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## What Fall Can Mean for Your Viable Sampling Results

We may think of the cleanroom as separate from what is happening outdoors, but seasonal changes can still show up in your viable sampling results. People, supplies, doors, pass-throughs, and the HVAC system all create connections between the cleanroom suite and the rest of the facility. As temperature, humidity, vegetation, and outdoor activity change, the types of microorganisms making their way into the facility can change too. That is why it is important not to look at every month's data as though the microbial environment is always the same.

### Fall, Harvesting, and What May Be Coming Through the Door

Fall often brings a change in the microorganisms found outdoors. Harvesting, falling leaves, landscaping, and disturbed soil can put more fungal spores and other

spore-forming organisms into the air. In agricultural areas, field activity can also increase dust and organic debris. But a facility does not have to be located beside a farm to experience an effect. Decaying vegetation, windy conditions, and routine outdoor activity can all contribute to higher mold- and bacterial-spore levels.

Those organisms do not have to travel straight from outdoors into the cleanroom. They may be carried into the building on clothing, shoes, hair, bags, cardboard, shipping containers, or incoming supplies. From there, door openings, material transfer, pressure disruptions, and gaps in cleaning can help move contamination closer to controlled areas.

Molds and bacterial spore formers are especially important because they are designed to survive. Their spores tolerate drying and environmental stress better than many vegetative



organisms. Recovering a *Bacillus*-like organism or a mold does not automatically mean that fall weather or harvesting is the cause. However, if the same types of organisms increase during the same time each year, that pattern may point to a weakness in material flow, personnel practices, cleaning, sporicidal disinfection, or another facility control.

### **Seasonality Gives Us Context, but It Is Not the Root Cause**

If an action level is exceeded or an objectionable organism is recovered, we cannot close the investigation by saying, "It is fall." Seasonal changes may help explain what is happening, but they do not replace the investigation. We still need to look at the sampling location, microorganism identification, personnel and activities in the area, cleaning and disinfection records, pressure and temperature or humidity data, maintenance work, door openings, material transfers, and recent results from nearby locations.

Often, the most useful information is the pattern rather than one individual result. Are molds showing up only in the anteroom or are they appearing in

the buffer rooms? Are spore formers tied to one material-transfer route? Do recoveries increase after deliveries, heavy rain, landscaping, or nearby harvesting? Are the counts still low but the types of organisms changing? Looking at the microorganism, location, timing, and activity together can help us spot a developing issue before it becomes a larger problem.

### **More Frequent Viable Air Sampling Can Help Tell the Story**

If fall has historically been a higher-risk time for your facility, more frequent sampling may make trends easier to see, especially for viable air. A few samples give us a few snapshots. Additional data points can help show whether a recovery was isolated or whether something is starting to shift. The point is not to collect more samples just to make more data. The point is to collect enough useful, comparable information to understand whether the cleanroom remains in control.

A seasonal sampling plan might include additional viable air samples near entrances to controlled areas, at busy transition points, after material



transfer, or during representative compounding activity. Keep the plan risk-based, and keep the sampling conditions as consistent as possible. Using the same locations, sample volumes, methods, incubation scheme, and identification approach makes the comparison much more meaningful. It is also helpful to document room activity, number of personnel, weather events, landscaping or construction, and HVAC issues that may affect the results.

Of course, viable air sampling is only one piece of the environmental monitoring program. It should be reviewed with surface sampling, personnel monitoring, cleaning observations, and facility data. Each type of monitoring tells us something different, and the clearest picture comes from looking at them together.

### **Do Not Stop at Month-to-Month Trending**

Month-to-month trending is important because it helps us identify a recent change. But if we only compare October with September, we may miss the bigger seasonal pattern. Comparing this October with the last

two or three Octobers can tell us whether the increase is recurring, getting worse, improving, or completely new. We need both views: month-to-month for a timely response and year-over-year for the historical context.

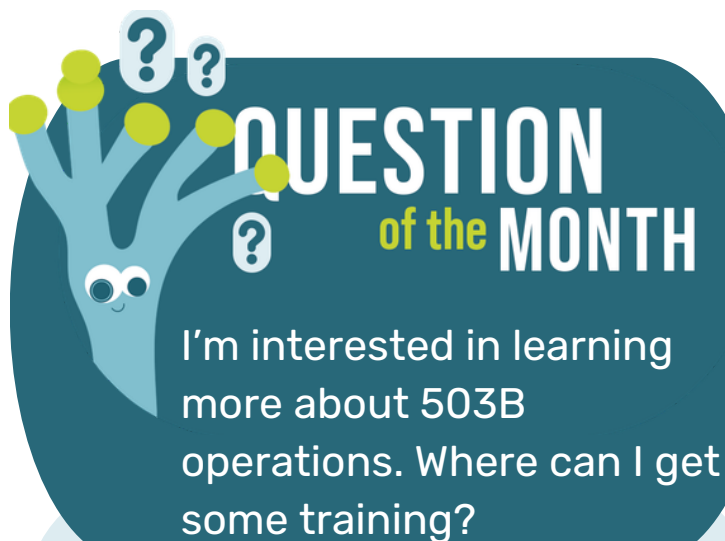
Year-over-year trending should include more than total colony-forming units. Look at how often samples are positive, recovery rates by room and location, the types of microorganisms recovered, repeating organisms, action-level excursions, and the percentage of recoveries that are molds or spore formers.

Consider whether you are seeing the same pattern as last fall. Are the recoveries starting earlier or continuing longer? Did last year's corrective actions make a difference? If the same group of organisms returns to the same area every fall, it may be time for a preventive seasonal plan instead of another one-time response. That could mean extra attention to transition-space cleaning, material staging, garbing, HVAC performance, or a temporary increase in monitoring.



## Use the Data to Get Ahead of the Season

The best time to address a seasonal trend is before it turns into an excursion. Take a look at your historical fall data, identify the microorganisms and locations that tend to repeat, and decide whether added monitoring or preventive controls make sense. Then, as new data come in, compare the results with both the previous months and the same time in previous years. Seasonal trending gives us an opportunity to see changes sooner and respond with better information.



The FDA's Compounding Quality Center of Excellence is an excellent resource. On its website, you will find training modules, recorded webinars, and other valuable information.



## best practice makes perfect

Take a look back before fall sampling begins. Review the same months from at least the previous two years and note any repeating molds, spore formers, locations, or facility conditions. If there is a consistent seasonal pattern, consider a temporary, risk-based increase in viable air sampling. Keep the locations, sample volumes, methods, and incubation conditions consistent so you can make a meaningful comparison.



## 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.

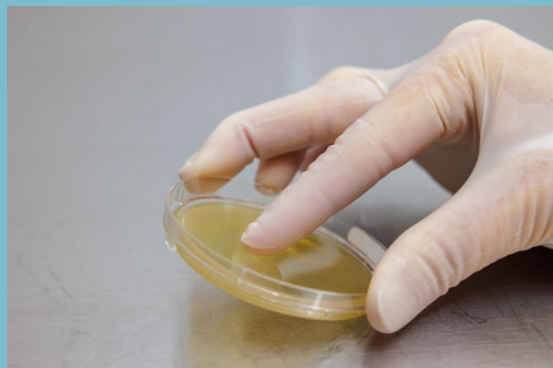
Through a new collaboration with UNC, this advanced microbiology micro-credential is designed to bridge the gap between knowledge and practice, equipping sterile compounders and leaders with the skills needed to confidently collect, interpret, and act on viable environmental monitoring data.



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](#)!**

**puremicrobiology.com**

**E: [abby.roth@premierinc.com](mailto: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.