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the pure observer

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Training and Competency Elements for the Designated Person

One of the greatest things about the latest version of USP <797> is that it gives the sterile compounding organization control over its training and competency program. From frequency (for certain individuals) to content, the training and competency program can be tailored to the organization's unique needs. Clear documentation of the program and detailed training and competency records are to prove compliance with the chapter and internal procedures.

For the designated person, the training and competency expectations are no different from other staff. Fortunately for us, the chapter provides designated person responsibilities, constructing a framework for what the designated person training should include.

The following table can be used as a guide to ensure the organization accounts for all designated person(s) responsibilities and training considerations.

Section 1.1.3 Personnel and settings affected
The compounding facility must designate one or more individuals (i.e., the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions as described in this chapter.
Training and Competency Elements
• Oversight and management of personnel • Cleanroom operations and workflow • Facility design and maintenance

Section 2. Personnel training and evaluation

Designated person(s) is responsible for creating and implementing a training program for personnel and for ensuring that compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties are initially trained and qualified by demonstrating knowledge and competency in maintaining the quality of the sterile compounding environment before being allowed to perform their job functions independently.

Training and observation may be performed by the designated person(s) or an assigned trainer.

Training and Competency Elements

- Drafting a training program specific to the facility needs
- Working with adult learners
- Training staff and administering competency assessments

Section 3. Personal hygiene and garbing

Individuals that may have a higher risk of contaminating the CSP and the environment (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections) must report these conditions to the designated person(s).

The designated person(s) is responsible for evaluating whether these individuals should be excluded from working in compounding areas before their conditions have resolved because of the risk of contaminating the CSPs and the environment.

Training and Competency Considerations

- Knowledge of cleanroom contamination risks
- Ability to determine whether staff or visitors may enter the sterile compounding area

Section 3.1 Personnel preparation

The designated person(s) may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected. Accommodations must be documented.

Training and Competency Considerations

- Knowledge of cleanroom contamination risks related to garbing and personal hygiene
- Ability to determine if an accommodation is appropriate
- Understanding of facility's SOP on documenting accommodations

Section 4.2 Facility design and environmental controls

The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities to be conducted in that area.

The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality.

Training and Competency Considerations

- Cleanroom ISO classification, design, and function
- PEC placement and function

Section 4.5 Placement and movement of materials

Materials necessary for performing compounding activities that have been exposed in patient care and treatment areas must not enter anterooms, buffer rooms, or segregated compounding areas unless thoroughly cleaned and disinfected. The designated person(s) is responsible for addressing other areas of risk in the facility's SOPs.

The designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected. Accommodations must be documented.

Training and Competency Considerations

- Cleanroom contamination control risks associated with material transfer
- Ability to determine if an accommodation is appropriate
- Understanding of facility's SOP on documenting accommodations

Section 5. Certification and recertification

All certification and recertification records must be reviewed by the designated person(s) to ensure that the classified environments meet the minimum requirements in this chapter.

Training and Competency Considerations

- Required cleanroom certification testing
- Ability to determine if testing was done appropriately and reported accurately

Section 9.3.1 Component selection

If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see Good Distribution Practices for Bulk Pharmaceutical Excipients <1197>).

Training and Competency Considerations

- Risks associated with components from a non-FDA-registered facility
- Testing of components for appropriateness before use

Section 10.2 Sterilization by filtration

The designated person(s) must ensure — from available published information, from supplier documentation, or through direct challenge (e.g., filtering the CSP) — that the filters 1) are chemically and physically compatible with all ingredients in the CSP (e.g., water miscible alcohols may damage filter integrity); 2) are chemically stable at the pressure and temperature conditions that will be used; and 3) have enough capacity to filter the required volumes.

Training and Competency Considerations

- Knowledge of filters and filtration

Section 17. SOPs

A designated person(s) must ensure that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function.

A designated person(s) must follow up to ensure that corrective actions are taken if problems, deviations, failures, or errors are identified. The corrective action must be documented.

All compounding personnel must be trained to report any problems, deviations, failures, or errors to the designated person(s).

SOPs must be reviewed initially and at least every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented.

Any changes or alterations to an SOP must be made only by a designated person(s) and must be documented.

Training and Competency Considerations

- Drafting, revising, reviewing, and maintaining SOPs
- Implementing a CAPA program

Section 18. Quality assurance and quality control

Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of:

1. Adherence to procedures
2. Prevention and detection of errors and other quality problems
3. Evaluation of complaints and adverse events
4. Appropriate investigations and corrective actions

Designated person(s) responsible for the QA program must have the training, experience, responsibility, and authority to perform these duties.

