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the pure observer

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

The Certifier Owns the Testing. The Designated Person Owns the Outcome.

Certification Is Not a Handoff

One of the most important distinctions in cleanroom certification is also one of the simplest: the certifier performs the testing, but the designated person remains accountable for the outcome. Bringing in an outside expert does not transfer responsibility for the facility's state of control. The designated person must ensure that certification occurs at the required intervals, the vendor is appropriately qualified, the report is reviewed and understood, deficiencies are investigated and corrected, and the findings are incorporated into the quality program.

This does not mean the designated person must become a certification technician. It does mean they need enough knowledge of the facility, engineering controls, workflows, and applicable testing requirements to ask informed questions and recognize when the documentation does not tell the full story.

Start with the Right Certification Vendor

Good oversight begins before testing day. Vendor selection should be a qualification process, not simply a purchasing decision. The designated person should understand who will perform the work, how those individuals were trained, and whether they have meaningful experience with sterile compounding facilities.

The vendor should also be able to explain which methods and standards will be used for the specific primary and secondary engineering controls in the facility. Ask whether procedures are documented and standardized, whether testing equipment is calibrated, and whether calibration records can be produced. Communication matters too. A

qualified certifier should be able to explain results clearly and document deficiencies, deviations, and unusual observations in a way that pharmacy personnel can understand and act upon.

A useful step during vendor qualification is to review a sample report. A report format should support the designated person's review and trending process. If the sample report provides little more than a pass or fail conclusion, it may not provide enough information to support meaningful oversight.

Read the Report, Not Just the Certification Sticker

A passing certification sticker is not a substitute for report review. The report should be traceable, defensible, and interpretable. At a minimum, the designated person should verify the vendor's information, the identity and qualifications of personnel, the methods used, the required testing results, equipment identification, instrument calibration information, and any deviations from standard practices.

Then move beyond completeness and ask what the data are saying about the facility. Were all required tests performed, and were any results out of specification? Were deviations documented and are corrective actions needed? Do the findings agree with what pharmacy personnel are seeing during routine operations?

The review should also look for patterns that a pass or fail designation may hide. Particle counts, pressure data, air changes per hour, airflow velocity results, HEPA filter integrity findings, and airflow visualization observations can all provide useful information. Pay particular attention to results approaching specification limits and observations repeated from previous certifications. Certification data become far more useful when they are compared over time rather than viewed as isolated snapshots.

Know When Change May Trigger Recertification

Recertification is not limited to the routine certification schedule. Major service, maintenance, or changes that could affect engineering control performance may require

recertification before use resumes. Examples include renovations, construction activity, HVAC modifications, relocation of a primary engineering control, HEPA filter replacement, significant repairs, changes in room configuration, new workflows that may affect airflow, or significant equipment additions.

The designated person should establish a change-management process that asks three questions every time a relevant change occurs: What changed? Could airflow or containment be affected? Is recertification required before the area or equipment returns to use?

Document the evaluation, including the rationale for the decision, and involve the certifier when the potential impact is uncertain. Change control is most effective when certification requirements are considered before work begins, not after the facility is ready to reopen.

Connect Certification to the Quality System

Certification findings should not live in a separate administrative silo. They should connect to environmental monitoring results, CAPA investigations, risk assessments, facility maintenance records, change-control processes, and management review activities. When a finding is identified, the question is not only whether the room or device passed; the question is whether the data change what we know about contamination control risk.

Think of oversight as a cycle.

- **Plan** by selecting and qualifying the vendor and scheduling the work.
- **Perform** by facilitating testing and ensuring dynamic conditions are represented when required.
- **Review** by evaluating report completeness, results, and observations.
- **Act** by investigating findings and implementing CAPA when appropriate.

Then use what was learned to strengthen the next cycle.

Cleanroom certification is data, not just documentation. Trend it. Analyze it. Compare it with other quality-system information. Use it to identify

emerging concerns, support investigations, and make better decisions about the facility. The certifier owns the testing. The designated person owns what happens next.

The Pure Microbiology takeaway: *A certification report should prompt review, discussion, and action. If it only prompts filing, the organization is missing its value.*

QUESTION of the MONTH

Is having a passing result on a certification report enough to demonstrate cleanroom compliance?

No. The designated person should review, sign, and date the full certification report and ensure that deficiencies, observations, and concerning trends are addressed.

best practice makes perfect

After each certification, document the designated person's review and immediately assign an owner and due date for every deficiency or follow-up item.

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.

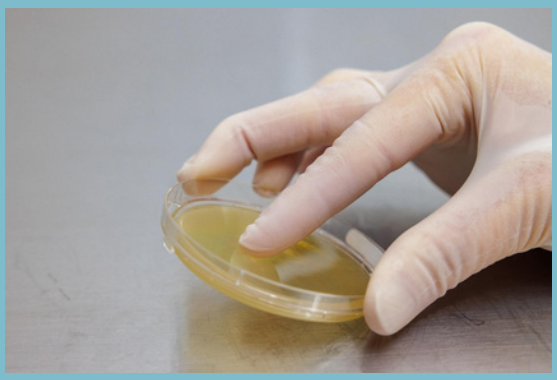
That's about to change.

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.