NEWSLETTER ISSUE: AUGUST 2024

the pure observer

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

Pure Microbiology Technical Opinion

An interpretation of "Testing Under Dynamic Conditions"

USP General Chapter <797> (2023) defines dynamic operating conditions as follows:

"Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s)."

The first sentence of the definition is universally agreed upon: dynamic conditions require compounding personnel to be present. However, the second sentence presents a more nuanced challenge. It states that conditions should reflect the greatest number of people; but in practice, practitioners, inspectors, and surveyors have misinterpreted this directive. Unfortunately, this has led to the "should" being treated as a "must."

The pivotal word in the second sentence is "routine." Routine should be understood as usual. How many people usually work in the compounding space? That is the number of people who should be present in the compounding space when performing tests that require dynamic operating conditions.

Ideally, during the commissioning of a new cleanroom suite, testing is conducted under worst-case conditions to establish a baseline of particle and microbial counts. These data establish the maximum occupancy of each room in the cleanroom suite. It is advisable to do so for facilities that have not conducted a baseline study during commissioning. The baseline study under worst-case conditions should be repeated at intervals defined by the sterile compounding organization.

Consideration must also be given to current challenges with staff shortages. Suppose only two staff members are available on the day of certification when four would typically be working. The

sterile compounding area should be tested with the two staff members and the certifier. It is not recommended to have two additional people garb and enter if they never enter the cleanroom suite as part of their responsibilities. The number of people present should be documented to allow for trending.

Finally, it's important to note that particle count testing and viable sample collection provide point-in-time measurements, offering a snapshot of what was in that location at a given moment. Although individual results are compared to defined acceptance criteria, the overall trend of the area is what truly matters. Collecting samples under routine staffing conditions and trending the data will provide the most accurate picture of the typical environmental bioburden for the sterile compounding area.

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best practice makes perfect.

Read "USP <797> Immediate-Use CSPs: Small Changes, Big Impact" by Kevin N. Hansen, PharmD, MS, BCPS, BCSCP; Amanda M. Choi, PharmD, MBA; Annie Lambert, PharmD, BCSCP. It's a great resource on immediate-use CSPs with helpful infographics.

Colony Enumeration Proficiency Assessment

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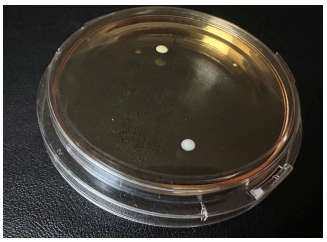

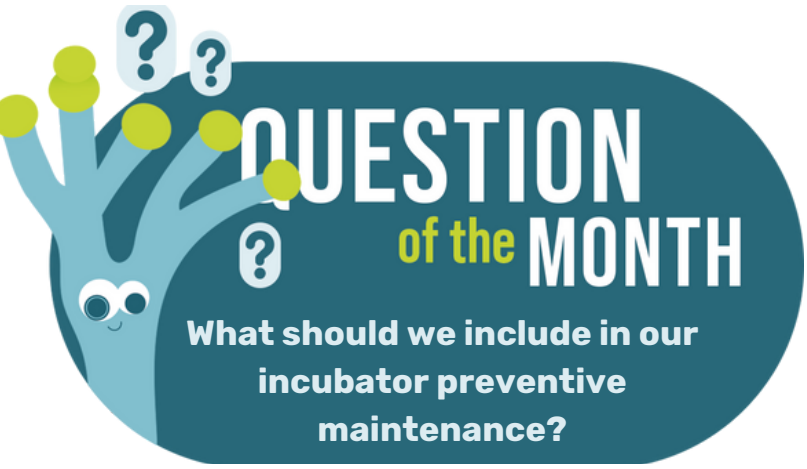

Annual preventive maintenance (PM) includes leveling the incubators, checking door seals, verifying clearance, checking cord integrity, and doing anything else the manufacturer recommends. And don't forget to include cleaning in your PM activities. All these activities should be defined in your SOPs and tracked at a frequency defined by your organization.

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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.

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Abby Roth, CMQ/OE
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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.