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the pure observer

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

Are you sure about that ID? Ensuring Microbial Identification Meets USP Standards

Last month I had the opportunity to present a webinar on microbial identification with ARL BioPharma. For those who may have missed that webinar, you can view it here. This month's newsletter will review some of the key points from that webinar.

When environmental monitoring (EM) data shows microbial growth above action levels, the decision isn't *whether* to react—it's *how* to react in a way that truly protects patients and satisfies regulators. Recent updates and guidance across USP chapters clarify what "good" looks like for identification (ID), why genus-level results may not be enough, and how to choose a lab and methods that deliver decisions you can defend.

What USP <797> actually requires

USP <797> states that when viable air or surface samples exceed the levels, you must attempt to identify the recovered microorganisms to at least the genus level, with help from a microbiologist and in alignment with USP <1113>. FDA separately considers any microbial growth in ISO 5 an insanitary condition—so your ID strategy should scale in rigor as the risk increases (e.g., more aggressive ID for ISO 5 recoveries, nonsterile-to-sterile operations, or when applying longer beyond-use dates).

Why species-level ID often matters

Genus-level identification can satisfy the letter of USP <797>, but species-level ID frequently provides the context needed for a sound investigation: source-tracking (e.g., human vs. environmental), assessing clinical relevance, and tailoring corrective and preventive

actions (CAPA). For many pharmacies and cleanrooms, a prudent best practice is to escalate to species level for all ISO 5 growth and whenever action levels are exceeded.

Speak the same language: characterization vs. identification

Many contract labs are performing characterization instead of identification. The proposed version of USP <1113> provides the following definitions.

Identification: Genus- and species-level identification using phenotypic, proteomic, or genomic methods.

Characterization: The use of colony growth, cellular morphology, differential staining, and key diagnostic features to characterize a laboratory isolated for trending and investigative purposes without identification, e.g., Gram stain reaction, cell shape, and arrangement.

Based on these definitions, identification meets USP <797> requirements. Characterization does not. "Characterization" (e.g., "gram-positive coccus," "yeast," "mold," or "coagulase negative") is like knowing the *neighborhood*; identification is the street address—*staphylococcus* (characterization) vs. *Staphylococcus aureus* (identification). Make sure your lab reports state the genus (and, when you request it, the species), not only broad descriptors.

What level of identification is needed?

This excerpt is from Table 1. Recommended identification program for microbial recoveries of the proposed version of USP <1113>. The recommendations for identification align with USP <797> and FDA's Insanitary Conditions Guidance.

Process	Type of Sample	Microorganisms to Identify	Minimum Recommended
CSP release test	Test for sterility	Any	Identification
Viable sampling	ISO 5	Any	Identification
	ISO 7 or 8	Above action level	Identification
	ISO 7 or 8	Above alert level	Characterization

Choosing the right tool: phenotypic, proteotypic, and genotypic approaches

Not all ID methods are created equal. Understanding strengths and limitations helps you set expectations with your lab and interpret results wisely.

- **Phenotypic (biochemical/physiologic)**
  - **What it does:** Uses expressed gene products and metabolites; often panel-based.
  - **Pros:** Widely available; familiar workflows.
  - **Caveats:** Needs a pure, robust culture; stressed organisms may misidentify; accuracy hinges on choosing the right panel and may require auxiliary tests (oxidase, catalase, coagulase).
- **Proteotypic (MALDI-TOF)**
  - **What it does:** Profiles cellular proteins for rapid species-level calls.
  - **Pros:** Fast ID for bacteria and fungi from pure culture; great for routine EM.
  - **Caveats:** Database quality is everything; not sufficient for strain-level differentiation.
- **Genotypic (sequencing)**
  - **What it does:** Reads genetic sequences for highly accurate IDs; can escalate to strain typing for source tracking and outbreaks.
  - **Pros:** High accuracy; rapid turnarounds are increasingly feasible.
  - **Caveats:** Still depends on sequence quality and curated databases; costs and turn-around-time can vary by lab.

Best practice: Start with MALDI-TOF for an accurate yet affordable identification. For microorganisms that cannot be identified using the MALD-TOF, consider DNA sequencing.

What “good” ID workflow looks like

For bacteria and yeasts, labs typically subculture to fresh media (e.g., TSA), incubate, and run the ID—sometimes with a Gram stain and auxiliary tests as needed. Molds may be identified via macro/microscopy (surface/reverse colors, hyphae, reproductive structures) or an ID system, depending on capability. Ask your lab to share its standard

workflow and when it moves to higher-level methods.

