NEWSLETTER ISSUE: MARCH 2025

the pure observer

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

## Viable Sampling Compounding Activity Red Flags

Dynamic operating conditions. When you hear this term, what do you think of? Hopefully, your definition is close to what we find in USP <797>.

“Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).”

Pure Microbiology agrees with the first sentence in the definition and part of the second sentence (the word ROUTINE). We could get off topic quickly about this, so we’ll direct you to our August 2024 newsletter where the feature was titled “Pure Microbiology Technical Opinion: An Interpretation of Testing Under Dynamic Conditions.”

As you look at your viable sampling program, you want to be honest with yourself about how your organization defines compounding activity and how it applies to the sample collection you perform.

Here are 4 red flags related to compounding activity:

1. Staff scatter and the certifier mimics compounding activity – If you outsource your viable air sampling to the certifier (or another vendor) and staff immediately exit the cleanroom suite, you have a problem. You need compounding staff present during viable sample collection.

How else are we to identify microbial risks and shortcomings in the compounding process and workflow without actual compounding staff present? This is especially important when it comes to the primary engineering control (PEC). Last time we checked, certifiers were experts in testing clean air devices and cleanrooms, not sterile compounding techniques. (We're sure our certifier friends agree.) Be present!

2. Sampling a static PEC – This happens way too often. There are 3 PECs in the buffer room and only 2 people working. The empty PEC gets air and surface sampled under static conditions, but the report indicates that sampling was done under dynamic conditions because the room was dynamic. This is not how things work. Sampling in the PEC must occur while someone is compounding or simulating compounding in the PEC. Get someone working in the empty PEC. It's the only way to comply with the chapter!

3. Forcing conditions that do not mimic actual work – This happens when regulators or accreditors take a chapter "should" and turn it into a chapter "must," whether through regulation or enforcement discretion. Yes, the definition listed above says "**should** reflect the largest number of personnel and highest complexity of compounding expected during routine operations." Remember, the key word is **ROUTINE**. The goal of viable sampling is to collect snapshots of the air and surface during normal operating conditions. This means your normal number of people and your normal workflows. Staff shortages can sometimes result in non-compounding staff needing to enter the cleanroom to simulate compounding during viable sampling just to meet a maximum number of people. When you force conditions that do not mimic actual work, you risk false excursions, and potentially unnecessary corrective actions.

4. Not using static sampling as an investigational tool or to evaluate cleaning – No static sampling ever is concerning. At some point, you will likely have to investigate an exceeded action level. What better way to do that than with a combination of static and dynamic sampling. When we use viable sampling as a tool, especially under static conditions, it can provide valuable insight in facility design and cleaning. Remember, when we sample under static conditions it tells us about the engineering controls and cleaning practices. When we sample under dynamic conditions, it tells us about staff aseptic techniques and how they impact the environment. Both have value!

If you need help with your viable sampling program, contact us today!

**best practice makes perfect**

Read “Defining Storage and Administration Terms for CSPs” by Kevin N. Hansen, PharmD, MS, BCSCP and Patricia C. Kienle, RPh, MPA, BCSCP, FASHP. It’s essential to know the difference between beyond-use dates and infusion (aka hang) time. Misunderstanding these terms could lead to unnecessary bag exchange and waste or a disruption in patient care.

# QUESTION of the MONTH

**We send our viable samples to a contract lab for incubation and analysis. Will the contract lab take a picture of the plates with growth?**

**It depends on the lab, but usually not. These labs are processing hundreds of samples a day and photographing each individual plate is a big ask. They may be willing to photograph plates with exceeded action levels. But you really should be asking yourself, why do I need a picture of the plate? If you thoroughly audited your lab partner, you should be confident in their ability to provide accurate results.**

The Aseptic Connection
by pure microbiology

**We are excited to announce that our Aseptic Connection is live!!**

**This comprehensive membership platform provides you with valuable tools and resources covering USP standards, best practices, and more.**

**Register for a Premium account by March 31st and be entered to win a seat in our Sterile Compounding and Handling Hazardous Drugs Live Training!**

**www.puremicrobiology.com/aseptic-connection/**

## Join Us For

# Pure Primer: Sterile Compounding and Handling Hazardous Drugs

**June 2-5, 2025**
**November 10-13, 2025**
**Bethlehem, PA**

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. This interactive training is appropriate for both pharmacists and technicians, especially those who hold a management or designated person role.

Attendees will receive 25.5 hours of live ACPE CE.

Instructors include:
Abby Roth, CMQ/OE
Patricia Kienle, RPh, MPA, BCSCP, FASHP
Kevin Hansen, PharmD, MS, BCSCP
Lew Exner

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**puremicrobiology.com**
**E: abby@puremicrobiology.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.