NEWSLETTER ISSUE: JUNE 2026

the pure observer

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

Viable Sampling and Media Reading Training: What Inspectors Expect vs. What Actually Works

One of the most common gaps we continue to see during site visits is not the lack of a viable sampling program, which is required by USP <797>, but a lack of defensible training and competency for the people executing it. Viable sampling and media reading sit at a critical intersection of compliance and microbiology. It is much easier for a sterile compounding pharmacy to justify doing its own sample collection if it has training and competency in place than justifying in-house media reading and building out a biosafety level-1 lab. If you missed our newsletter on this topic, you can read it here. This is also where state boards of pharmacy and accreditors are increasingly asking deeper questions.

So what is actually required—and where are organizations falling short?

USP <797> and State Board Expectations

Section 17.0 in USP <797> places clear responsibility on the designated person to ensure that personnel are trained and competent in performing assigned tasks. And although not clearly defined in the chapter, this would include viable sampling and reading media.

This includes:

- proper operation of sampling equipment
- aseptic technique during sampling
- handling of microbiological media
- incubation, reading of media, and interpretation of results

Many state boards of pharmacy enforce USP <797> as the minimum legal standard, meaning that training is not optional—it must be documented, current, and aligned with SOPs. Additionally, inspection focus has expanded to include whether:

- personnel can consistently reproduce accurate results
- results are interpreted correctly
- training aligns with actual job responsibilities

Accreditor Expectations

Accreditors such as The Joint Commission and ACHC are evaluating how well you operationalize USP requirements. Ensure there is ongoing training and competency; training programs that are not just theory; and alignment between SOPs, practice, and documentation.

The Joint Commission has specifically emphasized expanded expectations for training, education, and competency under updated compounding standards. In practice, this translates to survey questions like:

- How do you know your staff can properly enumerate colonies on a plate?
- How do you verify that sampling technique hasn't degraded over time?
- What triggers retraining?

Many organizations struggle here because training cadence may be driven by accreditation cycles rather than risk. And don't lose sight of state board of pharmacy expectations!

What Frequency of Training and Competency is Required?

For viable sampling and reading media, this is not defined in USP <797>. It is left to the designated person to determine the frequency and document it in the training program. Here's an example of what "right" could look like for a sterile compounding facility.

1. Initial training
Ensure personnel receive structured training that includes:

- sampling theory and USP <797> intent
- hands-on practice of sampling technique
- media handling, incubation, and chain of custody
- colony enumeration and interpretation basics

Training should include direct observation and documented competency.

2. Annual didactic reinforcement
At least annually, personnel should receive:

- refresher training on sampling principles and contamination control
- review of common errors (e.g., plate handling, sampler loading, overgrowth misinterpretation)
- updates based on internal trends or excursions

This aligns with the principle that viable sampling programs are intended to detect trends and maintain environmental control, not simply meet a frequency requirement.

3. Formal competency assessment (minimum of every 2–3 years)
Competency should be reassessed through:

- direct observation of sampling technique
- practical demonstration (e.g., aseptic manipulation of media)
- colony enumeration exercises or proficiency testing

There is increasing expectation for documented proof of competency in colony counting and interpretation, especially for sterile compounding personnel responsible for reading plates.

4. Event-driven retraining
Retraining should not only be time-based. It should also be triggered by:

- viable sampling excursions
- failed competencies
- significant SOP changes
- changes in equipment or sampling methods

This is one of the most overlooked—and most important—elements of a mature quality system and viable sampling program.

Closing Thought

Without a robust viable sampling and reading-media training program, you lose all data integrity. Organizations that treat training as a one-time event will continue to struggle during inspections. Organizations that build a structured, risk-based training program will not only pass inspections but will also have confidence in their data, which is far more valuable.

SUMMER TRAINING

Whether you are looking for live training or remote training, we have several classes available throughout the summer. Find a session that works with your schedule.

CLICK TO REGISTER

QUESTION of the MONTH

Can we do our own sampling and outsource the incubation and analysis?

Yes! This is something you should strongly consider. If you are incubating, then you are a lab. This is a huge responsibility to take on to ensure the integrity of your data. If getting your internal lab set up feels too easy, that's a red flag.

best practice makes perfect

If you are incubating your own viable samples, read *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). You can find it with a quick online search. Focus on BSL-1 labs.

puremicrobiology.com
E: abby.roth@premierinc.com | P: 610.417.4795

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.