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CriticalPoint Pearls of Knowledge — November 2025

Deconstructing USP <797> Core Skill Expectations

Introduction

Demonstrating knowledge of core skills and maintaining documented competencies are essential elements of compliance, ensuring that compounding personnel consistently apply proper aseptic technique when preparing compounded sterile preparations (CSPs). Unfortunately, these requirements are often treated as a box-checking exercise to satisfy USP <797> and state board expectations. If you've found yourself slipping into that mindset since the implementation of the new chapter, you're not alone. However, CriticalPoint challenges you to move beyond compliance for compliance's sake and reconnect with the true intent behind these standards.

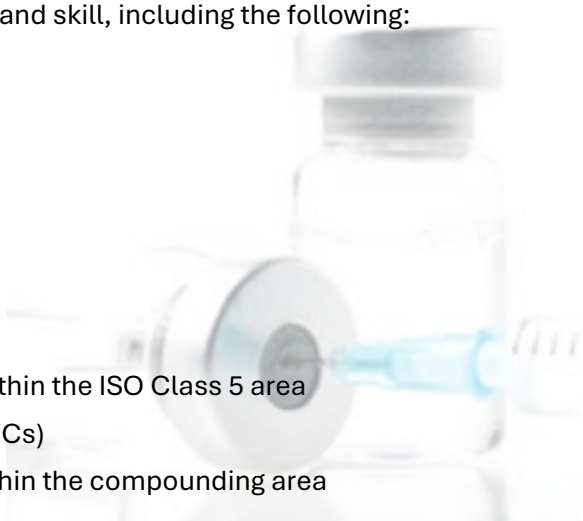
Staff competencies are routinely reviewed during inspections, and the documentation process often becomes a transactional exchange of "show me so I can cross this off the list." This month's Pearl of Knowledge focuses on redefining that process—helping you to identify initial and ongoing core competencies, understand the "why" behind observational evaluations, and adopt best practices that strengthen both compliance and quality.

Demonstrating knowledge and competency of core skills

USP <797> states that, before compounding CSPs independently or supervising others, personnel must complete training and demonstrate competency in sterile manipulation techniques and in maintaining appropriate environmental conditions for their assigned duties.

The chapter outlines several key principles of knowledge and skill, including the following:

- hand hygiene and garbing
- cleaning and disinfection
- calculations, measuring, and mixing
- aseptic technique
- achieving and maintaining sterility
- proper use of equipment
- documentation of the compounding process
- principles of HEPA-filtered unidirectional airflow within the ISO Class 5 area
- appropriate use of primary engineering controls (PECs)
- Principles of material and personnel movement within the compounding area



These competency topics serve as both a roadmap for role-based training and the essential foundation for safely preparing compounded medications for patient use. A designated person (DP) responsible for ensuring staff competency must establish and maintain a documented training program (ideally supported by a staff training matrix) that is completed initially for new hires and at least annually for all personnel appropriate for their assigned job functions, in accordance with USP <797>.

Is competency a worn-out word?

In today's pharmacy, "competency" has become a common compliance buzzword. However, it's essential to emphasize to compounding staff that competency goes beyond checking a box—it's about applying knowledge and skill in a way that directly impacts the state of microbial control in positive ways. Every action and behavior within the cleanroom influences environmental performance. Personal hygiene, proper garbing, and consistent aseptic technique as defined by pharmacy leadership are foundational to maintaining control and ensuring the quality of compounded preparations.

Competency and personnel sampling requirements

Demonstrating competency with garbing and hand hygiene as well as proper aseptic manipulations is part of <797> core skills. However, these specific "core skill" elements are also subject to evaluation from both visual assessment and performing personnel sampling. Unlike the general didactic studies of core skills training and testing evaluation, USP <797> Sections 2.2 and 2.3 require a minimum testing and evaluation frequency of every six months for Category 1 and 2 compounding and every three months for Category 3 compounding. This includes gloved fingertip and thumb sampling (GFT), media-fill testing (MFT), and post-compounding sampling on gloved fingertips and thumb, as well as the surfaces of designated direct compounding areas (DCAs).

Initial	6 Months (Category 1 & 2)
Garbing and Hand Hygiene • 3 consecutive times • visual observation • gloved fingertip and thumb	**Garbing and Hand Hygiene** • 1 time • visual observation • gloved fingertip and thumb
Aseptic Manipulation • media-fill replicates not specified • visual observation • gloved fingertip and thumb • surface sample on the DCA	**Aseptic Manipulation** • media-fill replicates not specified • visual observation • gloved fingertip and thumb • surface sample on the DCA

CriticalPoint recognizes the challenges pharmacies may face when managing these specific competency programs, especially hospital networks with a large compounding staff population. Consistency and how this task is performed are key. Spending time one-on-one with your compounding staff (media-fill tests are meant to be observed) is a great opportunity to build a relationship with your compounders. It allows you to invest in your compounding staff and impart critical aspects of patient safety awareness. This is a time to reinforce good technique or identify poor technique and bad habits, train accordingly, and reevaluate. Compounding staff are more likely to remember and utilize the skills learned during observed media-fill testing when leadership is invested in their success.

Consider that the process of performing a media fill affords additional opportunities to complete other required competencies during the media-fill test, especially for new staff. Think about all the aspects of sterile compounding that are needed to make the media-fill test happen. Material handling, hand hygiene and garbing, and aseptic technique and general conduct. Remember, USP <797> is a minimum-requirement standard. You may experience more success in your training and competency program by performing more frequent evaluations and personnel sampling depending on the type of CSPs and the methods used to prepare them.