Training and competence still matter

Even the best platform fails without trained people and current procedures. USP <1117> emphasizes role-specific training curricula, current SOPs, and documented competence. If you outsource, expect your lab's analysts to meet the same level of training and documentation you require in-house.

Qualifying a lab: what to ask for

1. **Accreditation scope:** Request the lab's current scope of accreditation. Confirm it's accredited for identification (not just characterization) of microorganisms.

2. **Method transparency:** Which ID systems are used (phenotypic panels, MALDI-TOF, sequencing)? What are it's detection limits, database sources, and verification practices?

3. **No identification:** What happens if it can't get an ID? Does it escalate to DNA-sequencing the microorganism? Ensure its procedures align with your identification needs.

4. **Reporting format:** Insist on reports that clearly distinguish identification from characterization, with genus/species spelled out (e.g., *Staphylococcus epidermidis* rather than "*coagulase-negative Staph*").

Putting it all together

- Meet the requirement: For exceeded action levels, ensure genus-level identification at minimum to comply with USP <797>.

- Manage the risk: Prefer species-level ID for ISO 5 growth and any significant excursions.

- Mind the method: Understand phenotypic, proteotypic, and genotypic tradeoffs, and partner with a lab whose accreditation scope and identification procedures match your needs.

- Sustain competence: Verify the lab trains to current SOPs, documents competency, and ensures its practices reflect USP <1113> and <1117> principles.

Inspectors and surveyors expect you to know what grew, why it grew there, and what you did about it. With a risk-based ID plan, the right laboratory partner, and a clear distinction between characterization and true identification, you can turn viable sampling recoveries into actionable insight—and keep your compounding operation compliant, consistent, and safe.

QUESTION of the MONTH

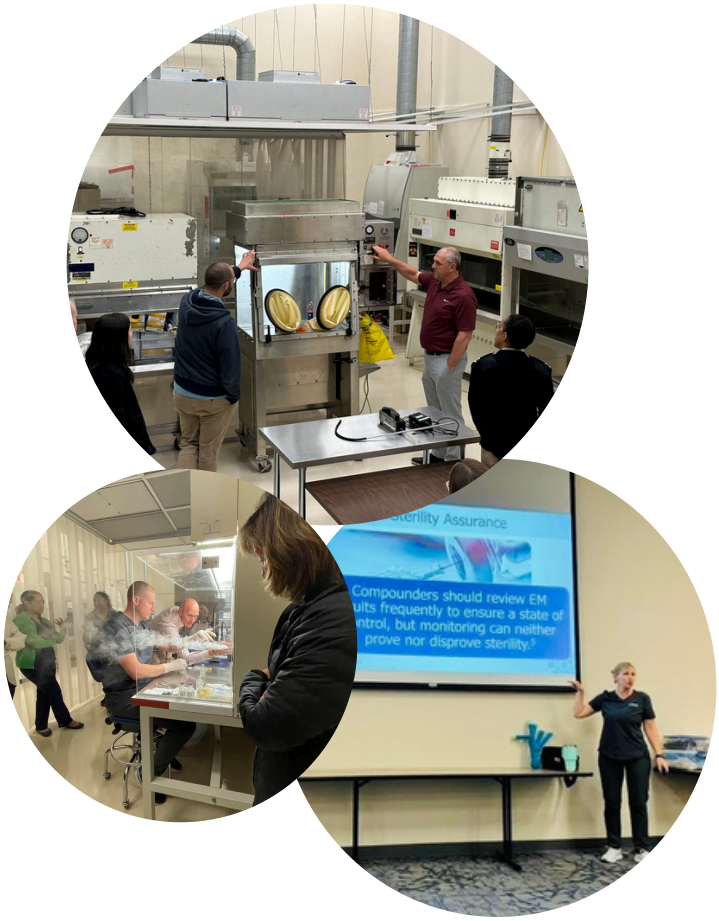
Is it a USP <797> requirement to have an audible alarm for pressure in the cleanroom suite?

No; however, USP <797> and <800> require all ISO-classified rooms to be continuously monitored and the room pressures be documented at a minimum of once a day. It is recommended that a continuous monitor with an audible and visual alarm be installed in the room where staff work. They can stop compounding in the event there is a pressure excursion.

Only a few seats remaining in our November Pure Primer: Sterile Compounding and Handling Hazardous Drugs live training.

November 10-13, 2025

REGISTER NOW



best practice makes perfect

Have your BSCs certified to NSF ANSI 49 and confirm that individuals doing this certification hold an accreditation through NSF or an equivalent organization. This ensures accurate and consistent testing is done according to an industry standard.

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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.