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the pure observer

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Setting Realistic Certification Expectations for USP <797> Facilities

Because of my contamination control background, I sit in a unique place between certification providers and sterile compounding facilities. I hear the good, the bad, and the ugly about both sides. Some things are true. Some things are exaggerated. It's a hard place to be because I know both sides can be at fault. Keeping in mind the sometimes-volatile relationship that exists between sterile compounders and certification providers, we need to set realistic expectations for cleanroom certification. Some sterile compounding organizations have nightmarish certification stories, while some hold the certification providers to unrealistic processes.

This needs to be said: Certification is not a clean process, especially after viable sampling and particle counts are collected. Let's look at some unrealistic expectations in order to set the stage for what you should expect from your certification provider.

#1 – Certification Equipment

Unrealistic expectation: All certification equipment is thoroughly wiped down with the facility's designated agent, removing all possible contamination.

Realistic expectation: The equipment wipe-down will not be perfect. First, some portions of the equipment can't be wiped with the facility-dedicated agent because it will damage the equipment. Second, it would take a crew of people hours to thoroughly wipe everything that enters the space for certification. We know this process is usually rushed so the certifier can get in and out, letting you get back to patient care. Instead of being hyper-focused on equipment and material transfer (aside from any viable testing they do for you), expect an average job of wiping equipment and plan your monthly clean for immediately after certification.

#2 – Cleanroom Garb

Unrealistic expectation: Certification providers must wear the required cleanroom garb the entire time they are in the compounding area, and this will mitigate all contamination risks.

Realistic expectation: Certain garb could be a safety risk depending on the servicing required. If you are a sterile compounder reading this, you are probably freaking out, but stay with me. Yes, certification personnel need to garb according to facility policy, but there also needs to be a focus on safety. Imagine for a moment that you are a certifier and you need to carry a 50-plus-pound fan filter unit up a ladder to install it in the cleanroom ceiling. How would you feel about wearing shoe covers while performing this task? I wouldn't want to do this, especially knowing one of my certifier friends fell off a ladder due to the slipperiness of the shoe covers. This is one example of a situation where the safety of the individual is more important than the cleanliness of the room. The other component to this expectation is that the garb will mitigate all contamination risks. Certification is physical work. Even if the temperature of the room is comfortable for compounding staff, it might not be comfortable for certification providers, resulting in sweating and the release of deeper skin bacteria. This is another reason to plan your monthly clean for immediately after certification.

Hopefully you can see that, even if the certifier is properly garbed and the equipment is wiped with the designated agent, there is still a chance that contamination will enter the space. Certification is a disruption, which is why sterile compounding leadership needs to plan around certification and identify how they will care for patients until the compounding area can safely be used again. This is tough for a 24/7 operation, but it is achievable.
In addition to clearing up some unrealistic certification expectations, we need to think of certification beyond just the testing and the report. Think of the providers. They are dragging around heavy equipment, climbing up and down ladders, and sometimes spending days away from their families every week to service long-distance customers. Certification professionals are brilliant in their own unique way, with knowledge about facility design, airflow, particles, and filters.

More sterile compounding personnel need to get to better know their certifiers. Because sterile compounders and certification providers each hold a very important role in patient care and safety, there must be a working relationship. And not only must each clearly communicate with the other, both sides must listen. Lots of love to both groups as we all work together to ensure the best possible patient care.

In the chapter's section on preparation per approved labeling, we are stuck on what the "resultant strength" means. Does it refer to the resultant strength of a vial after adding the diluent or the resultant strength of the entire CSP once the vial has reconstituted and further diluted into the final bag?

It would be the resultant strength of a vial after adding the diluent. Kevin Hansen and Patti Kienle wrote a great article that addresses preparation per approved labeling.

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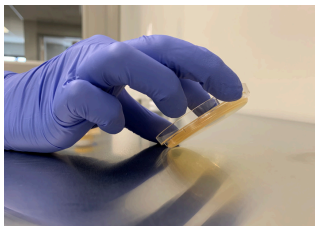

best practice makes perfect

Verify that your certifier is performing the backstreaming test on your LAFWs with all the materials in the PEC that would normally be there during compounding. This test is not mentioned in USP <797> but is described in CAG-003, and it's vital to identifying risks to the DCA.

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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.