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USP <795>

LIST OF STANDARD OPERATING PROCEDURES

Standard operating procedures (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 designed 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.

Total SOPs required: 20

INTRODUCTION AND SCOPE (2)

- **Practices Not Subject to the Requirements in This Chapter**
  - The following practices are not considered compounding and are not required to meet the requirements of this chapter. Handling of nonsterile HDs should additionally comply with USP Chapter <800>. Refer to facility SOPs for additional safe practices (e.g., labeling).
    - Nonsterile radiopharmaceuticals
    - Reconstitution
    - Repackaging
    - Splitting tablets
    - Administration
- **Oversight by Designated Person(s)**
  - The designated person(s) must be identified in the facility's SOPs.

PERSONNEL TRAINING AND EVALUATION (2)

- **Personnel Training and Evaluation**
  - Other personnel, who do not compound and only perform functions such as in process checks, final verification, or dispensing of compounded nonsterile preparations (CNSPs), must undergo training as required by the facility's SOPs.
  - In addition to the initial and annual competency training and evaluation described in this section, the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel.

PERSONAL HYGIENE AND GARBING (2)

- **Garb and Glove Requirements**
  - Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs.
  - The facility's SOPs must describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment.

BUILDINGS AND FACILITIES (2)

- **Compounding Area**
  - » An area must be designated for nonsterile compounding. The method of designation must be described in the facility's SOPs.
  - » The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s).

EQUIPMENT AND COMPONENTS (4)

- **Equipment**
  - » Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients, added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented.
- **Components**
  - » The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP.
- **Component Receipt**
  - » The following information must be documented (see 14. Documentation) according to the facility's SOPs: receipt date, quantity received, supplier name, lot number, expiration date, and results of any in-house or third-party testing performed.
- **Component Spill and Disposal**
  - » The management and documentation of nonhazardous components spills and disposal must be described in the facility's SOPs.

MASTER FORMULATION AND COMPOUNDING RECORDS (1)

- **Creating Master Formulation Records**
  - » Any changes or alterations to the master formulation records must be approved and documented according to the facility's SOPs.

LABELING (1)

- **Labeling**
  - » Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups.

QUALITY ASSURANCE AND QUALITY CONTROL (4)

- **Quality Assurance and Quality Control**
  - » A facility's quality assurance (QA) and quality control (QC) programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction.
  - » The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.
- **Complaint Handling**
  - » Compounding facilities must develop and implement SOPs for handling complaints.
- **Adverse Event Reporting**
  - » Adverse events potentially associated with the quality of CNSPs must be reported in accordance with the facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction.

CNSP PACKAGING AND TRANSPORTING (2)

- **Packaging of CNSPs**
  - The facility's SOPs must describe packaging of CNSPs.
- **Transporting of CNSPs**
  - If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed.

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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.