USP 800 Gap Analysis

Date:_____

☐ **USP <800> 1. SCOPE:** Entity must incorporate into occupational safety plan the following:

- ☐ A list of Hazardous Drugs (HDs)
- ☐ Facility and engineering controls
- ☐ Competent and trained personnel
- ☐ Detailed safe work practices
- ☐ Proper use of Personal Protective Equipment (PPE)
- ☐ Policies for HD waste segregation and disposal

☐ **USP <800> 2. LIST OF HAZARDOUS DRUGS:** Maintain list of antineoplastics and HDs used in healthcare as defined by National Institute for Occupational Safety and Health (NIOSH)

- ☐ HD List is reviewed every 12 months
- ☐ New agent(s) added to formulary is reviewed against NIOSH List
- ☐ Assessment of risk performed and documented every 12 months, must, at a minimum, consider the following:
  - ☐ Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
  - ☐ Risk of exposure
  - ☐ Manipulation
  - ☐ Dosage form
  - ☐ Packaging

☐ **USP <800> 3. TYPES OF EXPOSURE:** Assessment of potential opportunities of exposure based on activity

Activity	Potential Opportunity of Exposure
☐ Receipt	• Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces, or floors
☐ Dispensing	• Counting or repackaging tablets and capsules
☐ Compounding & other manipulations	• Crushing or splitting tablets or opening capsules • Pouring oral or topical liquids from one container to another • Weighing or mixing components • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting HD residue present on PPE or other garments • Deactivating, decontaminating, cleaning, & disinfecting areas contaminated with or suspected to be contaminated with HDs • Maintenance activities for potentially contaminated equipment and devices
☐ Administration	• Generating aerosols during administration of HDs by various routes (e.g., injection, irrigation, oral, inhalation, or topical application) • Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation) • Priming an IV administration set
☐ Patient-care activities	• Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials
☐ Spills	• Spill generation, management, and disposal
☐ Transport	• Moving HDs within a healthcare setting
☐ Waste	• Collection and disposal of hazardous waste and trace contaminated waste

☐ **USP <800> 4. RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS**:

- ☐ Designated person (DP) qualified/trained in developing Policy & Procedures, compliance, laws, & staff competency
- ☐ DP ensures environmental control of storage & compounding areas, risk prevention and reports risks to management
- ☐ DP responsible for oversight of monitoring facility, maintaining reports of testing/sampling performed, & acting on results
- ☐ All personnel understand practices and precautions of handling HDs to prevent patient harm, & minimize exposure and contamination of the work and patient-care environment; Documented review every 12 months

- ☐ **USP <800> 5. FACILITIES AND ENGINEERING CONTROLS:** HDs must be handled under conditions that promote patient safety, worker safety, and environmental protection
  - ☐ Signs designating the hazard prominently displayed before the entrance to the HD handling areas
  - ☐ Access to areas where HDs are handled restricted to authorized personnel to protect persons not involved in HD handling
  - ☐ HD handling areas located away from breakrooms and refreshment areas for personnel, patients, or visitors
  - ☐ Uninterrupted power sources (UPS) for ventilation systems of negative pressure compounding and storage areas
  - ☐ **USP <800> 5.1 Receipt:** Antineoplastic & all HD APIs must be unpacked (i.e., removal from external shipping containers) in a demarcated area that is neutral/normal or negative pressure relative to the surrounding areas
  - ☐ **USP <800> 5.2 Storage:** HDs must be stored in a manner that prevents spillage or breakage if the container falls. HDs are not stored on the floor
    - ☐ Antineoplastic HDs requiring manipulation and any HD API must be stored separately from non-HDs
    - ☐ HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH)
    - ☐ Written policy that states: Non-antineoplastic, reproductive risk only, & final dosage forms of antineoplastic HDs may be stored with other inventory
    - ☐ Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding
    - ☐ Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH; an exhaust located adjacent to refrigerator's compressor & behind the refrigerator should be considered
  - ☐ **USP <800> 5.3 Compounding:** Sterile and nonsterile HDs must be compounded within a Containment-Primary Engineering Control (C-PEC) located in a Containment- Secondary Engineering Control (C-SEC).
    The C-SEC must:
    - ☐ • Be externally vented
    - ☐ • Be physically separated (i.e., a different room from other preparation areas)
    - ☐ • Have an appropriate air exchange (e.g., 12 ACPH or 30 ACPH)
    - ☐ • Have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas

    The C-PEC:
    - ☐ C-PEC operates continuously if supplies some or all negative pressure in C-SEC or if used for sterile compounding
    - ☐ All activities occurring in CPEC suspended immediately if any loss of power or if repair/moving of C-PEC occurs
    - ☐ Once C-PEC can be powered on, decontaminate, clean, and disinfect (if used for sterile compounding) all surfaces and wait the manufacturer-specified recovery time before resuming compounding. Documented in SOPs
    - ☐ A sink available for hand washing. An eyewash station readily available.
    - ☐ Water sources and drains must be located at least 1 meter away from the C-PEC
    - ☐ If compound both nonsterile and sterile HDs, the respective C-PECs must be placed in separate rooms UNLESS: C-PECs used for nonsterile compounding sufficiently effective that room can maintain ISO 7 classification
      - ☐ If C-PECs used for sterile and nonsterile compounding are placed in same room, they must be placed at least 1 meter apart & particle-generating activity must not be performed when sterile compounding

- ☐ **USP <800> 5.3.1 NONSTERILE COMPOUNDING:** Nonsterile compounding must also follow standards in USP <795>
  - ☐ C-PEC not required if manipulations limited to handling of final dosage forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses
  - ☐ C-PECs used for nonsterile HDs must be externally vented (preferred) or have redundant–HEPA filters in series
  - ☐ Nonsterile HD compounding must be performed in a C-PEC:
    - ☐ Class I Biological Safety Cabinet (BSC)
    - ☐ Class II BSC or a compounding aseptic containment isolator (CACI)
    - ☐ Containment Ventilated Enclosure (CVE)
  - ☐ C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used for occasional nonsterile HD compounding but must be decontaminated, cleaned, and disinfected before resuming sterile compounding
  - ☐ Surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding
  - ☐ C-SEC is externally vented, 12 ACPH, & negative pressure between 0.01 and 0.03 inches of water column
- ☐ **USP <800> 5.3.2 STERILE COMPOUNDING:** Sterile compounding must also follow standards in USP <797>
  - ☐ C-PEC is externally vented
  - ☐ C-PEC provides an ISO Class 5 or better air quality, such as a Class II or III BSC or CACI. Class II BSC types A2, B1, or B2
  - ☐ C-PEC located in a C-SEC, which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified containment segregated compounding area (C-SCA).
    - ☐ ISO Class 7 buffer room with an ISO Class 7 ante-room:
      - ☐ Fixed walls and HEPA-filtered supply air
      - ☐ Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas
      - ☐ Minimum of 30 ACPH
    - ☐ Buffer room
      - ☐ Externally vented
      - ☐ Minimum of 30 ACPH of HEPA-filtered supply air
      - ☐ Maintain positive pressure of 0.02 inches of water column relative to adjacent unclassified areas
      - ☐ Maintain an air quality of ISO Class 7 or better
    - ☐ ISO Class 7 ante-room
      - ☐ Fixed walls
      - ☐ Hand-washing sink at least 1 meter from the entrance to the HD buffer room
    - ☐ If the negative-pressure HD buffer room is entered though the positivepressure non-HD buffer room:
      - ☐ A line of demarcation defining the negative-pressure buffer room for donning and doffing PPE
      - ☐ A method to transport HDs, HD CSPs, & HD waste into & out of the negative pressure buffer room
      - ☐ A pass-through chamber between the negativepressure buffer area and adjacent space is acceptable, if certified non-contaminating. Refrigerators passthrough must not be used.
    - ☐ C-SCA
      - ☐ Fixed walls
      - ☐ Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas
      - ☐ Minimum of 12 ACPH
      - ☐ Externally vented
      - ☐ Hand-washing sink must be placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA
    - ☐ Beyond Use Dating (BUD) follows USP <797> categories and definitions. Documented in SOPs

☐ **USP <800> 5.4 Containment Supplemental Engineering Controls:** May offer an additional level of protection during compounding or administration

- ☐ Closed-System Transfer Device (CSTD) must not be used as a substitute for a C-PEC when compounding
- ☐ CSTDs should be used when compounding HDs when the dosage form allows
- ☐ CSTDs must be used when administering antineoplastic HDs when the dosage form allows
- ☐ CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD

