NEWSLETTER ISSUE: DECEMBER 2025

the pure observer

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

Pure Microbiology Year in Review: 2025

As we reflect on the past year at Pure Microbiology, we're reminded of the remarkable progress, challenges, and learning that have shaped our journey together. Each month brought new insights, regulatory updates, and best practices that strengthened our commitment to patient safety and operational excellence. This special edition captures the highlights from our 2025 newsletters, celebrating the dedication and curiosity of our community. Thank you for joining us on this path of continuous improvement and learning.

January: Controls for USP <797> Viable Samples

We kicked off the year by demystifying the use of controls in viable sample collection. While USP <797> doesn't require controls, industry best practices and guidance from CETA and PDA strongly recommend negative and positive controls to ensure the reliability of environmental monitoring. The article emphasized risk assessment, collaboration with your lab, and the importance of documenting control failures and corrective actions.

February: Viable but Nonculturable Microorganisms (VBNC)

February's feature explored the hidden world of VBNC microorganisms—living microbes that evade detection by standard culturing methods. The article highlighted the limitations of traditional environmental monitoring and stressed the need for robust contamination control strategies, thorough cleaning, and ongoing staff education to mitigate these risks.

March: Red Flags in Viable Sampling Compounding Activity

March focused on common pitfalls in viable sampling, such as improper staff presence during sampling, static sampling misapplied as dynamic, and forced conditions that don't reflect routine operations. The article encouraged honest self-assessment, proper staff involvement, and the use of both static and dynamic sampling as investigative tools.

April: Incubation Documentation —What Really Applies?

April's main article clarified the documentation requirements for incubation temperatures under USP <797>. It addressed common misinterpretations by inspectors and compliance software, emphasizing that starting temperature documentation is only required for aseptic manipulation competency samples—not for all viable samples. The piece urged pharmacies to audit their labs and reference USP <797> directly during inspections.

May: The Case for ISO 17025-Accredited Third-Party Laboratories

May's collaboration with U.S. Micro-Solutions underscored the value of ISO 17025 accreditation for third-party labs. The article detailed how accredited labs guarantee technical expertise, accurate results, sample integrity, and impartiality—ultimately building trust and ensuring patient safety. It encouraged facilities to audit their lab partners and verify accreditation scope.

June: Demystifying the USP <797> Aseptic Manipulation Competency Assessment

June addressed the confusion surrounding aseptic manipulation competency assessments. The article broke down the four main components—observational competency, media-fill test, gloved fingertip and thumb testing, and surface sampling—and clarified what constitutes a failure and the need for remediation. It also distinguished between aseptic manipulation and hand hygiene/garbing competencies.

July: Top "People Bugs" in Sterile Compounding Pharmacies

July highlighted the most common human-associated microbial contaminants—*Staphylococcus epidermidis, Micrococcus luteus,* and

Corynebacterium spp.—found in sterile compounding pharmacies. The article discussed their pathogenicity, sources, and remediation strategies, reinforcing the importance of robust training and contamination control.

August: Reviewing Certificates of Analysis for Microbiological Media

August's issue provided a practical guide to reviewing certificates of analysis (COA) for TSA and TSB. It outlined key elements to verify—dates, visual characteristics, pH, growth promotion, sterility, and irradiation—and recommended standardized checklists and secure storage practices to ensure media quality and regulatory compliance.

September: Designing a Practical Media-Fill Program for Sterile Compounding

September's main article tackled the complexities of media-fill testing across different primary engineering controls (PECs). It advised facilities to follow state requirements first, then design risk-based programs that prioritize the most challenging environments and document rationale in SOPs. The article also clarified sampling requirements for HD storage rooms.

October: Highly Pathogenic Organisms—A Risk-Based Approach

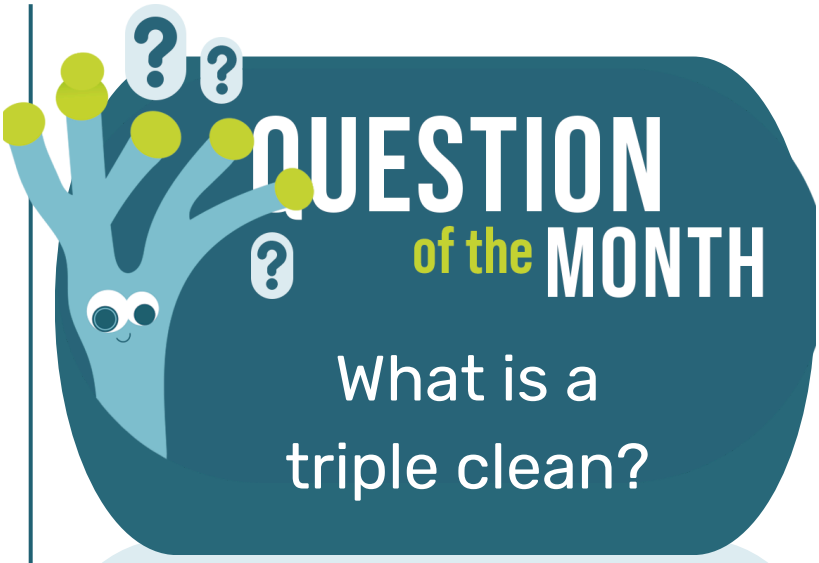
October revisited the contentious term "highly pathogenic organisms" and advocated for a risk-based framework focused on "organisms of concern." The article provided guidance for evaluating recoveries, building corrective action plans, and partnering with microbiologists to interpret data and maintain patient safety.

