NEWSLETTER ISSUE: JULY 2026

the pure observer

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

What You Should Be Reading (and Rethinking) About Viable Air and Surface Sampling

If your organization performs viable air and surface sampling, you are participating in one of the most misunderstood areas of USP <797>. What we continue to see across compounding locations is not a lack of effort, but a gap between what is being done and *what is actually expected.*

For those responsible for viable sampling programs—whether you are collecting samples, reviewing data, or overseeing compliance—there are a few key sources and concepts that deserve to be read at least once if not receiving regular review. More important, they need to be interpreted correctly and applied in a way that is defensible during inspections and surveys.

Start with USP <797>: What to Do and Why, Not How to Do It

Most teams performing viable sampling can recite frequencies and chapter-required locations. Far fewer can clearly explain why sampling is performed, even though this is discussed in USP <797>. You might find this hard to believe, but during competency assessments, one of the questions we ask is, “What is the purpose of viable sampling?” Pharmacists and pharmacy technicians who are designated persons struggle with this answer, even after sitting through two days of focused training. If people struggle with the why, the whole program is likely to suffer. USP <797> gives some foundational whys that should be included in your SOPs.

The biggest issue with USP <797> is that there is no “how to.” This requires organizations to review other USP chapters and industry documents to know how viable air and surface sampling is to be

performed. This is not just the sample collection technique but everything related to the viable sampling program, like trending, planning a sampling session, and investigating microbial excursions.

Revisit USP <1116>: The Missing Link in Most Programs

USP <1116> provides the context many programs are lacking. It emphasizes that environmental monitoring is not just about pass/fail—it is about understanding trends, recovery rates, and state of control.

Key areas to revisit in USP <1116>:

- The concept of contamination recovery rate (CRR)
- Trending expectations over time—not just individual events
- Differentiating between normal flora recovery and meaningful excursions

Facilities that ignore <1116> often default to reactionary decision-making rather than scientifically informed assessment. There is also tremendously valuable information on the fundamentals of viable sampling such as challenges and limitations. Remember, viable sampling is not perfect, and if we have unrealistic expectations, we'd be setting ourselves up for overall program failure.

If You Incubate In-House, USP <1117> Is Essential

Many facilities incubate their own samples but do not routinely consult USP <1117>, which outlines expectations for microbiological best practices. If your organization is responsible for generating its own data, you are also responsible for ensuring the conditions that produce that data are controlled and appropriate. USP <1117> helps support that defensibility.

Strengthen Your Program with Industry Guidance

While USP chapters provide the regulatory framework, additional industry guidance can significantly strengthen your program.

Consider resources such as:

- PDA Technical Report 13 (TR 13) – Fundamentals of an Environmental Monitoring Program

- Controlled Environment Testing Association Guidance (CAG-009) – Viable Environmental Monitoring for Sterile Compounding Facilities

While these resources require membership, many organizations find value in having at least one team member maintain access. These documents often provide the "how" that USP chapters intentionally leave flexible.

Evaluate Your Sampling Technique (Not Just Your Results)

One of the most common blind spots is assuming that a result reflects the environment without evaluating whether the technique itself introduced variability.

You should periodically review:

- surface sampling consistency (contact pressure, angle, coverage)
- air sampling setup (placement, duration, and disruption)
- media handling (transport, incubation timing, and plate integrity)

If your sampling technique is inconsistent, your data is inherently unreliable no matter how good it looks on paper. This is also why it is best to either take all viable air and surface sampling in-house or outsource it all. Having your certifier do some and you do some doesn't "validate" anything. It just makes trending much more difficult.

Assess Your Investigation Process

Another area inspectors and surveyors consistently focus on is how organizations respond to recoveries. A common failure point is treating every excursion the same—or worse, treating them all as insignificant.

Your investigation process should include these high-level steps:

1. Immediate corrective actions
2. Investigation into the source (root cause analysis)
3. Development of a remediation plan
4. Long-term corrective actions
5. Verification that the corrective actions were effective

Review your process if these areas are not clearly outlined; it might be time for an SOP revision.

