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the pure observer

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

USP <797> Microbial Identification: Chapter Minimum or Best Practice?

Nothing makes my skin crawl more than hearing the term “highly pathogenic organisms.” And it’s not because I’m a germaphobe. I think it’s because the term is so misunderstood. For those of you familiar with the 2008 version of USP <797>, the term was used to describe microorganisms that need to be “immediately remedied” if they are recovered on viable air or surface samples, because of their risk to patient safety. The chapter went further and provided examples of the types of microorganisms that could be pathogenic. The examples were meant to be just that, examples. Unfortunately, these examples became the “bad bugs” and have had a profoundly negative impact on sterile compounders’ ability to effectively operate while investigating their recovery.

So, what are “highly pathogenic organisms”? According to USP <797> (2008), they “can be potentially fatal to patients receiving CSPs.” I truly believe it was the intention of the Expert Compounding Committee responsible for the 2008 chapter that ALL recovered microorganisms needed to be evaluated for risk; otherwise, why would they require identification of all growth recovered? Unfortunately, the list of examples distracted stakeholders from the concept of evaluating all recovered microorganisms and coagulase-positive staphylococcus, gram-negative rods, yeast, and mold became the enemies of the sterile compounding organization. This list also became the excuse to not care about anything else that was recovered.

You must remember that this is a list of very generic categories of microorganisms except for the coagulase-positive staphylococcus, which is very specific. But if you look at gram-negative rods, yeast, and mold, these categories contain thousands of microorganisms, some more pathogenic/virulent than others. And the scary reality about the list in the

chapter is that it doesn't mention spore-forming bacteria. There are some spore-forming organisms that I would be more concerned about recovering in a sterile compounding environment than those that fall within one of the categories on the 2008 chapter's "highly pathogenic organism" list.

Looking at this list in its simplest form, it did provide practitioners and inspectors with an easy to way to say this organism is bad and this one is not. And contract labs played into it by indicating in their reports that, if you recovered one of the organisms in these four categories, the sample location fails, or you have to take action, etc. But when it comes to "highly pathogenic organisms" in real life, it isn't that black and white. In an article by Pirofski and Casadevall titled "Q and A: What is a Pathogen? A Question that Begs a Point," they discuss pathogenicity. One mind blowing concept is that many think a microorganism's ability to cause disease or even death is an inherent microbial property; when in reality, this ability can only exist in a susceptible host. Immunity and the immune response play a role here. If the patient receiving a contaminated CSP is immune or is generally healthy, pathogenicity is not expressed. Simply put, pathogenicity is more due to the immune response of the patient rather than the pathogen itself. This is why you'll hear that any microorganism can be pathogenic given the right circumstances, like route of administration, time/temperature of CSP storage, and microorganism health.

The discussion up to this point has been based on the 2008 version of the chapter. As you work to implement the 2023 version of USP <797>, you will only be required to identify microbial growth that exceeds the action level and the "highly pathogenic organism" list goes away. This is a definite benefit; however, a best practice recommendation is to base your identification needs on your risk. Remember, the chapter is the minimum standard. For example, you could identify all ISO 5 growth, which is strongly recommended as FDA considers any microbial growth in an ISO Class 5 environment an insanitary condition and would warrant an investigation. Or you just identify growth in ISO Class 5 and 7 areas. Finally, you have the option to identify all recovered growth. Here are some factors to consider when making this decision:

- categories compounded
- BUDs assigned
- nonsterile-to-sterile compounding
- facility design
- past trends

Evaluating your microbial risk can be overwhelming. Yes, looking up microorganisms online can give you an idea of the source of the contamination, but do not rely on Google to define pathogenicity for you. You want to have a multidisciplinary team in place that includes a pharmaceutical microbiologist and infection preventionists to assist you in the true risk of the recovered microorganism.

Are you still unsure about how to design your identification program? Pure Microbiology provides consulting services to support your sterile compounding microbiology needs.

best practice makes perfect.

Have the right tools available for counting colonies and evaluating media-fill units. This would include a good light source and light and dark solid backgrounds. Magnification can also be helpful.

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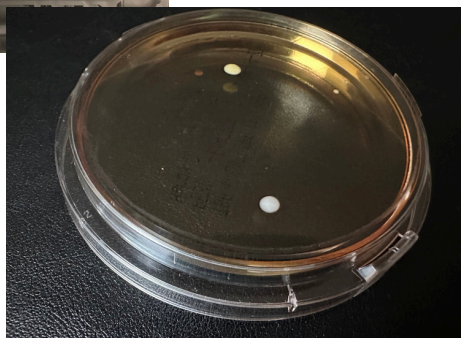

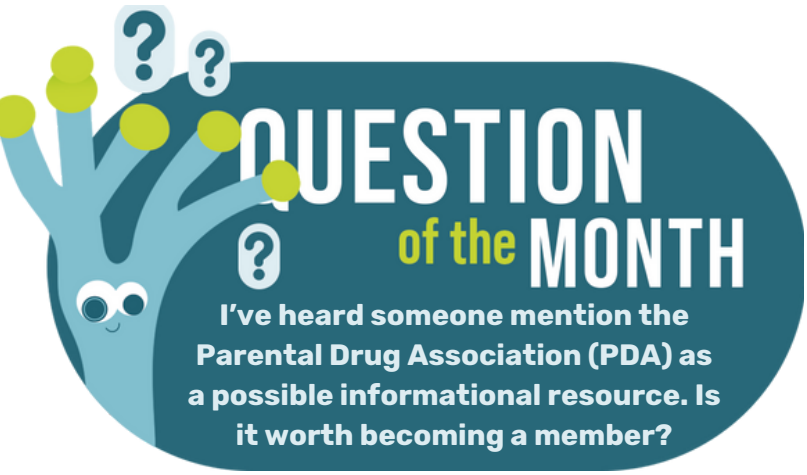

PDA is an exceptional resource for pharmaceutical manufacturing and microbiology information. Many of the technical reports can apply to sterile compounding. Having an individual from your organization join PDA would be beneficial.

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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.