NEWSLETTER ISSUE: AUGUST 2026

the pure observer

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

When Your Samples Leave the Pharmacy: Do You Know Where They Go?

Most pharmacies spend significant time evaluating vendors. They review certification companies. They compare pricing. They ask about turnaround times and reporting formats. Some will even request copies of SOPs or accreditation certificates.

But there is one question that is rarely asked: What actually happens to air and surface samples taken by the certifier after they leave the facility?

Think about it.

When a certifier collects viable air and surface samples, those samples often leave with the technician. The pharmacy may receive a report several weeks later but often has very little visibility into where the plates were incubated, who handled them, what training those individuals received, or whether appropriate microbiological controls were in place throughout the process.

The assumption is that, because a service provider collected the samples, everything downstream must be acceptable. Unfortunately, that assumption is not always justified.

Out of Sight Does Not Mean Under Control

Viable sampling data is only as reliable as the process used to generate it. Most pharmacies would never tolerate uncertainty regarding the certification equipment entering their cleanrooms. Yet many accept microbiology results without asking basic questions about the laboratory responsible for producing those results.

- Where are the samples incubated?
- Are they going to an accredited laboratory or being incubated at your certifier's office?
- Who performs the colony counts?
- What qualifications do those individuals have?
- What quality systems are in place to ensure data integrity?
- How are media, incubators, and equipment monitored?

If those questions cannot be answered, the pharmacy may not actually know whether the data being used to assess environmental control is reliable.

The microbiology laboratory is not simply delivering a report. It is generating data that may influence investigations, regulatory responses, corrective actions, and decisions that ultimately impact patient safety. That deserves scrutiny.

Not All Laboratories Are Created Equal

Many pharmacies assume that all environmental monitoring laboratories operate under similar conditions.

They do not.

Some laboratories maintain dedicated microbiology facilities with robust quality systems, trained personnel, validated methods, controlled storage conditions, environmental monitoring programs, calibrated equipment, and documented competency assessments.

Others may operate with significantly less oversight. The difference is not always visible from the final report. A professional-looking report does not necessarily provide insight into the qualifications of the laboratory or the individuals evaluating the samples.

That is why vendor qualification should extend beyond the collection process. The laboratory itself should be evaluated.

Consider Auditing Your Laboratory Vendor

For years, pharmaceutical manufacturers have audited critical suppliers as part of their quality programs. Why should environmental monitoring laboratories be treated differently?

An audit does not need to be adversarial. In many cases, it can strengthen the relationship between the pharmacy and the laboratory while providing confidence that appropriate controls are in place. And remember, the "laboratory" might just be your certifier with a few incubators.

Areas worth evaluating include:

- Personnel training and competency
- Microbiological experience of laboratory staff
- Incubation procedures
- Colony-counting practices
- Equipment calibration and maintenance
- Data-integrity controls
- Investigation and deviation procedures
- Sample custody and traceability
- Facility cleanliness and maintenance
- Quality-management systems

In some cases, the results may be reassuring. In others, the pharmacy may discover that samples are being handled very differently than expected. Either outcome provides value.

Ask About Training

One of the most important questions is also one of the simplest. Who is reading the plates? The answer matters.

Recovering microorganisms from a cleanroom is only the first step. Interpreting the significance of those recoveries requires microbiological knowledge, training, and experience. Yet many pharmacies never ask about the education or qualifications of the personnel performing the analysis.

- Would the individual recognize contamination concerns?
- Would they identify atypical growth?
- Would they understand the limitations of the method?
- Would they notice when something does not make sense?

These are not insignificant responsibilities.

Viable air and surface data influence decisions about state of control, remediation activities, and patient risk. Those decisions should be supported by individuals with appropriate microbiological expertise.

An Uncomfortable Question

Here is a question worth asking: If the individual performing analysis at the laboratory has no more microbiology training than the personnel inside the pharmacy, what value is actually being gained by outsourcing the work?

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.

Outsourcing can provide tremendous benefits.

- Independent review
- Specialized expertise
- Additional quality oversight
- Access to resources and knowledge not available internally

But those benefits only exist when the laboratory truly provides expertise beyond what already exists within the organization. A laboratory should be more than a place where plates sit in an incubator. It should be a source of scientific knowledge, technical guidance, and confidence in the data being generated.

Final Thought

Viable sampling is one of the most important tools available for understanding microbial control. Yet many organizations focus exclusively on sample collection while paying little attention to everything that happens afterward. The next time samples leave the facility, ask a few questions.

- Where are they going?
- Who will handle them?
- What training do those individuals have?
- What quality systems support the data?

Because once samples leave the pharmacy, trust alone should never be the quality system.

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.

QUESTION of the MONTH

If hair is covered, does it matter what's underneath the bouffant?

Sometimes. The goal is complete containment of hair and particles, regardless of whether the hair is natural, synthetic, or extensions. If hair is escaping the head covering or preventing proper garbing, contamination control may be compromised.

best practice makes perfect

Ask for the qualifications of the people reading your plates and request to see the lab through pictures, video, or an onsite visit. If a laboratory is asking pharmacies to trust its data, the laboratory should be comfortable showing how that data is generated.

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.

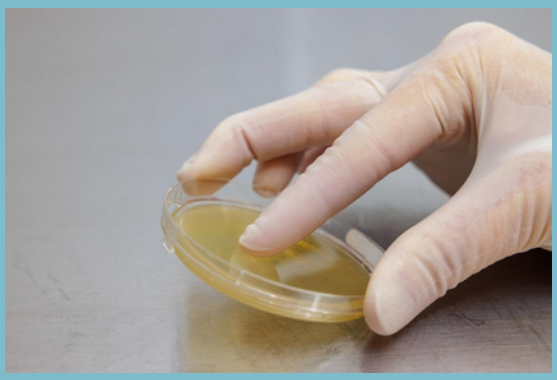
That's about to change.

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.

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.