The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed.

Training and Competency Considerations

- Implementing and maintaining a quality management system (QMS)

Section 18.2 Complaint handling

A designated person(s) must review all complaints to determine whether the complaint indicates a potential quality problem with the CSP.

Training and Competency Considerations

- Reviewing complaints and handling them as defined in the (QMS)
- Investigating quality problems with CSPs

Section 19.1 Handling and storing CSPs

When it is known that a CSP has been exposed to temperatures either below or above the storage temperature limits for the CSP, a designated person(s) must determine (e.g., by consulting literature or analytical testing) whether the CSP is expected to retain its integrity or quality. If this cannot be determined, it must be discarded.

Training and Competency Considerations

- Evaluating CSP safety in the event of a storage temperature excursion

Section 21.1 Personnel qualifications for compounding allergenic extract prescription sets

A designated person(s) with training and expertise in allergen immunotherapy is responsible for ensuring that personnel who will be preparing allergenic extract prescription sets are trained, evaluated, and supervised.

Personnel who fail competency evaluations must successfully pass reevaluations in the deficient area(s) before they can resume compounding of allergenic extract prescription sets. The designated person(s) must identify the cause of failure and determine appropriate retraining requirements.

Training and Competency Considerations

- Understanding facility training and competency requirements
- Investigating staff assessment failures

Glossary

Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.

Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

best practice makes perfect.

Verify staff are wearing gloves during material transfer into the cleanroom suite or SCA. This new chapter requirement is meant to protect the staff member from the agent and to prevent recontamination of the wiped item.

Now Available

Colony Enumeration Proficiency Assessment

Pure Proficiency's Colony Enumeration Proficiency Assessment is a state-of-the-art proficiency test that provides an in-hand assessment without the use of live microbial samples. It gives you the third-party documentation you need to demonstrate proficiency in counting colonies.

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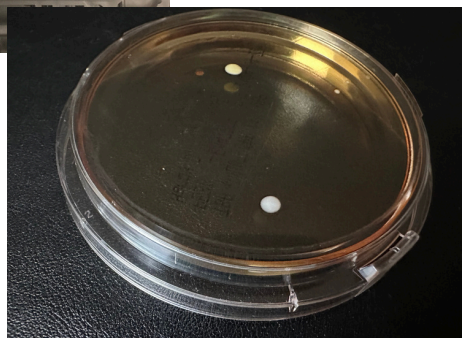

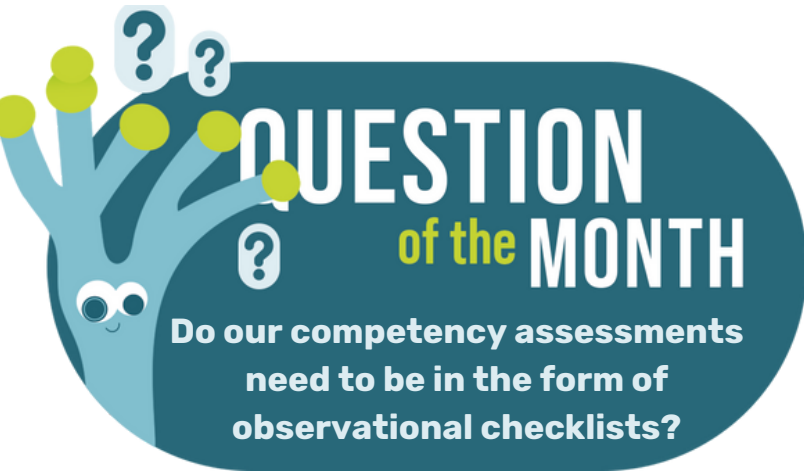

No. You certainly can use checklists, but that's not practical for all assessments. Essays, interviews, interactive group activities, and even tests can be structured in such a way to express an individual's ability to do something successfully or efficiently.

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Join us for a 3.5-day in-person training, including lectures and skill-building activities. Two and a half days are spent focusing on USP General Chapter <797> requirements, best practices, and implementation strategies, while one day emphasizes the importance of USP General Chapter <800>, exploring requirements and real-life solutions. This interactive training is appropriate for both pharmacists and technicians, especially those who hold a management or designated person role. Attendees will receive 25.5 hours of live ACPE CE.

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Kevin Hansen, PharmD, MS, BCSCP
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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.