Q&A with Joshua Snyder

Q1: What are the key distinctions in quality control for bacteria and USP testing when comparing environmental labs to compounding pharmacies?

Whether performing quality control for an environmental lab or a compounding pharmacy, analytical reproducibility, traceability, and overall data integrity are paramount. The primary distinction here is one of scope and purpose.

Compounding pharmacies have regulatory oversight by FDA and must abide by the United States Pharmacopeia (USP), local boards of pharmacy, and in some cases Common Good Manufacturing Practices (cGMP). Especially in the case of sterile compounding, this requires maintaining some of the most rigorously controlled built environments in the world. To do this, compounding pharmacies use extensive engineering controls and sanitation/sterilization protocols while taking a zero-tolerance approach to contamination risk. Bacteriological testing for compounding pharmacies focuses on sterility and endotoxin, ensuring not only that all microorganisms have been killed but that even their pyrogenic remnants have been eliminated.

In comparison, environmental labs primarily receive regulatory oversight from EPA and CDC at the federal level and are assessed by accrediting bodies to the ISO 17025 set of standards. Environmental labs receive a wide range of samples for microbiological testing, from treated wastewater tested for coliforms to cooling tower water tested for *Legionella*. In general, the samples received by environmental labs are “dirtier” than those collected in a compounding pharmacy because they are from uncontrolled environments. When an environmental lab receives samples for USP testing, it is usually from a compounding pharmacy or a third-party that provides service to a compounding pharmacy. These include environmental monitoring air and surface samples, as well as media fill test samples. While the compounding pharmacy and their service providers primarily focus on keeping everything clean, they do not often specialize in the identification and quantification of organisms that are recovered. This is where environmental labs can offer their broad expertise with environmental isolates to aid in overall USP compliance.

Q2: As QA Manager, what's your biggest challenge in ensuring consistent bacteriological analysis in your labs, and how do you tackle it?

Reproducibility of data is a priority for all of our analytical services. For bacteriology in particular, this can be challenging because of the very nature of the analytical target. Bacteria are very diverse even in their ideal state, but environmental samples often contain bacteria that have endured extraordinary stresses (e.g., chlorination) that can alter their characteristics, including their ability to grow in a lab. We have specialized methods for identifying and quantifying a wide range of bacteria using various isolation, cultivation, and detection methods. There are many different media and reagents, several controlled incubation environments, and multiple technologies (e.g., microscopy, MALDI-TOF, PCR, etc.). Controlling all those variables is the challenge.

The key from a quality assurance perspective is ensuring qualification, standardization, and traceability of everything influencing the analysis. This requires (1) establishing scientifically valid standard operating procedures (SOPs), (2) carefully choosing third-party vendors and service providers for our supplies, equipment, and instrumentation, (3) training and maintaining fully qualified personnel, and (4) conducting internal quality control checks at every step along the way, from supply receipt to sample preparation and through final data reporting.

Q3: How do your roles on the AIHA LAP and ASTM committees influence Eurofins Built Environment Testing's quality assurance and new testing methods?

I participate in both AIHA LAP's Technical Advisory Panel (TAP) and ASTM's D22.08 committee on Assessment, Sampling, and Analysis of Microorganisms to stay at the forefront of discussions that impact analytical standards and accreditation criteria.

AIHA LAP is always working to improve their enforcement of requirements in ways that will improve our industry. Their voluntary advisory panels and review boards are comprised of experts from across the industry and its many specializations. This creates a great opportunity for benchmarking and identifying areas in need of improvement. Being involved in the TAP and broader AIHA LAP community helps me bring strategic points of emphasis to Eurofins Built Environment Testing so we can stay ahead of the curve.

ASTM is a tremendous resource for reference methods that are both widely accepted within the industry and rigorously validated. As a committee member, I can stay up to date on the expert consensus best practices developed by ASTM. This can inform decisions to adopt ASTM methods directly, as well as guide creation of our in-house methods.

Q4: What crucial advice do you have for clients regarding sample preparation or result interpretation for bacterial contamination or USP testing?

Before collecting any samples, it's essential to have a plan that includes a valid sampling method performed by qualified personnel using appropriate techniques (aseptic technique is critical for USP testing) and supplies, while abiding by all handling and storage requirements. All samples must be clearly labeled and the sampling event should be thoroughly documented, including locations, times, volumes, etc. Analytical results will have little if any value without this context. Results should always be interpreted in context. For example, if coliforms are recovered from a wastewater system, nobody is surprised, but if coliforms are recovered in a cleanroom, that should be very alarming.

When interpreting results, it's also crucial to understand the analytical target and the analytical limitations, including interferences and detection limit. For example, if a square foot of a cleanroom table is swabbed and has a non-detect result, that means the table has <1 CFU/sqft but does *not* mean that the table has 0 organisms on it. It may or may not have organisms in the area that was not sampled. Furthermore, sampling systems are not perfect. It is possible for a swab to fail to collect an organism or for the preparation of that swab to fail to recover an organism from the swab. Negative results do not absolutely indicate the absence of contaminants, just as positive results do not necessarily indicate a widespread contamination

event. Ultimately, the value of environmental monitoring for USP and microbial monitoring programs in general is in the visibility of ongoing trends and extreme outliers.