Facilities + Engineering Controls
Hazardous Drugs Readiness Checklist

HIPP DESIGN + CONSULTING

	Completed	In Progress	To Be Addressed	Responsible Individual
HDs must be handled under conditions that promote patient safety, worker safety and environmental protection	☐	☐	☐	
Signs designing the hazard must be prominently displayed before the entrance to the HD handling areas	☐	☐	☐	
Access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling	☐	☐	☐	
HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients or visitors to reduce exposure likelihood	☐	☐	☐	
Designated areas must be available for: - Receipt and unpacking - Storage of HDs - Nonsterile HD compounding – if performed in the entity - Sterile HD compounding – if performed in the entity	☐	☐	☐	
Negative pressure in certain areas is **required** to contain HDs and minimize risk of exposure	☐	☐	☐	
Receipt				
Antineoplastic HDs and all HD APIs must be unpacked in an area that is neutral / normal or negative pressure relative to its surroundings	☐	☐	☐	
HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas	☐	☐	☐	
Storage				
HDs must be stored in a manner that prevents spillage or breakage of containers if they fall	☐	☐	☐	
In areas with risk of natural disasters (e.g., earthquakes) the storage practice must meet applicable safety precautions (e.g., secured shelving and raised front lips shelving)	☐	☐	☐	
Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD APIs must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure	☐	☐	☐	
The above HDs and HD APIs must be stored in an externally ventilated, negative pressure room with at least 12 air exchanges per hour (ACPH)	☐	☐	☐	
Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 air changes per hour (ACPH) (e.g. containment segregated compounding area (C-SCA) or storage room)	☐	☐	☐	
Compounding				
Engineering controls are required to protect the preparation from cross-contamination and if sterile, microbial contamination. Engineering controls for containment are divided into three categories of engineering control: 1. Primary – The primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs 2. Secondary – The secondary engineering control (C-SEC) is the room in which the C-PEC is placed 3. Supplementary – An example of a supplementary engineering control is a closed-system drug transfer device				
Sterile and Nonsterile Compounding				
Sterile and nonsterile HDs **must** be compounded within the C-PEC located in the C-SEC. The C-SEC used for sterile and nonsterile compounding **must**:				
Be externally vented	☐	☐	☐	
Be physically separated (i.e., a different room from other preparation areas)	☐	☐	☐	
Have appropriate air exchange (e.g., ACPH)				
Have negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas	☐	☐	☐	
The C-PEC **must** operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding. If there is any power loss to the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC **must** be suspended immediately (If necessary, follow the manufacturer's recommendations for closure and restart)	☐	☐	☐	
A sink **must** be available for hand-washing	☐	☐	☐	
An eyewash station and/or emergency or safety precautions that meet applicable laws and regulations **must** be readily accessible	☐	☐	☐	
Water sources and drains **must** be located at least 1 meter (3.28084 feet) away from the C-PEC	☐	☐	☐	
Compounding sterile and nonsterile HDs:				
The respective C-PECs **must** be placed in separate rooms (unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity)	☐	☐	☐	
Sterile and nonsterile compounding are done in the same room - They must be at least 1 meter (3.28084 feet) apart and particle-generating activity must not be performed when sterile compounding is in process	☐	☐	☐	
Nonsterile Compounding				
In addition to the <800> chapter standards, nonsterile compounding **must** follow the standards in USP <795> Pharmaceutical Compounding – Nonsterile Preparations. Engineering controls C-PEC **are not required** if manipulations are limited to handling of final dosage forms (e.g., counting or repackaging of tablets or capsules) that do not produce particles, aerosols or gases.				
C-PECs used for manipulation of nonsterile HDs: C-PEC must be place in a C-SEC that has at least 12 ACH	☐	☐	☐	

Surfaces such as ceilings, walls, floors, fixtures, shoveling, counters and cabinets **must** be smooth, impervious, free from cracks and crevices and non- shedding to allow cleaning of the area	☐	☐	☐	
HDs **must** be: Vented – externally preferred or have redundant-HEPA filters in a series	☐	☐	☐	
Performed in a C-PEC that provides personnel and environmental protection, such as Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE)	☐	☐	☐	
Sterile Compounding				
NOTE: In addition to this <800> chapter, sterile compounding **must** follow standards in <797>.				
All C-PECs used for manipulation **must** be externally vented	☐	☐	☐	
Sterile HD compounding **must** be performed in a C-PEC that provides an ISO Class 5 or better air quality	☐	☐	☐	
Laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) **must not** be used for the compounding of an antineoplastic HD	☐	☐	☐	
The C-PEC **must** be located in a C-SEC (ISO Class 7 anteroom preferred)	☐	☐	☐	
If the C-PEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared **must** be limited as described in <797> for CSP prepared in a segregated compounding area. (See Engineering Controls for Sterile HD Compounding in <800> for more information.)	☐	☐	☐	
ISO Class 7 Buffer Room with an ISO Anteroom				
NOTE: The C-PEC is placed in an ISO Class 7 room that has fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 30 ACH.				
Buffer room **must** be externally vented	☐	☐	☐	
The following is **required**: Minimum of 30 ACH of HEPA-filtered supply air	☐	☐	☐	
Maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent areas	☐	☐	☐	
Maintain an air quality of ISO Class 7 or better	☐	☐	☐	
NOTE: An ISO Class 7 anteroom with fixed walls is necessary to provide inward air migration of equal cleanliness classified air into the negative pressure buffer room to contain any airborne HD.				
Hand-washing sink **must** be placed in the anteroom at least 1 meter (3.28084 feet) from the entrance to the HD buffer room	☐	☐	☐	
Although not recommended by facility design, if the negative-pressure buffer room is entered through a positive-pressure non-HD buffer room, the following is **required**: - Line of demarcation must be defined within the negative- pressure buffer room for donning and doffing PPE	☐	☐	☐	
A method of transportation HDs, HD CSP and HD waste in and out of the buffer room to minimize contamination. This may be accomplished by a pass through chamber between the negative-pressure buffer area and adjacent space. The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality in the negative-pressure buffer room	☐	☐	☐	
A refrigerator pass-through **must not** be used	☐	☐	☐	
Containment Segregated Compounding Area (C-SCA)				
NOTE: The C-PEC is placed in an unclassified C-SCA that has fixed walls, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 12 ACPH.				
C-SCA **must** be externally vented	☐	☐	☐	
Containment segregated compounding area **must** have a hand-washing sink 1 meter (3.28084 feet) from C-PEC and may be either inside the C-SCA or directly outside the C-SCA	☐	☐	☐	
HD CSPs prepared in the C-SCA **must not** exceed the BUDs described in <797> for CSPs prepared in a segregated compounding area	☐	☐	☐	
Containment Supplemental Engineering Controls				
NOTE: Containment supplemental engineering controls, such as closed-system drug-transfer devices (CSTD), provide adjunct controls to offer an additional level of protection during compounding or administration. However, there is no certainty that all CSTDs will perform adequately. Until a published universal performance standard for evaluation of CSTD containment is available, users should carefully evaluate the performance claims associated with available CSTDs based on independent, peer-reviewed studies and demonstrated containment reduction.				
CSTD **must not** be used as a substitute for a C-PEC when compounding	☐	☐	☐	
CSTD **must** be used when administrating 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	☐	☐	☐	