Tips for evaluating staff performance

Depending on the organization's stage in developing a robust training program, initial observations and competency assessments may fall solely on the designated person. To alleviate this burden and build internal expertise, the DP should identify a senior technician or pharmacist who excels in sterile compounding and compliance. Look for an individual who is frequently scheduled in the compounding environment, thoroughly understands the facility's standard operating procedures (SOPs), and demonstrates interest in training and mentoring peers. Devote time and resources to train this person not only on how to oversee competencies but also on how to conduct respectful and effective retraining that results in lasting behavioral change. The goal is to invest in and empower your staff, enabling them to progressively take on the vital tasks of observation and competency evaluation.

When evaluating staff during competencies, consider the following.

Material Handling ✓ Observe the transfer of materials into secondary engineering controls (SECs) and primary engineering controls (PECs). Are they wiping items properly? Are they using the correct agent and observing appropriate dwell (contact) times?	**Hand Hygiene and Garbing** ✓ Observe the hand hygiene and garbing process. Are they using a nail pick? Washing for minimum 30 seconds? Gowning and gloving appropriately?
Cleaning and Disinfection ✓ Observe the daily, weekly, and monthly cleaning processes. Are they following the facility's SOPs? ✓ Are they using the correct cleaning agent? Do they know the different dwell times depending on the type of cleaning agent used? Do they know the correct cleaning frequency? Proper cleaning technique? Documenting appropriately?	**Aseptic Technique** ✓ Observe aseptic technique during and outside of media-fill testing. Are they blocking first air? Touching critical sites? Are they adjusting their masks and proceeding to compound without changing their gloves? Do they promote patient safety with proper area clearance in between CSPs?

Conducting observed competencies

Observation of competencies should be conducted randomly and unannounced! This strategy yields the most accurate demonstration of the routine behaviors and daily practices within your compounding environment, particularly for tenured staff who may otherwise change their procedures under scrutiny.

To implement this effectively, the designated person or a delegated trainer should

- **Create a schedule matrix**: Using specific USP <797> tasks (e.g., garbing, cleaning and disinfection, aseptic technique), develop a random number generator or a matrix that selects staff members, and implement observation times without following a patterned frequency. This helps to eliminate the testing bias, providing you with a realistic look at technique and behavior when you are not present.

- **Integrate observation into the routine**: The observer should have a role that naturally places them in the vicinity of the compounder's DCA. This reduces the appearance of a dedicated, high-stakes assessment, allowing staff to perform as they would on any given day.
- **Document immediately and objectively**: Following the observation, move quickly to a neutral area to document findings using a standardized checklist. The purpose of this checklist prevents the observer from relying on memory and ensures an objective record of the daily process.
- **Provide timely, constructive feedback**: While the observation is unannounced, the feedback session should be scheduled promptly and delivered respectfully. Focus on the observed process and SOP requirements, not personal failings.
- **Installation of cameras in the SEC**: Cameras are not a requirement but are an easy way to help randomly conduct competencies while compounding staff don't even realize they are being observed. Be sure the cameras cover all areas and corners of the SEC.
  - ✓ Cameras will add a level of performance for compounding staff, as they never know who will be observing them. They also add a level of quality to their work and behavior.
  - ✓ Another benefit of cameras in the compounding areas is that they provide evidence of what occurred when investigating an exceeded action level from an environmental monitoring session.

Handling media-fill testing or competency failures

In the event of media-fill testing (MFT) or competency failures, USP <797> requires a fundamental response: retrain and resample. We strongly encourage organizations to conduct a thorough investigation and base all retraining on the specific circumstances of the failure. This focused approach identifies explicit training needs, allowing for necessary and beneficial investment in improving staff competency and, ultimately, proficiency.

The depth of retraining must be proportional to the seriousness of the error.

- **Failure related to critical sites or blocked first air**: These fundamental aseptic technique errors demand a high level of intervention. Spend focused time with the compounder to correct the poor technique. Conduct simulated compounding with smoke studies to visualize how air behaves in the primary engineering control (PEC) and how incorrect hand positioning can block first air from accessing critical sites. Follow up with additional observed MFT or competencies as necessary to ensure proficiency.

- **Failure related to a specific garbing or hand hygiene issue**: These issues are often less complex than aseptic manipulation failures, and the retraining should be less time-consuming (e.g., a staff member not using a nail pick versus blocking first air). Review the specific garbing step to help the compounder understand why it is critical for contamination control. Revisit the issue over the next few days and have the compounder successfully repeat the garbing and hand hygiene competency.

Documentation and communication

It is crucial to document all observation findings, both positive and negative. Staff thrive on encouragement, and recognizing compliant behavior is the best way to sustain good work practices and boost morale. Regardless of the outcome of an observation, it is important to track compounding staff's progress and work techniques to follow their skill development over time. To ensure lasting improvement, the observational documentation should be given directly to the staff members. Since verbal feedback is easily forgotten, allowing them to keep a log of their progress enables them to look back at the information, affirm their areas of strength, and deliberately address deficiencies. Finally, be sure to establish a robust system to manage and track all staff members' competencies and test results, a process that must be clearly described in your standard operating procedures (SOPs).

Summary

Make it a priority to elevate chapter required competencies from a transactional "box-checking" exercise to a foundational, patient-safety-driven program. Establish clearly with your staff that demonstrating expertise in core skills—such as hand hygiene, garbing, and aseptic technique is essential not only for the organization's compliance but, more importantly, for patient safety. Ultimately, success relies on thorough documentation and empowering staff by granting them access to their progress logs, thereby ensuring continuous skill development and adherence to SOPs.

References

United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding—Sterile Preparations. 2024.