Bringing It All Together

A strong viable sampling program is not defined by zero growth; it is defined by understanding your environment and demonstrating control over it. That requires more than routine sampling. It requires intentional design, consistent technique, and meaningful interpretation.

If you haven't recently reviewed how your program aligns with USP <797>, USP <1116>, and other industry documents, now is the time. In today's inspection landscape, "we've always done it this way" is no longer sufficient. If this is beyond your area of expertise, get help. Pure Microbiology and Premier have a variety of training and consulting offerings to meet your needs.

QUESTION of the MONTH

Can our staff members wear post earrings in the cleanroom if they are covered by a hair cover?

No. The chapter states to "remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the CSP. Cover any jewelry that cannot be removed." If it can be removed, it needs to be removed.

Pure Primer: Sterile Compounding and Handling Hazardous Drugs Live Training

August 31 - September 3, 2026

Join us for a 3.5-day in-person training, including lectures and skill-building activities. Two and a half days are spent focusing on USP General Chapter <797> requirements, best practices, and implementation strategies, while one day emphasizes the importance of USP General Chapter <800>, exploring requirements and real-life solutions.

REGISTER NOW

Use the discount code **20LiveTrain2026** for 20% off the list price.

best practice makes perfect

While USP <797> requires that "all certification and recertification records must be reviewed by the designated person(s) to ensure that the classified environments meet the minimum requirements in this chapter," don't forget about other certification tests that are NOT included in the chapter, specifically those for PECs. Talk to your certifier about the tests that need to be done to show proper PEC performance.

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.

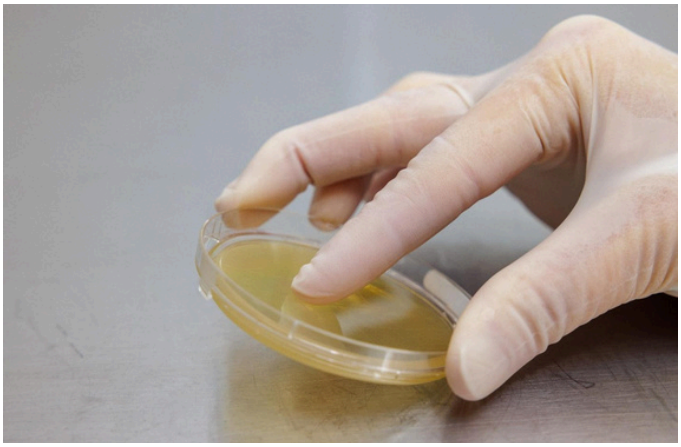
That's about to change.

Through a new collaboration with the University of North Carolina (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.

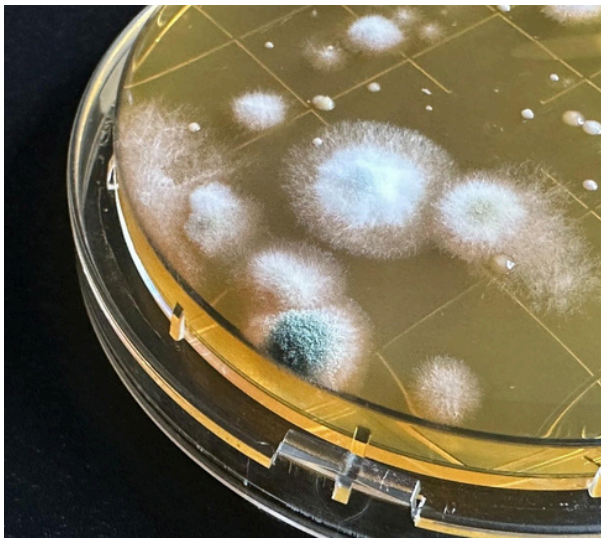
Just as important, the program emphasizes consistency across teams. In environments where variation in technique or interpretation can impact results, this training provides a shared foundation—helping organizations align practices, strengthen competency, and improve overall microbial control.

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.

More details on how to participate in this UNC collaboration are coming soon.

Want more on why this is important? Check out June's newsletter!



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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.