☐ **USP <800> 6. ENVIRONMENTAL QUALITY AND CONTROL:** Environmental wipe sampling for HD surface residue should be performed routinely (e.g., initially as a benchmark and at least every 6 months, or more often as needed, to verify containment). Surface wipe sampling should include:

- ☐ Interior of the C-PEC and equipment contained in it
- ☐ Pass-through chambers
- ☐ Surfaces in staging or work areas near the C-PEC
- ☐ Areas adjacent to C-PECs (e.g., floors directly under C-PEC, staging, and dispensing area)
- ☐ Areas immediately outside the HD buffer room or the C-SCA
- ☐ Patient administration areas
- ☐ If measurable contamination found, the DP must identify, document, and contain the cause of contamination
  DP actions include:
  - ☐ Re-evaluating work practices
  - ☐ Re-training personnel
  - ☐ Perform thorough deactivation, decontamination, cleaning
  - ☐ Corrective action to improve engineering controls
- ☐ Repeat the wipe sampling to validate that the deactivation/decontamination and cleaning steps have been effective

☐ **USP <800> 7. PERSONAL PROTECTIVE EQUIPMENT (PPE):** Reduce exposure to HD aerosols & residues
Additional PPE may be required to handle the HDs outside of a C-PEC, such as treating a patient or cleaning a spill

- ☐ SOPs developed for PPE based on the risk of exposure and activities performed
- ☐ Disposable PPE must not be re-used
- ☐ Reusable PPE must be decontaminated and cleaned after use
- ☐ Gowns, head, hair, shoe covers, & two pairs of chemotherapy gloves are required for compounding sterile & nonsterile HDs
- ☐ Two pairs of chemotherapy gloves are required for administering injectable antineoplastic HDs
- ☐ Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs
- ☐ Appropriate PPE must be worn when handling HDs including during:
  - ☐ Receipt
  - ☐ Storage
  - ☐ Transport
  - ☐ Compounding (sterile & nonsterile)
  - ☐ Administration
  - ☐ Deactivation/decontamination, cleaning, and disinfecting
  - ☐ Spill control
  - ☐ Waste disposal
- ☐ **USP <800> 7.1 Gloves:**
  - ☐ Meets American Society for Testing and Materials (ASTM) standard D6978 (or its successor)
  - ☐ Worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs
  - ☐ Chemotherapy gloves must be powder-free
  - ☐ Gloves must be inspected for physical defects before use
  - ☐ When used for sterile compounding, the outer chemotherapy gloves must be sterile
  - ☐ Chemotherapy gloves should be changed every 30 mins unless otherwise recommended by manuf documentation
  - ☐ Chemotherapy gloves must be changed when torn, punctured, or contaminated
  - ☐ Hands must be washed with soap and water after removing gloves

- ☐ **USP <800> 7.2 Gowns:**
  - ☐ Gowns must be disposable and shown to resist permeability by HDs
  - ☐ Gowns must be selected based on the HDs handled
  - ☐ Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit
  - ☐ Gowns must not have seams or closures that could allow HDs to pass through
  - ☐ Washing of non-disposable clothing contaminated with HD residue should only be done according to facility policy
  - ☐ Gowns must be changed per the manufacturer's information for permeation of the gown
  - ☐ If no permeation info available for the gowns used, change them every 2–3 hours or immediately after a spill or splash
  - ☐ Gowns worn in HD handling areas must not be worn to other areas
- ☐ **USP <800> 7.3 Head, Hair, Shoe, and Sleeve Covers**
  - ☐ Head and hair covers (including beard and moustache, if applicable), shoe covers, and sleeve covers are worn
  - ☐ A second pair of shoe covers must be donned before entering the HD C-SEC and doffed when exiting the HD C-SEC
  - ☐ Shoe covers worn in HD handling areas must not be worn to other areas
  - ☐ Disposable sleeve covers may be used to protect areas of the arm that may come in contact with HDs
- ☐ **USP <800> 7.4 Eye and Face Protection**
  - ☐ Eye/face protection worn when risk for spills/splashes of HDs or HD waste materials when working outside of a C-PEC
  - ☐ Goggles must be used when eye protection is needed
  - ☐ Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes
  - ☐ Eye glasses & face shields alone or safety glasses with side shields do not protect the eyes adequately from splashes
- ☐ **USP <800> 7.5 Respiratory Protection**
  - ☐ Personnel who unpack HDs not contained in plastic should wear an elastomeric half-mask with a multi-gas cartridge and P100-filter until assessment of the packaging integrity can be made
  - ☐ Full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) should be worn when there is a risk of respiratory exposure to HDs when:
    - ☐ Attending to HD spills larger than what can be contained with a spill kit
    - ☐ Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
    - ☐ There is a known or suspected airborne exposure to powders or vapors
  - ☐ N95 respirators offer no protection against gases and vapors and little protection against direct liquid splashes
  - ☐ Fit test the respirator and train workers to use respiratory protection. Follow all requirements in the OccupationalSafety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134)

