NEWSLETTER ISSUE: MAY 2025

the pure observer

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

Pure Microbiology is excited to collaborate with U.S. Micro-Solutions on this month's newsletter!

Ensuring Quality and Trust: The Case for ISO-17025-Accredited, Third-Party Laboratories

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The realm of laboratory testing is evolving rapidly. In-house laboratories are being developed to process and analyze self-collected samples. But what implications or risks does this hold? What distinguishes a company that relies on an internal lab from one that collaborates with a third-party laboratory? Let's explore further.

Facilities performing in-house incubation should be recognized as a laboratory and must adhere to the same standards and expectations that apply to third-party laboratories. While cost-cutting is often a priority, conducting a risk assessment may help you determine whether the savings you achieve now are worth potential long-term consequences.

Third-party laboratories, particularly those accredited under ISO 17025, provide numerous advantages, such as demonstrating technical proficiency, enhancing the accuracy and traceability of results, and fostering greater trust among customers.

While the use of a third-party lab with ISO 17025 accreditation isn't explicitly mandated by USP <797>, it serves as a crucial safety net for your samples and, ultimately, for your patients' well-being.

Let's review a few compelling reasons to choose a third-party laboratory that holds ISO 17025 accreditation:

1. Guarantees technical expertise: An ISO-17025-accredited laboratory operates under a comprehensive quality management system and possesses the technical expertise necessary for conducting testing and calibration. Testing personnel must demonstrate their capabilities through internal competency tests and external proficiency tests for each analytical method utilized.

2. Provides accurate and dependable results: ISO 17025 mandates the use of validated methods and calibrated equipment, resulting in more accurate and precise test outcomes. All measurements must be traced back to national or international standards, providing a solid foundation for comparisons. Temperature monitoring is another critical aspect of ISO 17025. Many accredited laboratories employ advanced cloud-based temperature monitoring systems for their incubators and refrigerators, ensuring they consistently remain within the necessary temperature ranges. These systems operate 24/7, alerting multiple team members via text and email if any unit deviates from the set parameters. Regardless of the time—be it a weekday, weekend, holiday, or the early morning hours, the on-call personnel are responsible for addressing these alerts and ensuring the proper handling of the samples, even if it requires a late-night trip to the lab.

3. Maintains sample integrity: Accredited laboratories follow evidence-based protocols for receiving and processing samples, including shipping and storage temperature requirements. Samples not meeting these criteria may be rejected and necessitate resampling. Such measures are implemented to maintain sample integrity to avoid the risk of reporting false-negative or false-positive results, which pose significant patient safety risks and liability for your facility. It's essential to inquire of your current lab or certifier about the safeguards they have in place to prevent such issues.

4. Ensures impartiality and objectivity: Accredited laboratories are routinely audited by national accreditation organizations and even by 503A/B compounding pharmacies. This guarantees that a lab's performance is assessed in an unbiased manner. Sample or project irregularities or nonconformities are transparently reported on final reports. Transparency is vital for the customer to investigate any issues that could have arisen. In-house laboratories may pose a conflict of interest since there is no external entity supervising the reporting of discrepancies.

5. Builds customer confidence: Clients can trust that the results generated by an ISO-17025-accredited laboratory are reliable and accurate.

In conclusion, it's crucial to understand where your samples are headed and how they are being processed, whether that be to your own internal lab, a certification company lab, or a true third-party lab. Create a service provider/vendor questionnaire that the laboratory must complete, and perform on-site inspections/audits of its testing facility.

If you have any questions regarding ISO 17025 compliance or third-party laboratory testing, please don't hesitate to reach out.

Thoughts from Pure Microbiology

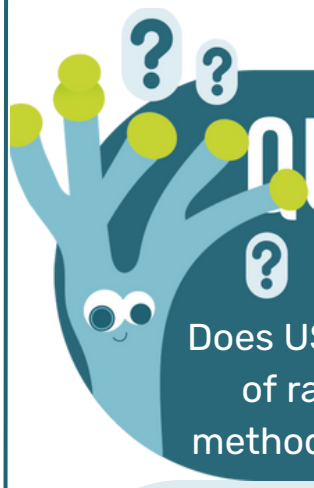
The integrity of your USP <797> viable samples is critical—these samples are the voice of your cleanroom! Without reliable data, you can't truly know if your environment is safe for sterile compounding. That's why calibration, validation, training, experience, and a properly controlled laboratory space aren't just nice-to-haves—they're essential. Accurate calibration ensures your equipment performs as expected. Validation proves your methods work. Skilled, well-trained personnel with real-world experience know how to properly handle samples without introducing error. And a proper lab environment protects the samples from external contamination. If you have not

visited your lab partner, get on site or, at the very least, ask for a video-call tour. Remember, the processing of your samples is more than just counting colonies; it's an indirect part of patient care. Your patients deserve the best.

Have questions about what "right" looks like when it comes to your lab? Reach out! We can help.

best practice makes perfect

Ask for and verify that the contract lab's ISO 17025 scope of accreditation includes the testing you need it to perform. This should include USP <797> incubation and analysis and microbial identification according to USP <1113>.



QUESTION of the MONTH

Does USP <797> allow the use of rapid microbiological methods for sterility testing?

USP <797> does not prohibit the use of rapid microbiological methods (RMMs). However, any alternative methods must be appropriately validated to show that they are equivalent to or better than USP <71>, which is the compendially accepted method. Take a look at USP <1223> and <1225> for more information.

Join Us For

Pure Primer: Sterile Compounding and Handling Hazardous Drugs

June 2-5, 2025
November 10-13, 2025
Bethlehem, PA

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. This interactive training is appropriate for both pharmacists and technicians, especially those who hold a management or designated person role.

Receive a $500 discount using the code APRILPURE2025.

Instructors include:
Abby Roth, CMQ/OE
Patricia Kienle, RPh, MPA, BCSCP, FASHP
Kevin Hansen, PharmD, MS, BCSCP
Lew Exner

Click to Learn More or Register

We are excited to announce that our Aseptic Connection is live!!

This comprehensive membership platform provides you with valuable tools and resources covering USP standards, best practices, and more.

A premium membership gives you the ability to ask industry experts 12 questions a year.

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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.