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the pure observer

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

Cleanroom Certification Under USP <797> and <800>: More Than a Passing Report

At last month's CETA conference, there was a strong emphasis on something that often gets overlooked in day-to-day operations: the relationship between the pharmacist and the cleanroom certifier. Speaker after speaker reinforced that certification should be a collaborative process, grounded in mutual understanding of what is being tested and why. Cleanroom certification under USP <797> and <800> is not simply about receiving a compliant report; it's about ensuring pharmacists and pharmacy technicians can interpret the data, understand the intent behind each test, and use the results to support real contamination control decisions. When pharmacists and pharmacy technicians understand the testing, certification becomes far more than a regulatory requirement. It becomes part of a defensible quality system.

For pharmacists and pharmacy leaders, understanding what is tested, why it is tested, and what the results actually mean is essential. If you can't explain why a test exists, it's hard to use the data to identify risk, defend decisions, or respond confidently during an inspection.

Why Cleanroom Certification Matters

USP <797> requires that sterile compounding environments be designed, operated, and maintained to minimize the risk of microbial, particulate, and chemical contamination. Cleanroom certification provides objective evidence that the engineering controls (airflow, filtration, pressure) are performing as intended at the time of testing.

USP <800> adds another layer by focusing on containment for hazardous drugs. While many certification tests overlap with <797>, the intent shifts from compounded sterile preparation (CSP) protection alone to also protecting staff and the surrounding environment.

Certification, however, only answers one question: Is the room performing as designed right now?

Interpreting that answer correctly requires understanding the tests themselves.

Cleanroom Certification Tests Required by USP <797>

These tests are expected during initial certification, recertification (every 6 months), and after significant changes.

1. Total Particle Count Testing (ISO classification)

What it tests: The concentration of airborne particles ≥0.5 µm

Why it matters: Particles act as carriers for microorganisms. ISO classification verifies that the area or room meets the required air cleanliness level (ISO 5, 7, or 8) under dynamic conditions.

2. HEPA Filter Integrity Testing

What it tests: Leaks in HEPA filters, frames, and seals using an aerosol challenge

Why it matters: Even small leaks can allow contamination to bypass filtration and reach critical areas.

3. Airflow Volume and Velocity

What it tests: The amount and speed of air being delivered to the room or PEC

Why it matters: Proper airflow is needed to maintain ISO classification and dilution of contaminants.

4. Room Pressure Differential Testing

What it tests: Pressure relationships between rooms (e.g., buffer to anteroom)

Why it matters: Correct pressure prevents contaminants from migrating into cleaner spaces or, under <800>, escaping hazardous drug areas.

5. Airflow Visualization (smoke studies)

What it tests: Direction and uniformity of airflow in the PEC or proper airflow in rooms without low wall returns

Why it matters: Confirms that critical sites are protected during dynamic conditions or that the cleanroom does not have stagnant air.

Certification Tests Commonly Performed but NOT Required for USP <797> Certification

These are often included in certification testing and would be considered best practice.

Temperature and Relative Humidity – Having the temperature and humidity in the cleanroom suite documented by the certifier could be valuable in future investigations.

Recovery Time Testing **–** This is an exceptionally useful study that is used to assess how quickly a room returns to ISO classification after disturbance. It's worth the cost when it comes to handling HVAC issues.

Lighting, Noise, or Vibration Testing – Many certifiers can offer this as a service. Remember, USP <797> does indicate that a well-lighted work environment is a must. USP <1066> provides guidance that your certifier can test to.

Why Pharmacists and Pharmacy Technicians Need to Understand the "Why"

A certification report won't tell you:

- whether airflow supports your actual workflow
- why viable samples are trending upward despite "passing" certification
- how a pressure failure increases exposure risk

Understanding certification allows pharmacists and pharmacy technicians to connect engineering controls, environmental monitoring, and personnel practices into a single contamination control strategy instead of three disconnected programs.

Cleanroom certification is not something that happens *to* a pharmacy—it is something that must be done with the pharmacy. Certifiers verify engineering control performance, but pharmacists and pharmacy technicians are responsible for how that environment supports compounding practice every day. When pharmacists collaborate closely with their certifiers and understand the intent behind each test, certification data becomes meaningful. USP <797> and <800> place accountability on the pharmacy, not the certification report. Collaboration turns certification from a compliance event into an informed, defensible quality decision—one that protects patients, staff, and the integrity of the cleanroom long after the certifier leaves.

best practice makes perfect

Get access to the CETA Application Guides. Some states require compliance with these documents, taking USP <797> compliance to a whole other level!

QUESTION of the MONTH

We have low wall returns in our cleanroom. Is there any benefit in doing the visual smoke study defined in USP <797>?

While not required in your case, there still could be a benefit, especially if you have higher particle counts or viable air excursions in the room. Remember, these rooms are not unidirectional, they are turbulent. And some areas may not clean up as well as others, even with low wall returns. The visual smoke study could help identify those trouble locations.

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

Use the discount code **20LiveTrain2026** for 20% off the list price.

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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.