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DESIGNATED PERSON(S) RESPONSIBILITY ASSIGNMENTS

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Designated Person(s) (DP): 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 CSPs and CNSPs.

RESPONSIBILITY	APPLIES TO	Director of Compounding	Regulatory Coordinator	Director of Medication Safety	Site Compounding Leader	Other?
PERSONNEL TRAINING AND EVALUATION						
Creating and implementing a training program	795/797					
Training and observation (DP or assigned trainer)	795/797/825					
Documentation/sign-off of competency (DP or assigned trainer)	795/797/825					
Monitor and observe compounding activities and take immediate corrective action if deficient practices identified	795/797					
PERSONAL HYGIENE AND GARBING						
Determine if certain personnel should be excluded from the working environment due to risks of contaminating the compound or environment	795/797/825					
Determine if accommodations are necessary provided the quality of the product and environment will not be affected. Document accommodations.	795/797					
FACILITIES AND ENGINEERING CONTROLS						
Ensure each area related to CSP preparation meets classified air quality standard appropriate for activities conducted in that area	797/825					
Ensure the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality.	797/825					
Determine if accommodations are necessary provided the quality of the product and environment will not be affected. Document accommodations.	797					
CERTIFICATION AND RECERTIFICATION						
All certification and recertification records must be reviewed to ensure the classified environments meet the minimum requirements	797					
EQUIPMENT, SUPPLIES, AND COMPONENTS						
Responsible for selecting components to be used in compounding (e.g., API's)	795/797					
Sterilization and Depyrogenation	797					
Ensure that filters are chemically compatible with all ingredients, chemically stable at pressures and temperatures used, have sufficient capacity to filter the required volumes.	797					

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SOPS						
Ensure SOPs are appropriate and are fully implemented	795/797					
Ensure that follow-up occurs if problems, deviations, failures, or errors are identified	795/797					
Corrective actions documented	795/797					
Review SOPs at least every 12 months to ensure they reflect current practices (review must be documented)	797/800					
Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgement of the communication	797					
CSP Handling, Storage, Packaging, Shipping, and Transport	797					
Determine whether a CSP is expected to retain its integrity or quality during temperature excursions.	797					
COMPOUNDING ALLERGENIC EXTRACTS						
Ensure that personnel who will be preparing allergenic extract prescription sets are trained, evaluated, and supervised.	797					
Identify the cause of failure and determine appropriate training requirements when personnel fail competency evaluations	797					
Establishing Beyond-Use Dates (BUDs)	795/797					
Perform due diligence to determine if existing stability data require a shorter BUD (in absence of specific stability information)	795					
For extended BUDs, evaluate antimicrobial effectiveness testing (USP <51>) once per formulation and container closure system	795					
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	825					
QUALITY ASSURANCE AND QUALITY CONTROL						
Ensure facility has formal written QA and QC programs	795/797/825					
DP responsible for QA program must have the training, experience, responsibility, and authority to perform these duties.	795/797					
QA/QC program reviewed at least every 12 months	795/797/825					
Review all complaints to determine whether the complaint indicates a potential quality problem with the CNSP	795/825					

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DYNAMIC OPERATING CONDITIONS						
Determine the largest number of personnel and the highest complexity of compounding expected during routine operations	797					
RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS						
Responsible for developing and implementing appropriate procedures	800					
Overseeing entity compliance with the chapter and applicable laws, regulations, and standards	800					
Ensure environmental control of the storage and compounding areas	800					
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	800					
Responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results	800					
ENVIRONMENTAL QUALITY AND CONTROL						
If any measurable contamination is found, the DP must identify, document, and contain that cause of contamination	800					
RECEIVING						
Responsible for managing damaged packages or shipping cartons (considered spills) and managed according to SOPs	800					

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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.