☐ **USP <800> 8. HAZARD COMMUNICATION PROGRAM:** Establish policies and procedures that ensure worker safety during all aspects of HD handling. Must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS). Hazard communication program plan must include:

- ☐ A written plan that describes how the standard will be implemented
- ☐ All containers of HD/chemicals are labeled, tagged, or marked with identity of material and appropriate hazard warnings
- ☐ Entities must have an SDS for each hazardous chemical they use (29 CFR 1910.1200)
- ☐ SDSs for each HD/chemical used are readily accessible to personnel each work shift and when they are in their work areas
- ☐ Personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes
- ☐ Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

☐ **USP <800> 9. PERSONNEL TRAINING:** All personnel who handle HDs must be trained based on their job functions

All training and competency assessment must be documented. The training must include:

- ☐ Personnel must be trained prior to the intro of new HD or equipment & prior to a new/significant change in process or SOP
- ☐ Training must occur before the employee independently handles HDs
- ☐ Effectiveness of training for HD handling competencies must be demonstrated by each employee
- ☐ Personnel competency must be reassessed at least every 12 months
- ☐ Overview of entity's list of HDs and their risks
- ☐ Review of the entity's SOPs related to handling of HDs
- ☐ Proper use of PPE
- ☐ Proper use of equipment and devices (e.g., engineering controls)
- ☐ Response to known or suspected HD exposure
- ☐ Spill management
- ☐ Proper disposal of HDs and trace-contaminated materials

☐ **USP <800> 10. RECEIVING:** Entity must establish SOPs for receiving HDs

- ☐ HDs should be received from the supplier in impervious plastic segregated from other drugs
- ☐ PPE, including chemotherapy gloves, must be worn when unpacking HDs
- ☐ A spill kit must be accessible in the receiving area
- ☐ HDs must be delivered to the HD storage area immediately after unpacking
- ☐ Entity must enforce policies that include a tiered approach, starting with visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass)

Requirements for Receiving and Handling Damaged HD Shipping Containers
☐ If the shipping container appears damaged
☐ Seal container without opening and contact the supplier
☐ If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous"
☐ If the supplier declines return, dispose of as hazardous waste
☐ If a damaged shipping container must be opened
☐ Seal the container in plastic or an impervious container
☐ Transport it to a C-PEC (non-sterile preferred) and place on a plastic-backed preparation mat
☐ Open the package and remove undamaged items
☐ Wipe the outside of the undamaged items with a disposable wipe
☐ Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous"
☐ If the supplier declines return, dispose of as hazardous waste
☐ Deactivate, decontaminate, and clean the C-PEC
☐ Discard the mat and cleaning disposables as hazardous waste

- ☐ Damaged packages/shipping cartons must be considered spills; must be reported to DP & managed according to SOPs
- ☐ Segregate HDs waiting to be returned to the supplier in a designated negative pressure area
- ☐ Clean-up must comply with established SOPs

- ☐ **USP <800> 11. LABELING, PACKAGING, TRANSPORT AND DISPOSAL:** Entity must establish SOPs for the labeling, packaging, transport, and disposal of HDs. SOPs must address prevention of accidental exposures or spills, personnel training on response to exposure, and use of a spill kit
  - ☐ **USP <800> 11.1 Labeling**
    - ☐ HDs requiring special handling precautions must be clearly labeled at all times during transport
    - ☐ Staff must ensure compounded preps labeling processes do not introduce contamination into non-HD handling areas
  - ☐ **USP <800> 11.2 Packaging:** Entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport
    - ☐ Personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport
    - ☐ Packaging materials must protect the HD from damage, leakage, contamination, and degradation during transport
  - ☐ **USP <800> 11.3 Transport**
    - ☐ HDs must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations
    - ☐ HDs must be transported in containers that minimize the risk of breakage or leakage
    - ☐ When shipping HDs to locations outside the entity, the entity must consult the Transport Information on the SDS
    - ☐ Entity must ensure that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies
    - ☐ Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs
  - ☐ **USP <800> 11.4 Disposal**
    - ☐ All personnel who perform routine custodial waste removal and cleaning activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment to prevent HD contamination
    - ☐ Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations

