleagues in one place was the highlight of the year. The number of hugs was off the charts, and it reminded me how powerful genuine connections can be. Networking isn't just about exchanging business cards; it's about building relationships that turn colleagues into friends and friends into collaborators. I'm grateful for every conversation, every laugh, and every shared moment. Here's to continuing those connections and creating even more in the year ahead!

There's More Than One Right Way

Pure Microbiology taught three live classes in Bethlehem, Pennsylvania, this year, along with numerous training sessions at client facilities. One theme we found ourselves repeating over and over was this: there's more than one right way to do things. Too often, sterile compounding pharmacies want the "easy button"—just tell us the best practice and we'll do it. The challenge is that there can be multiple best practices depending on the specifics of your operation. Let's look at a few areas where this principle applies.

Gloved Fingertip Media

Many locations I visit use 100 mm settle plates for gloved fingertip testing (GFT), assuming it's the only option. USP <797> does not define the type of sampling device—only that tryptic soy agar (TSA) with neutralizers be used. This means you have flexibility. If you're already using contact plates for surface sampling, you can also use contact plates for GFT. Contact plates can be easier to handle and may reduce variability in sampling technique. On the other hand, settle plates might

On the other hand, settle plates might be preferred in facilities where they are already integrated into workflows. The point is, both approaches can meet compliance requirements. The "right way" depends on your facility's processes, staff training, and risk assessment.

Garbing

Garbing procedures should be tailored for each facility. Even cleanrooms within the same health system often differ. Factors that influence garbing order include:

- Facility-related: sink location, anteroom size, shared spaces, door placement
- Process-related: category compounded, complexity, anteroom activity

The garbing order should minimize contamination risk while maintaining efficiency. A simple risk assessment—observing traffic flow, identifying contamination points, and reviewing SOPs—can help determine the best sequence for your operation. There is no universal one-size-fits-all garbing procedure; it must fit your space and workflow.

Training

Every facility has unique workflows, and training should reflect actual roles—not just generic SOPs. For example, cleaning staff may need deeper contamination control training than those who only verify compounded sterile preparations (CSPs). A pharmacist who checks final products might need more emphasis on aseptic verification and documentation, while a technician performing compounding needs hands-on garbing and aseptic technique practice. Media-fill design ties in here too—your training should prepare staff for the specific challenges they'll face in your cleanroom. Don't be afraid to customize; there's little you can do that's truly "wrong" if it meets your risk profile and regulatory requirements. Effective training is about relevance, not uniformity.

Cleaning and Disinfection

One area where we often see rigid thinking is cleaning and disinfection, especially when it comes to the primary engineering control (PEC). While USP <797> emphasizes maintaining a clean-to-dirty flow, the principle of cleaning from top to

bottom is equally important and should not be overlooked. The best approach is to gather your team, talk through the process, and agree on a method that everyone understands and can consistently follow. Ensure alignment through thorough training and clear execution. The key is designing a program that fits your environment and documenting the rationale behind your choices. Flexibility here not only supports compliance but can also reduce unnecessary costs.

Consider a Cleanroom Swap

Have the designated person(s) visit another location's cleanroom suite and vice versa. Seeing how others operate can spark ideas for improvement. When you work in the same space daily, it's easy to miss small inefficiencies, like the placement of supplies or the sequence of tasks. A cleanroom swap allows you to compare practices, identify differences, and evaluate whether changes could enhance your own processes. Sometimes, the best insights come from observing another team's approach and asking, "Why do they do it that way?" This exercise reinforces the idea that there's more than one right way—and that continuous improvement often starts with fresh perspective.

Closing Thoughts

The takeaway? There's more than one right way. Best practices aren't universal—they're contextual. What works in one cleanroom may not work in another, even within the same organization. The key is understanding your processes, assessing risk, and making informed decisions. When we embrace flexibility and critical thinking, we move beyond "easy buttons" and toward sustainable, compliant operations. Here's to a new year of learning, collaboration, and doing things the right way—your way.

best practice makes perfect

Handwashing can be challenging. Use a visual tool like Glo Germ® during training to help staff see exactly where they miss spots when washing.

Check one thing off your 2026 New Year's resolution list and register for an upcoming live training!

Pure Primer: Sterile Compounding and Handling Hazardous Drugs Live Training.

May 12 - 15, 2026
August 31 - September 3, 2026

REGISTER NOW

QUESTION of the MONTH

How do you manage disinfectant residue on stainless steel PEC surfaces?

Implement a residue removal program. While USP <797> does require wiping the PEC with sterile 70% IPA after any EPA-registered one-step disinfectant cleaner application, this may not be enough. A second wiping with sterile 70% IPA after the use of sporicidal agent may be needed.

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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.