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DESIGNATED PERSON(S) RESPONSIBILITIES

BACKGROUND

The USP compounding chapters (<795>, <797>, <800>, <825>) each require that a designated person(s) be assigned responsible and accountable for the oversight at each entity/facility. The designated person(s) must be qualified and trained to serve as the subject matter expert and be responsible for the content outlined below. The designated person(s) must be identified in a standard operating procedure (SOP).

DEFINITIONS

Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile preparations (CSPs) or compounded nonsterile preparations (CNSPs)

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

USP <795> NONSTERILE COMPOUNDING

- **Introduction and Scope**
  - The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs.
  - Responsibilities of the designated person(s) include but are not limited to: (1) overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs, (2) selecting components, (3) monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed, (4) ensuring that SOPs are fully implemented and the designated person(s) must ensure that follow-up is carried out if problems, deviations, or errors are identified, and (5) establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and components of CNSPs.
  - The designated person(s) must be identified in the facility's SOPs. If the compounding facility has only one person responsible for all compounding in the facility, then that person is the designated person.
- **Personnel Training and Evaluations**
  - Responsible for creating and implementing a training program that describes the required training, the frequency of training, and the process for evaluating the competency of personnel.
  - Training and observation may be performed by the designated person(s) or an assigned trainer. The personnel will then be expected to repeat the procedures independently while under the direct supervision of the designated person(s) or assigned trainer.
  - Upon completion of the training program, the designated person(s) or assigned trainer must document that personnel have been trained and successfully completed competency assessments.
  - The designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed.
- **Personal Hygiene and Garbing**
  - Individuals that may have a higher risk of contaminating the CNSP 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).

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  - 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 CNSPs and the environment.
  - The designated person(s) may permit accommodations provided that the quality of the environment and CNSP will not be affected. All accommodations should be documented.

- **Equipment and Components**
  - Designated person(s) must be responsible for selecting components to be used in compounding (e.g., active pharmaceutical ingredients).
- **Establishing Beyond-Use Dates (BUDs)**
  - The BUDs in *Table 4* are the BUD limits for CNSPs in the absence of specific stability information. This does not absolve the designated person(s) from performing due diligence to determine if there is existing stability data that would require a shorter BUD.
  - If the BUD of the CNSP is extended beyond the BUDs in *Table 4*, an aqueous CNSP must be tested for antimicrobial effectiveness (see Antimicrobial Effectiveness Testing <51>). The designated person(s) may rely on antimicrobial effectiveness testing that is conducted (or contracted for) once for each formulation in the particular container closure system — including materials of composition of the container closure system — in which it will be packaged. Alternatively, the designated person(s) may rely on antimicrobial effectiveness testing results provided by a Food and Drug Administration (FDA)-registered facility or published in peer-reviewed literature as long as the CNSP formulation (including any preservative) and container closure materials of composition are the same as those tested (unless a bracketing study is performed).
- **SOPs**
  - One or more person(s) must be designated to ensure that the facility's SOPs are fully implemented.
  - The designated person(s) must ensure that follow-up occurs if problems, deviations, or errors are identified.
- **Quality Assurance and Quality Control**
  - Designated person(s) must ensure that the facility has formal, written quality assurance (QA) and quality control (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, and (4) appropriate investigations and corrective actions. The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.
  - 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).
  - A designated person(s) must review all complaints to determine whether the complaint indicates a potential quality problem with the CNSP.

USP <797> STERILE COMPOUNDING

- **Introduction and Scope**
  - 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.
- **Personnel Training and Evaluation**
  - Designated person(s) are 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 disinfecting 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.
- **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.
- 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.

- **Facilities and Engineering 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.
  - The designated persons(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.
- **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.
- **Microbiological Air and Surface Monitoring**
  - The designated person(s) must develop and implement a microbiological air and surface monitoring plan.
  - Sampling procedures, sampling results, and any corrective actions must be documented. Sampling results must be reviewed regularly, and the review documented, to detect trends.
- **Equipment, Supplies, and Components**
  - 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>).
- **Sterilization and Depyrogenation**
  - 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 pressures and temperature conditions that will be used, and (3) have enough capacity to filter the required volumes.
- **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.
  - 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 the designated person(s) and must be documented.
  - Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgement of the communication.
- **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, and (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 persons(s). The results of the review must be documented, and appropriate action must be taken if needed. A designated person(s) must review all complaints to determine whether the complaint indicates a potential quality problem with the CSP. If it does, a thorough investigation into the cause of the problem must be initiated and completed.

- **CSP Handling, Storage, Packaging, Shipping, and Transport**
  - 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, the CSP must be discarded.
- **Compounding Allergenic Extracts**
  - 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 extra prescription sets. The designated person(s) must identify the cause of failure and determine appropriate training requirements.
- **Dynamic Operating Conditions**
  - This refers to 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 the highest complexity of compounding expected during routine operations as determined by the designated person(s).

USP <800> HAZARDOUS DRUGS

- **Responsibilities of Personnel Handling Hazardous Drugs**
  - Each entity must have a designated person who is qualified and trained to be responsible for: (1) developing and implementing appropriate procedures, (2) overseeing entity compliance with this chapter and other applicable laws, regulations, and standards, (3) ensuring competency of personnel, and (4) ensuring environmental control of the storage and compounding areas.
  - The designated person must thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of noncompliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team.
  - The designated person must also be responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results.
- **Environmental Quality and Control**
  - If any measurable contamination is found, the designated person must identify, document, and contain that cause of contamination.
- **Receiving**
  - Damaged packages or shipping cartons must be considered spills that must be reported to the designated person and managed according to the entity's SOPs.
- **Documentation and SOPs**
  - The SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented.

USP <825> RADIOPHARMACEUTICALS

- **Personnel Qualifications, Training, and Hygiene**
  - The designated person is responsible for evaluating whether individuals with certain conditions that may pose a higher potential of contaminating the product or environment should be excluded from working in sterile processing areas before their conditions are resolved.
  - Evaluation includes observation of person performing evaluation/qualification in aseptic technique, garbing/hand hygiene, primary engineering control (PEC) cleaning and disinfecting, gloved fingertip and thumb sampling, and media-fill testing.
- **Facilities and Engineering Controls**
  - The designated person is responsible for ensuring that each area related to sterile radiopharmaceutical processes meets the classified air quality standard appropriate for the activities to be conducted in that area. They must also ensure that the ISO Class 5 PEC are located, operated, maintained, monitored, and certified to have appropriate air quality.

- **Compounding**
  - The designated person is responsible for ensuring that the final preparation complies with the pre-established standards or acceptance criteria for identity, quality, and purity, and must consider all possible interactions between the components, such as altered chemical stability, radiopharmaceutical stability, solubility, or other parameters (e.g., osmolarity) related to changes in pH, excipients, or other factors, in determining an appropriate BUD. This may require testing to validate the appropriateness of a particular BUD.
- **Quality Assurance and Quality Control**
  - The designated person 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, and (4) appropriate investigations and corrective actions.
  - The overall QA and QC program must be reviewed at least every 12 months by the designated person. The results of the review must be documented, and appropriate corrective action taken, if needed.
  - The designated person must review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical. If a complaint is received, an investigation into the potential cause of the problem must be completed. The investigation must consider whether the quality problem could extend to other radiopharmaceuticals. Corrective action, if necessary, must be implemented for all potentially affected radiopharmaceuticals.

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Kevin and Patti are members of the USP Compounding Expert Committee, but this resource is not affiliated with or endorsed by USP.