- ☐ **USP <800> 12. DISPENSING FINAL DOSAGE FORMS**
  - ☐ Clean equipment should be dedicated for HDs (counting or repackaging) and should be decontaminated after every use
  - ☐ Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines

- ☐ **USP <800> 13. COMPOUNDING**
  - ☐ Entities and personnel involved in compounding HDs must be compliant with USP standards including <795> and <797>
  - ☐ A plastic-backed preparation mat should be placed on the work surface of the C-PEC when compounding HDs
  - ☐ Mat is changed immediately if spill occurs & regularly during use, & is discarded at the end of daily compounding activity
  - ☐ Disposable/clean equipment for compounding (i.e mortars and pestles, and spatulas) must be dedicated for use with HDs
  - ☐ APIs or other powdered HDs must be handled in a C-PEC, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder)

- ☐ **USP <800> 14. ADMINISTERING:** HDs must be administered safely using protective medical devices and techniques
  - ☐ Use protective medical devices which include needleless and closed systems
  - ☐ CSTDs must be used for administration of antineoplastic HDs when the dosage form allows
  - ☐ Use protective techniques include spiking/priming IV tubing with nonHD solution in C-PEC & crushing tabs in a plastic pouch
  - ☐ PPE must be worn when administering HDs. After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration
  - ☐ Equipment (i.e tubing and needles) and packaging materials must be disposed of properly, in HD waste containers
  - ☐ Healthcare personnel should avoid manipulating HDs such as crushing tablets or opening capsules if possible

- ☐ **USP <800> 15. DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING:** Entity must establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection. Cleaning of nonsterile compounding areas must comply with USP <795> and cleaning of sterile compounding areas must comply with USP <797>
  - ☐ Written procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements
  - ☐ All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD areas must be trained
  - ☐ Deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials
  - ☐ Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle
  - ☐ All disposable materials must be discarded to meet EPA regulations and the entity's policies
  - ☐ Perform cleaning in areas that are sufficiently ventilated
  - ☐ **USP <800> 15.1 Deactivation:** Render compound inert or inactive
    - ☐ EPA-registered oxidizing agents (peroxide formulations, sodium hypochlorite) should be used when possible
    - ☐ Residue from deactivation must be removed by decontaminating the surface
    - ☐ Sodium hypochlorite must be neutralized with sodium thiosulfate or by following with an agent to remove the sodium hypochlorite (e.g., sterile alcohol, sterile water, germicidal detergent, or sporicidal agent)
  - ☐ **USP <800> 15.2 Decontamination:** inactivating, neutralizing, physically removing HD residue from non-disposable surfaces
    - ☐ Check surface compatibility and facility requirements. It is imperative to adhere to manufacturer's use instructions
    - ☐ Document the effectiveness of any agent used for decontamination of HD residue from work surfaces
    - ☐ Solution used for wiping HD packaging must not alter the product label
    - ☐ Work surface of the C-PEC must be decontaminated between compounding of different HDs
    - ☐ C-PEC decontaminated at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved
    - ☐ C-PECs may have areas under the work tray where contamination can build up. These areas must be deactivated, decontaminated, and cleaned at least monthly. Respiratory protection is required.
  - ☐ **USP <800> 15.3 Cleaning:** Remove organic and inorganic material from objects and surfaces
    - ☐ Use water, germicidal detergents, surfactants, solvents, and/or other chemicals
    - ☐ Cleaning agents used on compounding equipment should not introduce microbial contamination
    - ☐ No cleaning step may be performed when compounding activities are occurring
  - ☐ **USP <800> 15.4 Disinfection:** process of inhibiting or destroying microorganisms
    - ☐ Surfaces must be cleaned before disinfection process
    - ☐ Disinfection must be done for areas intended to be sterile, including the sterile compounding areas
    - ☐ Use EPA-registered disinfectant and/or sterile alcohol
- ☐ **USP <800> 16. SPILL CONTROL:** SOPs must be developed to prevent spills and to direct the clean up of HD spills
  - ☐ All personnel who clean up a spill of HDs must receive proper training in spill mgt & use of PPE & NIOSH-certified respirators
  - ☐ Spills must be contained and cleaned immediately only by qualified personnel with appropriate PPE
  - ☐ Qualified personnel must be available at all times while HDs are being handled
  - ☐ Signs must be available for restricting access to the spill area
  - ☐ Spill kits containing all of the materials needed to clean HD spills must be readily available in all HD areas
  - ☐ The circumstances and management of spills must be documented
  - ☐ SOPs must address the size & scope of the spill & specify who is responsible for spill management & the type of PPE required
  - ☐ SOP must address the location of spill kits and clean-up materials as well as the capacity of the spill kit

