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the pure observer

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

Viable but Nonculturable Microorganisms (VBNC): Yes, this is a thing.

Did you know that the media and incubation parameters we use in viable sampling cannot support the growth of every microorganism that may be recovered in the sterile compounding environment? This is one of the reasons why environmental monitoring (EM) is considered “semi-quantitative.” It’s not perfect. Kind of scary, right?

In the intricate world of microbiology, the concept of viable but nonculturable (VBNC) microorganisms presents a unique challenge, particularly in environments where sterility of the patient preparation is non-negotiable, such as sterile compounding facilities. Understanding VBNC microorganisms, their implications, and how they relate to sterile compounding is critical to maintaining safety, regulatory compliance, and preparation integrity.

What Are VBNC Microorganisms?

VBNC microorganisms are bacteria or other microbes that, while alive and metabolically active, fail to grow under standard laboratory conditions. Factors such as environmental stress, nutrient deprivation, or exposure to disinfectants can induce the VBNC state. These organisms can remain dormant for extended periods and may resuscitate under favorable conditions, posing a hidden threat to sterile environments. And yes, this is happening in YOUR sterile compounding environment. Getting all zeros for your viable sampling results only means that you didn’t recover anything, not that microorganisms were not present.

Unlike microorganisms that are easily detected through standard culturing methods, VBNC organisms evade detection due to their inability to grow on common agar media or under the incubation parameters provided. This characteristic makes them particularly concerning in sterile compounding, where microbial monitoring and control are pivotal.

VBNC and Sterile Compounding: A Hidden Threat

Sterile compounding facilities are regulated environments tasked with preparing medications free from microbial contamination. Despite rigorous cleaning, disinfection, and EM protocols, VBNC microorganisms can persist undetected. Their presence can undermine the effectiveness of sterility assurance programs in the following ways:

1. Undetected contamination - Traditional viable air and surface sampling methods rely on the ability of microorganisms to grow on specific media and at specific times and temperatures. VBNC microorganisms bypass this detection, creating a false sense of security in the cleanliness of the sterile compounding environment.

2. Potential resuscitation - Under favorable conditions, such as nutrient-rich environments or a return to optimal growth conditions, VBNC microorganisms can revert to an active state, such as a bacterial spore. In sterile compounding, this can lead to contamination of compounded sterile preparations (CSPs), posing risks to patient safety.

3. Regulatory implications - USP <797> emphasizes maintaining an appropriate compounding environment. While VBNC microorganisms are not directly addressed, their potential presence challenges the effectiveness of existing EM protocols.

Addressing VBNC Microorganisms in Sterile Compounding

While the nature of VBNC microorganisms makes them challenging to manage, there are strategies to mitigate their impact in sterile compounding environments:

1. Sound contamination control strategy – Spending time developing the processes and procedures in the contamination control strategy is essential. Keeping microorganisms out is the goal.

2. Robust cleaning and disinfection protocols - Regular cleaning with sporicidal agents and proper disinfection techniques can reduce the risk of VBNC microorganisms persisting in the environment. During the monthly clean, focus on hard-to-reach areas and equipment surfaces that might harbor dormant microbes.

3. Training and awareness - Educating compounding personnel about VBNC microorganisms and their implications is crucial. Training programs should highlight the limitations of traditional monitoring and emphasize the importance of strict aseptic techniques and environmental controls.

The Forward Path

While traditional methods remain integral to environmental monitoring, vigilance and continuous improvement are paramount. By acknowledging the risks posed by VBNC microorganisms and implementing proactive measures, sterile compounding facilities can uphold the highest standards of patient safety and regulatory compliance.

best practice makes perfect

Focus on your contamination control strategy. As scary, as VBNC microorganisms are, working in a well-designed facility, implementing solid garbing and material transfer procedures, and teaching proper cleanroom behavior can help mitigate the risk.

QUESTION of the MONTH

Can we leave the 20 to 25°C samples at controlled room temperature? Is an incubator a must?

USP <797> requires any incubation to be in an incubator. This provides more control over the temperature distribution and ensures a consistent temperature.

The Aseptic Connection
by pure microbiology

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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.

Attendees will receive 25.5 hours of live ACPE CE.

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