

## USP 795 Requirements – The Musts

Pharmacy must have a Designated Person (DP) who is responsible and accountable for the performance and operation of the facility and personnel.

All personnel must be trained and demonstrate proficiency in the following core competencies:

- Handy hygiene
- Garbing
- Cleaning & Sanitizing
- Component selection, handling, and transport
- Performing calculations
- Measuring and mixing
- Proper use of equipment and devices selected to compound CNSPs
- Documentation of the compounding process (Master Formulation Records and Compounding Records)

All personnel must undergo annual refresher training to demonstrate competency.

The DP is responsible for implementing the training program and evaluating competency.

Training must be documented and retained.

All personnel must:

- Remove personal outer garments
- Remove all hand, wrist, and other exposed jewelry or piercing that can interfere with the effectiveness of the garb or hand hygiene
- Remove headphones and earphones

Hands must be washed for at least 30 seconds and dried thoroughly before donning gloves.

Gloves must be worn for each CNSP and inspected for punctures tears or holes and replaced if necessary.

A designated compounding area is required.

A source of hot and cold water and an easily accessible sink must be available.

All components, equipment, and containers must be stored off the floor.

Storage area temperature must be monitored daily, and results must be logged and retrievable.

All surfaces must be cleaned and sanitized. This must be documented.

If a closed system measuring device is required, BSCs and CVEs must be certified every 12 months or/and directed by the manufacturer and all applicable laws and regulations.

Active Pharmaceutical Ingredients (APIs) must comply with the USP-NF Monograph if there is one and must be sourced from an FDA registered facility.

Master Formulation record must include at least the following:

- Name, strength or activity, and dosage form of the CNSP
- Identities and amounts of all components; if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility)
- Container closure system(s)
- Complete instructions for preparing the CNSP including equipment, supplies, and description of compounding steps
- Physical description of the final CNSP
- Beyond-use date (BUD) and storage requirements
- Reference source to support the assigned BUD
- If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s)
- Labeling requirements (e.g., shake well)
- Quality control (QC) procedures (e.g., pH testing, visual inspection) and expected results
- Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)

A Compounding Record must be created for all CNSPs.

- Be reviewed for completeness before the CNSP is release
- Name or other unique identifier of person completing the review and date of the review
- Permit traceability of all components in case of a recall or quality issue

A CR must include at least the following:

- Name, strength or activity, and dosage form of the CNSP
- Date—or date and time—of preparation of the CNSP
- Assigned internal identification number (e.g., prescription, order, or lot number)
- A method to identify the individuals involved in the compounding process and individuals verifying the final CNSP
- Name, vendor or manufacturer, lot number, and expiration date of each component
- Weight or measurement of each component
- Total quantity of the CNSP compounded
- Assigned beyond-use date (BUD) and storage requirements
- If applicable, calculations to determine and verify quantities and/or concentrations of components activity of the API(s)
- Physical description of the final CNSP
- Results of quality control procedures (e.g., pH testing and visual inspection)
- MFR reference for the CNSP

Label must contain:

- Assigned internal identification number (e.g., prescription, barcode or lot number)
- Chemical and/or generic name(s), or active ingredient(s), and amounts or concentrations
- Dosage form
- Total amount or volume
- Storage conditions
- BUD, the date, or the hour beyond which the preparation cannot be used and must be discarded.

Labeling on the CNSP should display:

- Route of administration
- Indication that the preparation is compounded
- Any special handling instructions
- Any warning statements that are applicable
- Name and contact information of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded

Facilities must develop SOPs on all aspects of the compounding operation and all personnel must be trained on the facility's SOPs.

Must have a formal, written QA and QC program and that program must be reviewed at least once every 12 months by the designated person.

Results of review must be documented, and action taken as necessary.

Must have a Recall SOP and procedures in place.

Must have a Complaint SOP and procedures in place, for handling complaints and adverse event reports.

Documentation: Must have and maintain written or electronic documentation to demonstrate compliance with chapter.

Documentation must include, but is not limited to, the following:

- Personnel training, competency assessment, and qualification records including corrective actions for any failures
- Equipment records (e.g., calibration, verification, and maintenance reports)
- Receipt of components
- SOPs, Master Formulation Records, and Compounding Records
- Release testing, including corrective actions for any failures
- Results of investigations and corrective actions
- Records of cleaning and sanitizing the designated area
- Temperature logs
- Accommodations to personnel compounding CNSPs
- Information related to complaints and adverse events including corrective actions taken
- Any required routine review (e.g., yearly review of QA/Q, yearly review of chemical hazard and disposal information)

All required Compounding Records must be readily retrievable for at least 2 years after preparation or as required by applicable regulatory bodies.

## USP 795 Requirements – The Shoulds

Gloves should be wiped or replaced before beginning a CNSP with different components.

Garb should be worn as needed to protect personnel or prevent contamination:

- Gown may be reused for one shift if not soiled and if it is retained in the compounding area.
- Gloves, shoe covers, hair covers, facial hair covers, face masks or heard coverings must be replaced with new ones after each use.

Designated compounding area should not be carpeted.

All components other than the APIs should have a COA which verifies it meets the USP-NF monograph and any additional specifications.

All components other than the APIs should be manufactured by an FDA registered facility.

Should use purified water, distilled water or RO water to rinse equipment and utensils.