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the pure observer

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

Choosing the Right Contract Microbiology Lab for USP <797>: Why Lab Type Matters

In November 2024, The Pure Observer introduced key considerations for choosing a contract laboratory to process USP <797> viable environmental monitoring samples. Since then, one concern has continued to surface during audits, investigations, and client consultations: Many labs processing USP <797> samples are simply not the right type of lab for this work. This issue deserves a deeper and more serious discussion.

USP <797> viable sampling data directly informs contamination control decisions in sterile compounding. When results are misunderstood, misidentified, or generated by a lab without pharmaceutical microbiology expertise, the downstream risk is significant—misguided CAPAs, unresolved root causes, and ultimately patient risk. Choosing the right lab is not about convenience or turnaround time; it is about technical competence and regulatory alignment.

Look for a Pharmaceutical Microbiology Lab

Not all microbiology labs are created equal. Environmental, food, water, or industrial-hygiene labs may be excellent within their own domains—but USP <797> viable samples belong in a pharmaceutical microbiology laboratory.

A pharmaceutical microbiology lab understands:

- the intent and application of USP <797> requirements
- cleanroom classifications and dynamic vs. static conditions
- sterile compounding risk, not just organism recovery

- how environmental monitoring data is used during excursion investigations

Labs without pharmaceutical microbiology experience often treat viable samples as routine environmental isolates. This is a fundamental mismatch. USP <797> viable data is not collected for trend reports alone—it is collected to assess contamination risk in spaces where sterile drugs are prepared.

Demonstrated USP <797> Experience Is Not Optional

A lab processing USP <797> samples must have demonstrated experience with sterile compounding environments, not just familiarity with the chapter's existence. At a minimum, the lab should routinely support:

- viable air and surface samples from ISO-classified spaces
- USP <797>-compliant incubation schemes
- investigation support when action levels are exceeded, especially for the microorganisms recovered

Importantly, USP <797> testing should ideally be included in the lab's ISO 17025 scope, not offered as an informal or "off-menu" service. A lab that truly understands USP <797> will be able to explain how their methods, incubation conditions, and reporting align with the chapter's expectations.

Deep Understanding of USP <1113>, <1116>, and <1117>

USP <797> does not stand alone. Competent labs must also demonstrate working knowledge of:

- USP <1113> Microbial Characterization, Identification, and Strain Typing
- USP <1116> Microbiological Control and Monitoring of Aseptic Processing Environments
- USP <1117> Microbiological Best Laboratory Practices

USP <1117> sets expectations for laboratory practices—aseptic technique, media control, equipment qualification, analyst training, and quality oversight. Labs unfamiliar with this chapter frequently lack the quality systems needed to support pharmaceutical testing.

USP <1116> informs how data should be interpreted in the context of cleanroom control. Without this understanding, results may be reported accurately but interpreted incorrectly.

Identification Means Identification—Not Characterization

One of the most common and most serious gaps seen in contract labs today is misrepresentation of microbial identification.

USP <1113> clearly distinguishes between:

- identification (assignment to a taxonomic level based on defined criteria, in other words genus- and species-level identification)
- characterization (descriptive information that does not meet identification criteria)

For USP <797> investigations, identification is required. Based on the proposed definition of identification in USP <1113>, that means at least a genus-level identification using a phenotypic, proteomic, or genomic technology. A report that lists colony morphology, Gram stain, or partial biochemical traits without a genus-level call is not an identification.

Characterization alone is insufficient for:

- risk assessment
- source attribution
- meaningful CAPA development

Labs must be able to explain how an identification was achieved, what method was used, and whether that method is appropriate for pharmaceutical environmental isolates. Tools such as MALDI-TOF can be highly effective when properly validated and interpreted, but only in the hands of trained microbiologists.

ISO 17025 Accreditation Is Key—and the Scope Matters

ISO/IEC 17025 accreditation is not a checkbox; it is a critical indicator of laboratory competence and quality management. For USP <797> support, the accreditation should:

- be current and issued by a recognized accreditation body

- include viable air and surface sample analysis
- ideally include microbial identification

Accreditation that excludes identification work should prompt scrutiny. If microbial identifications are not part of the lab's scope of accreditation, clients should understand why and assess the associated risk.

A Final Word of Caution

The demand for USP <797> testing has increased rapidly, and many labs have stepped into this space without the necessary pharmaceutical microbiology foundation. There's microbiology… and then there's pharmaceutical microbiology. Processing samples is not the same as understanding them.

When choosing a contract lab, ask hard questions. Request scopes, methods, and examples. A qualified microbiology lab will welcome these discussions—because they understand what is at stake.

At Pure Microbiology, we continue to see the consequences of choosing the wrong lab during investigations, audits, and regulatory reviews. This is not an area for compromise. The right lab protects your data, your program, and ultimately your patients.

best practice makes perfect

Qualify your contract microbiology lab like a critical supplier—because it is. Start by obtaining the lab's ISO/IEC 17025 accreditation and, just as important, the scope. Ensure the scope includes viable air and surface sample colony enumeration in accordance with USP <797>.

QUESTION of the MONTH

Our contract lab reports "gram-positive cocci" with colony morphology and notes the isolate is "consistent with Micrococcus." They call this an 'ID.' Is that acceptable for USP <797> investigations?

No. That is characterization, not identification. USP <1113> distinguishes identification from characterization; and for USP <797> excursion investigations, you need an identification based on an appropriate phenotypic, proteomic, or genomic technology.

Pure Primer: Sterile Compounding and Handling Hazardous Drugs Live Training.

May 12 - 15, 2026
August 31 - September 3, 2026

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.

REGISTER NOW

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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.