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Demystifying the USP <797> Aseptic Manipulation Competency Assessment

There is a lot of confusion surrounding the aseptic manipulation competency assessment required by USP <797>, and we get a lot of questions about what's involved, how it's evaluated, and what causes a failure. This assessment is a critical part of ensuring compounding personnel are capable of maintaining the sterility of compounded sterile preparations (CSPs). However, its various components and requirements are often misunderstood.

What is the aseptic manipulation competency assessment?

Under USP <797>, personnel who compound sterile products must successfully complete an aseptic manipulation competency assessment prior to compounding independently and at least every three or six months (depending on the category compounded). The goal is to verify that individuals can consistently apply aseptic technique in a controlled environment to prevent microbial contamination. This assessment consists of four main components:

1. Observational Competency

This is a direct observation of the compounder's aseptic technique during the preparation of a simulated sterile compound. An evaluator typically uses a checklist to verify adherence to proper aseptic practices, including:

- Maintaining first air (not blocking airflow from the HEPA filter)
- Proper cleaning and disinfection of work surfaces and supplies
- Correct handling of vials, syringes, and needles
- Avoiding touch contamination of critical sites

Importantly, USP <797> requires documentation of this observational assessment by a qualified individual. While something like coring (when a piece of the vial stopper is punched into the vial) does not automatically fail the media-fill test, it can result in a failure of the observational assessment if it reflects poor technique or a risk to preparation sterility.

2. Media-Fill Test (MFT)

The media-fill test is designed to simulate the most challenging aseptic manipulations that a compounder might perform, using sterile tryptic soy broth (TSB) in place of drugs. Personnel must simulate a full compounding process using aseptic technique.

USP <797> requires that the media-fill procedure be representative of the most complex compounding the individual performs and that it must be performed under conditions that reflect actual compounding practice (i.e., same environment, number of people in the room, equipment, and garb).

The media-fill unit is incubated at two temperature ranges, 20–25 °C for 7 days and 30–35 °C for 7 days, for a total of at least 14 days. If any turbidity or other visual manifestations of growth are observed, the test is failed.

3. Gloved Fingertip and Thumb Testing (GFT)

As part of the aseptic manipulation competency, this test evaluates the compounder's ability to maintain the cleanliness of sterile gloves during sterile compounding. At the completion of the media-fill test, the individual rolls gloved fingertips onto a tryptic soy agar (TSA) with lecithin and polysorbate 80 plate. One plate is used per hand. Gloves must be disposed of after sample collection.

The samples are incubated at 30–35 °C for at least 48 hours and at 20–25 °C for at least 5 days, counting and documenting the colonies recovered after each incubation.

4. Surface Sampling

Performed at the conclusion of the media-fill test, this sampling checks contamination of the work surface in the ISO Class 5 PEC. A TSA with

lecithin and polysorbate 80 plate is rolled over the surface where compounding occurred. After collecting, the surface must be wiped with an EPA-registered one-step disinfectant cleaner, followed by sterile 70% IPA.

The samples are incubated at 30–35 °C for at least 48 hours and at 20–25 °C for at least 5 days, counting and documenting the colonies recovered after each incubation.

What constitutes a failure?

A failure in any component requires remediation, retraining, and a repeat of the ENTIRE assessment. Here's what constitutes a failure:

- **Observational Competency Failure:**
  - Any deviation from proper aseptic technique (e.g., blocking first air, touching critical sites)
  - Unsafe or unsterile manipulation techniques
  - Coring or particulate (Remember, this is based on organizational policy.)
- **Media-Fill Test Failure:**
  - Turbidity or other visual manifestation of growth
  - Recovered growth is NOT required to be identified
- **Gloved Fingertip and Thumb Test Failure:**
  - Exceeding the USP-defined action levels of >3 CFU/both hands
  - Recovered growth is NOT required to be identified, even if the action level is exceeded
- **Surface Sampling Failure:**
  - Exceeding the USP-defined action levels of >3 CFU/plate
  - Recovered growth exceeding the action level MUST be identified to at least the genus level (Section 2.3 does not clearly state this. Instead, it tells you to follow Section 6.3, which indicates identification is required.)

Common Misunderstandings

One of the most frequent points of confusion is the difference between the aseptic manipulation assessment and the hand hygiene

and garbing competency. These are entirely separate assessments under USP <797> and are evaluated independently. The hand hygiene and garbing evaluation focuses on donning garb properly and good personal hygiene, whereas, the aseptic manipulation competency evaluates behavior inside the cleanroom while actively compounding.

Another common misconception involves coring. While it doesn't automatically fail the media-fill test, as the chapter states failure is due to microbial growth, coring may indicate improper needle insertion technique, which could result in a failure of the observational portion if it reflects a risk to CSP sterility.

Conclusion

The aseptic manipulation competency assessment is a cornerstone of sterile compounding practice, but it's not always straightforward. Because of the multiple components and specific pass/fail criteria, it's no surprise that we get a lot of questions about how to interpret and implement it.

Understanding each part of the assessment — and what USP <797> explicitly requires — is essential for maintaining compliance and protecting patient safety.

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If you are incubating your own aseptic manipulation samples, be sure your "lab" space is not carpeted. A spilled/broken contaminated media-fill container will be very hard to clean up.

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QUESTION of the MONTH

If the media-fill test is positive before day 14, can we remove it from the incubator and discard it?

Because the chapter states that you are to “incubate the final containers at 20°–25° and 30°–35° for a minimum of 7 days at each temperature,” removing them early could be a regulatory risk. Additionally, if you would choose to identify the recovered growth, some microorganisms take longer to grow than others. If you recovered a variety of microorganisms, you want to give them all the full time to grow out.

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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.