USP Chapter <800> Quick Assessment

With the USP Chapter <800> deadline quickly approaching, many institutions are assessing their facilities compliance readiness. Answer these sample of questions to determine your institution's current status. All questions are designed to be answered as "Yes" or "No." A "Yes" answer for any question requires that all elements of that question be answered "Yes."

1. Has your organization established a designated person(s) responsible for the hazardous drug (HD) program, and do/does s/he/they manage all of the following:
   a. Develop and implement HD policies and standard operating procedures (SOPs);
   b. Assess risk prevention at each step of the medication use process;
   c. Ensure compliance with facility requirements and configurations;
   d. Ensure appropriate oversight of the preparation of sterile and non-sterile HD products;
   e. Train and assess competency of personnel.

☐ YES
☐ NO

2. Does your organization maintain a list of all HDs, including all of the following:
   a. All formulary drugs on the current NIOSH list;
   b. All non-formulary drugs used in the organization that are on the current NIOSH list;
   c. Drugs introduced into the market after last published NIOSH list and that meet NIOSH criteria for HD; and,
   d. Drugs with insufficient information to determine hazardous properties are treated as HDs.

☐ YES
☐ NO

3. Is your HD list reviewed annually, and when any new drug or dosage form is added to the formulary?

☐ YES
☐ NO

4. In all areas where sterile HD manipulation occurs, are all water sources located outside of the ISO-7 buffer room or at least one meter away from a containment primary engineering control (C-PEC) if located within a containment segregated compounding area (C-SCA)?

☐ YES
☐ NO

5. Are all HDs unpacked from external shipping containers in a negative or neutral pressure room that is not used for sterile compounding?

☐ YES
☐ NO

6. Are all HDs that require further manipulation and are HD active pharmaceutical ingredient (HD API) stored separate from non-HD drugs:
   a. On storage shelves that are secured and equipped with features to prevent drugs from falling (e.g., raised shelf front lips in facilities located in earthquake-prone areas); and,
   b. In rooms with 12 air changes per hour, at negative pressure between 0.01 and 0.03 inches water column, that are externally vented; and,
   c. In HD refrigerators (if appropriate).

☐ YES
☐ NO

7. Are both of the following true regarding HD storage in your organization:
   a. No drugs, equipment, or containers are stored on the floor;
   b. HDs are stored on stable level shelving with additional precautions to prevent container breakage and spilling.

☐ YES
☐ NO

8. Are non-sterile HD compounded:
   a. In a C-PEC located in a separate negative-pressure C-SEC that is externally vented with at least 12 air changes per hour located in a room that is adequately vented; OR,
   b. In the same room as sterile HDs, where sterile and non-sterile C-PECs are separated by at least one meter, C-PECs are decontaminated, cleaned, and disinfected before resuming sterile compounding, and ISO 7 air quality is maintained throughout all compounding activity?

☐ YES
☐ NO

9. Is HD sterile compounding done using a containment primary engineering control (C-PEC) that:
   a. Is either a BSC or CACI; and,
   b. Provides ISO 5 air quality, with unidirectional flow, and is externally vented; and,
   c. Is in an ISO 7 C-SEC with an ISO 7 anteroom or in a containment segregated compounding area (C-SCA)?

☐ YES
☐ NO

10. If BUDs of 12 hours at room temperature or of 24 hours under refrigeration are assigned, is the buffer room for sterile compounding a separated hard-walled room with ISO 7 air quality via HEPA-filtered supply, externally vented, with 30 air changes per hour, and negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas?

☐ YES
☐ NO

11. If BUDs of 12 hours at room temperature or of 24 hours under refrigeration are assigned, does your sterile products area have a separated hard-walled anteroom with ISO 7 air quality via HEPA-filtered supply, with 30 air changes per hour, and positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas?

