

news & blog

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unrealistic certification expectations

Because of my contamination control background, I sit in a weird 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. So, when I write my daily USP 797 countdown tips, I am especially careful of wording, keeping in mind the sometimes-volatile relationship that exists between sterile compounders and certification providers. The last thing I want is a comment battle on my LinkedIn post. If you don't know what I'm talking about, you're either new to the industry or you are SUPER LUCKY.

I carefully wrote the January 17th tip about allowing the certifier to bring in the necessary electronic devices so they can do their job. With these tips I also provide some context as to why I make the recommendation. My head was spinning about what to say. Reason being is that there are some unrealistic expectations related to the certification of sterile compounding facilities and I was afraid of the comments. Some sterile compounding organizations have nightmarish certification stories. I needed to support those certification providers who do right, while being realistic with the sterile compounding audience.

So, I was very blunt and made it clear that certification is not a clean process. Here are where the unrealistic expectations that I mentioned earlier come in.

Unrealistic expectation #1: All certification equipment is thoroughly wiped down with the facility's designated agent. This sounds great, but we need to be real here. 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.

Unrealistic expectation #2: Certification providers must wear the required cleanroom garb the entire time they are in the compounding area and this will mitigate all contamination risks. 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+ 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.

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, the other reason I wanted to follow up that LinkedIn post with a blog is because when I think of certification, I think beyond the testing. I think of people dragging around heavy equipment, climbing up and down ladders, and sometimes spending days away from their family every week to service long-distance customers. I think of people who are brilliant in their own unique way, with knowledge about airflow, particles, and filters. I think about people who are my friends.

I have had the amazing opportunity to befriend dozens of certification and industry-related professionals. These individuals have shown me how to leak test a HEPA filter, calculate air changes per hour, and what it really takes to certify a cleanroom. (I've actually helped with cleanroom certification. It can be brutal.) I'm always amazed by their knowledge, experience, and origin stories. Seriously, ask your certifier how they got into the industry. It's likely a fascinating, complicated story.

After reading this, I hope that more sterile compounding personnel get to better know their certifiers, so that they may have the same appreciation for this amazing industry that I do. Because sterile compounders and certification providers have 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.

610.417.4795
1702 West Allen St. #633
Allentown, PA 18104