November: Ensuring Microbial Identification Meets USP Standards

November's feature reviewed best practices for microbial identification in environmental monitoring. It clarified USP <797> requirements for genus-level identification; explained the value of species-level ID; and compared phenotypic, proteotypic, and genotypic methods. The article stressed the importance of partnering with accredited labs and maintaining staff competence.

Heartfelt Message to Our Readers

As we close out 2025, we want to extend our deepest gratitude to every reader, contributor, and member of the Pure Microbiology community. Your commitment to excellence, patient safety, and continuous improvement inspires us every day. Thank you for your engagement, your questions, and your trust in us as a resource. Together, we've navigated regulatory changes, tackled new challenges, and shared best practices that elevated our field. We look forward to another year of learning, growth, and collaboration. Wishing you a safe, successful, and fulfilling 2026!



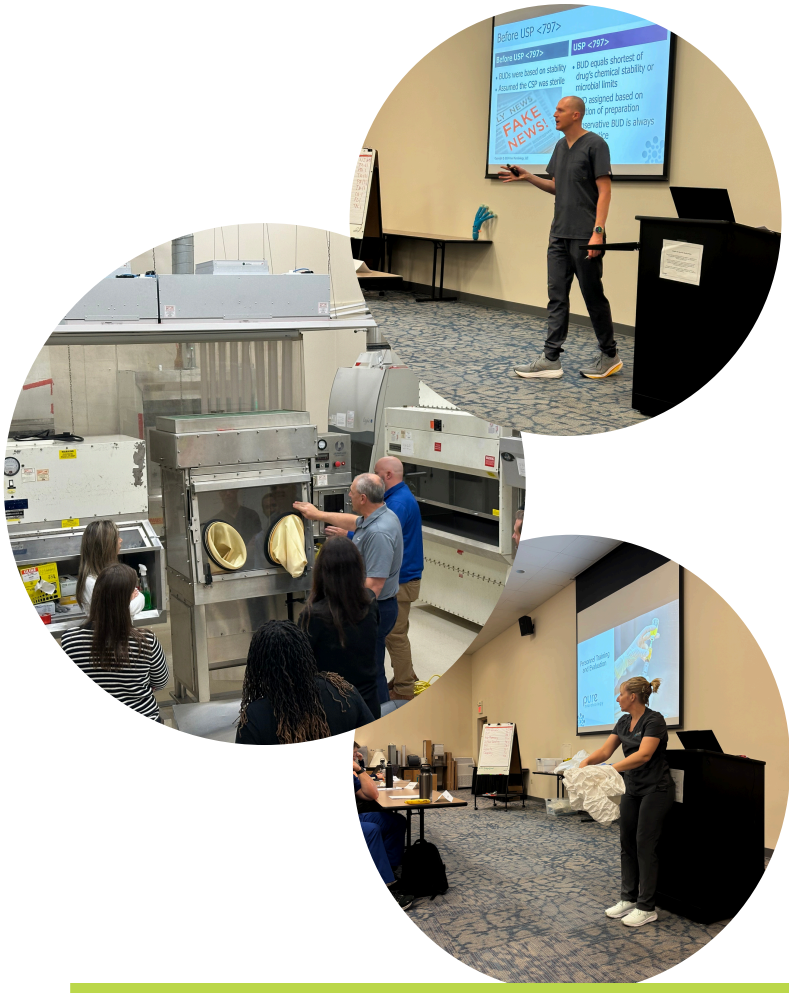
As it applies to a sterile compounding facility, a triple clean consists of 3 applications of an EPA-registered one-step disinfectant cleaner. It could be 2 applications of a bactericidal agent, followed by a sporicidal agent or 1 application of a bactericidal agent followed by 2 applications of a sporicidal agent. If the triple clean is done in the PEC, the third application is followed with sterile 70% IPA.

New 2026 dates announced for our Pure Primer: Sterile Compounding and Handling Hazardous Drugs Live Training

May 12 - 15, 2026

August 31 - September 3, 2026

REGISTER NOW



best practice makes perfect

Evaluate the sterile compounding area for ergonomic risks. Staff should be able to work in a neutral posture at a comfortable height, have items within easy reach, and limit the use of excessive force.

puremicrobiology.com
E: abby.roth@premierinc.com | P: 610.417.4795

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.