☐ YES
☐ NO

12. Do your organization's SOPs include required work practices, quality control, and documentation for all of the following HD handling procedures:
    a. Receiving and unpacking;
    b. Storing;
    c. Sterile compounding;
    d. Non-sterile compounding;
    e. Labeling, packing, transport, and disposal;
    f. Administration;
    g. Use of personal protective equipment (PPE);
    h. Disposal;
    i. Deactivating, decontaminating, cleaning, and disinfecting; and,
    j. Spill control and post-exposure requirements

☐ YES
☐ NO

13. Do your organization's general HD policies and procedures include all of the following:
    a. Designated individual's role and responsibilities;
    b. Responsibilities of staff handling HD;
    c. Reviewing, updating, and approving the HD list;
    d. Determination of HD drug and/or dosage form-specific work practices, if an assessment of risk was done;
    e. Review and documentation requirements for HD list and assessment of risk, if an assessment of risk was done;
    f. Risk assessment/mitigation plan for power outage, equipment failure or malfunction in all areas where HD are used or stored;
    g. Required certifications for equipment, clean room air quality, and other facility features

☐ YES
☐ NO

14. Are both of the following statements true regarding HDs prepared in your organization:
    a. Sterile and non-sterile HDs are compounded according to USP general chapters <797> and <795> and other applicable USP chapters.
    b. All HD compounding is done within a CPEC that is located within a containment secondary engineering control (C-SEC).

☐ YES
☐ NO

15. Are all HDs administered to patients in your organization given according to all of the following parameters:
    a. HDs are administered by personnel who use required PPE.
    b. Injectable HDs are administered using closed system transfer devices (CSTDs) when the dosage form allows.
    c. SOPs address the use of CSTDs.

☐ YES
☐ NO

16. Is PPE used by staff members during HD compounding removed and placed in a contaminated receptacle either inside the C-PEC or sealed in a plastic bag if to be discarded in a receptacle for trace-contaminated materials outside the C-PEC?

☐ YES
☐ NO

17. Is PPE, appropriate for each job role specified in SOPs, used by staff in all departments of the organization for all of the following HD functions:
    a. Receipt;
    b. Storage;
    c. Transport;
    d. Compounding;
    e. Administration;
    f. Deactivation/decontamination;
    g. Cleaning and disinfecting;
    h. Spill control;
    i. Waste disposal.

☐ YES
☐ NO

18. Are all appropriate processes used for deactivating, decontaminating, cleaning, and disinfecting your facilities?
    a. The entire compounding facility is cleaned daily or weekly
    b. Sterile area and non-sterile area cleaning processes and agents are specified
    c. Cleaning agents are appropriately selected and used
    d. Sanitization is done in the correct order
    e. Written SOPs for cleaning procedures, agents used, dilutions, frequency, and documentation requirements are followed without exception

☐ YES
☐ NO

19. Are staff assessed and determined to be competent to handle HDs prior to assuming job responsibilities and are they reassessed for competency at least every 12 months thereafter?

☐ YES
☐ NO

20. Does initial HD staff training for those who handle HDs include all of the following training elements:
    a. The list of HDs and their risks;
    b. SOPs for handling HDs;
    c. Use of PPE;
    d. Engineering controls, equipment, and devices;
    e. Response to exposure or potential exposure;
    f. Spill management;
    g. Disposal of HDs and related contaminated material;
    h. Staff members are trained on any new HD, new equipment, or significant change in policy or SOP prior to introduction into the organization
    i. All training and competency assessment is documented

☐ YES
☐ NO

If you answered "NO" to any of the above questions, your facility may not be fully compliant with NEW USP Chapter <800> requirements.

This is a small sample of the complete assessment that should be conducted to ensure full compliance by November 1, 2023. ASHP Consulting is ready to conduct a comprehensive gap analysis and assist with strategies for correction and implementation to help you reach full compliance with USP Chapter <800> requirements.

To learn how ASHP Consulting can assist your organization, contact consulting@ashp.org by email.

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