☐ **USP <800> 17. DOCUMENTATION AND STANDARD OPERATING PROCEDURES:** Entity must maintain SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a facility

- ☐ SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented
- ☐ Personnel who transport, compound, or administer HDs must document training according to OSHA standards & other laws
- ☐ SOPs for handling of HDs should include:
  - ☐ Hazard communication program
  - ☐ Occupational safety program
  - ☐ Designation of HD areas
  - ☐ Receipt
  - ☐ Storage
  - ☐ Compounding
  - ☐ Dispensing
  - ☐ Transport
  - ☐ Disposal
  - ☐ Use/maintenance of proper engineering controls (eg. C-PECs, C-SECs, CSTDs)
  - ☐ Hand hygiene & use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal)
  - ☐ Deactivation, decontamination, cleaning, and disinfection
  - ☐ Administering
  - ☐ Environmental monitoring (e.g., wipe sampling)
  - ☐ Spill control
  - ☐ Medical surveillance

☐ **USP <800> 18. MEDICAL SURVEILLANCE:** Comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE.

- ☐ Healthcare workers who handle HDs as regular job assignment should be enrolled in a medical surveillance program
- ☐ Assessment and documentation of symptom complaints, physical findings, and laboratory values
- ☐ Medical surveillance program should be consistent with the entity's Human Resource policies and should include:
  - ☐ Development of organized approach to identify workers who are potentially exposed to HDs on basis of job duties
  - ☐ Use of an entity-based or contracted employee health service to perform the medical surveillance
  - ☐ Initial baseline assessment (pre-placement) of a worker's health status and medical history. Data elements collected:
    - ☐ Medical (including reproductive) history
    - ☐ Work history to assess exposure to HDs
    - ☐ Physical examination
    - ☐ Laboratory testing
    - ☐ Methods used to assess exposure history :
      - ☐ Records of HDs handled, with quantities and dosage forms
      - ☐ Estimated number of HDs handled per week
      - ☐ Estimates of hours spent handling HDs per week and/or per month
      - ☐ Baseline complete blood count
    - ☐ Medical records of surveillance maintained according to OSHA regs concerning access to emp exposure & MR
    - ☐ Monitoring workers' health prospectively through periodic surveillance using data elements collected
    - ☐ Monitoring of the data to identify prevention failure leading to health effects
    - ☐ Development of a follow-up plan for workers who have shown health changes due to exposure to HDs
    - ☐ Completion of an exit examination when a worker's employment at the entity ends

- ☐ **USP <800> 18.1 Follow-Up Plan:** Immediate re-evaluation of primary preventive measures
  - ☐ Entity should take the following actions:
    - ☐ Post-exposure examination tailored to the type of exposure.
    - ☐ Compare performance of controls with recommended standards; conduct environmental sampling
    - ☐ Verify and document that all engineering controls are in proper operating condition
    - ☐ Verify and document that the worker complied with existing HD and PPE policies
    - ☐ Develop and document a plan of action that will prevent additional exposure of workers
    - ☐ Ensure confidential communication between the worker and the employee health unit(s) regarding notification, discussions about a change in health condition, or detection of an adverse health effect
    - ☐ Provide and document a follow-up medical survey to demonstrate that the plan implemented is effective
    - ☐ Ensure that any exposed worker receives confidential notification of any adverse health effect. Offer alternative duty or temporary reassignment
    - ☐ Provide ongoing medical surveillance of all workers at risk for exposure to HDs to determine whether the plan implemented is effective