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the pure observer

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Designing a Practical Media-Fill Program for Sterile Compounding

The one question that seems to keep coming up is about the media-fill test; and it goes a little something like this: “For an employee who compounds CSPs in an LAFW and hazardous CSPs in a BSC, must they complete separate compounding competencies because they work in different operating PECs?” It’s a great question, with an “it depends” answer. Let’s look at how to tackle this situation.

Start with Regulatory Triage

1. Verify state requirements. If your board of pharmacy or drug control division prescribes frequency, scenarios, or PEC coverage, follow that first.

2. If no direction is given, you decide the frequency and scope, documenting your rationale in a policy or SOP.

When the State Is Silent

Many sterile compounding facilities schedule staff to complete both types of media fills once each year. A common approach is to have the HD media fill in, let’s say, January and the non-HD media fill in July. This method ensures that both scenarios are tested without requiring excessive testing throughout the year. By following this model, sites are generally able to cover the primary PECs used, such as LAFWs and BSCs, as well as a variety of compounding techniques, including the use of CSTDs, ampules, and other manipulations.

When You Have “All the Things”

If your site has a broad mix of PECs (LAFWs, BSCs, CAIs, CACIs, IVLFZs), it isn’t reasonable or practical to test every individual in every device every six months. Do a risk assessment and find common ground:

1. Prioritize the most difficult environments. For example, for someone working in a horizontal LAFW, a vertical BSC, and a vertical CACI, testing them in the LAFW and the CACI would likely make the most sense. A well-designed media fill in a CACI (generally more restrictive to work in) provides confidence that the individual can perform in a BSC.

2. Consider an initial "all-PECs" baseline. For new staff, test them in all PECs that the individual will use to demonstrate baseline competency and PEC-specific technique. After that, shift to the PECs that best represent the most challenging conditions.

Remember, your goal is to represent your most complex manipulations and highest-risk setups, not to check a box.

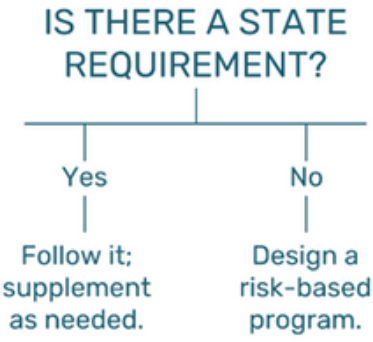
Document the Why

However you decide to set up this aspect of the training program, document it in your SOP with clear rationale:

- Risk assessment summary (devices in use, manipulations performed, HD vs non-HD, typical batch size, ampule use, CSTD use, line changes, etc.).
- Selection logic (why CACI over BSC for ongoing testing, why this cadence).
- Scenario coverage (how HD and non-HD are both addressed annually).
- Exceptions process (when to add an extra device or scenario for a given compounder).
- Remediation (what happens after a technique deviation or media-fill failure).

Bringing It All Together

In the absence of state-specific requirements, build a program that models your highest risks, balances practicality with coverage, and centers on observed technique.



Be sure to document the reasoning so you can confidently defend it. You got this!

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best practice makes perfect

Stay inspection ready! Don't prepare for inspections once a year. Design all your programs so that, if inspectors walked in tomorrow, you'd already meet requirements.

There is no need to perform viable air and surface samples in the unclassified HD storage room, unless the state board of pharmacy or another regulator requires it. If the unclassified storage room has a pass-through into your HD buffer room, you must take a surface sample in the pass-through.

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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.