NEWSLETTER ISSUE: DECEMBER 2024

the pure observer

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

Viable Sampling Materials Red Flags

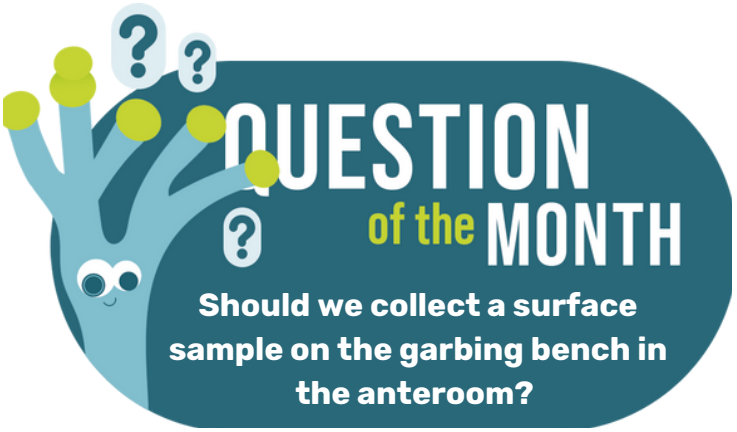
USP <797> requires that SOPs are reviewed at least annually. Depending on your review schedule, December may be crunch-time for SOP review. When reviewing your viable sampling SOP, be sure you have outlined the materials necessary to execute a successful sampling session. You also want to look for red flags associated with these materials. Here are 5 red flags to watch out for:

1. Using an air sampler with a poor recovery efficiency – Not all air samplers are created equal and some collect microorganisms better than others. Ask your air sampler manufacturer for the D50 value of your air sampler. Don't know a whole lot about air samplers? Check out The Pure Observer from January 2024 or our September 2023 webinar titled Choosing a Viable Air Sampler and Media Webinar.
2. Using aseptically filled media – This is still a common problem in the sterile compounding industry; sampling with media that we don't know for certain is sterile! Why would you want to take that risk? Yes, it's cheaper, but it's another variable in an excursion investigation. You want to choose terminally sterilized media. Learn more about selecting media from the November 2023 issue of The Pure Observer.
3. No procedure for the use of open media – Many locations reuse open media. There is nothing in USP <797> preventing the use of open media, but it does come with risks. If you don't have this process defined in your SOP, make sure it is documented and be sure to consider where and how the media was opened and what the plates will subsequently be used for. Also, check the manufacturer's instructions for use when it comes to using the media on its expiration date. Many state that the media can be used to sample on the expiration date if it is in its original packaging.

4. Unnecessarily taping/parafilming plates – Tape and parafilm come with contamination risks, as most of what is used is not sterile. If you are using locking lid plates and incubating in-house, there is NO reason to tape your plates. If you are shipping to a contract lab, consider placing the plates in a sterile bag as opposed to sealing them entirely with tape or parafilm. If your plates do not have locking lids, consider using two small pieces of tape to secure the lid instead of sealing the entire plate. Talk to your lab for additional recommendations.

5. Not using a disinfectant cleaner to wipe after surface sampling – This may not be an issue if you are doing your own sampling, but if you are outsourcing to a vendor, make sure they are up to date on this new chapter requirement. Within the PEC the sample locations are wiped with a sterile EPA-registered one-step disinfectant cleaner and allowed to dwell for the required time. Then the surface is wiped with sterile 70% IPA. In the room, simply wipe the surface with a one-step disinfectant cleaner and allow it to dwell for the required time.

Still have questions or need help, contact us today!



It depends on how the bench is used. If it is truly only used to sit on to don shoe covers, then no. If items are placed on it that will eventually end up in the buffer room and the PEC, then yes. Watch work practices to decide what is right for your facility.

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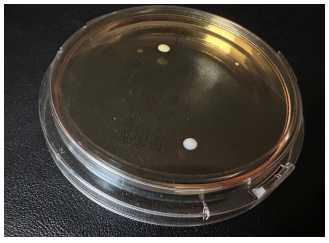

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Abby Roth, founder of Pure Microbiology, has been supporting the testing and consulting needs of the pharmaceutical, medical device, and compounding industries since 2004. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring. Abby also has participated in multiple microbial excursion investigations, providing guidance on contamination sources and remediation options.