Description	Compliant?			Notes
	Yes	No	Unsure	
Getting Started				
Compliance team identified with roles/responsibilities assigned and agreed to (CNO/COO/CMO, Pharmacy, Facilities, Infection Control, Quality, Safety, USP Cleanroom Professionals, A&E)				
USP GAP analysis/assessment performed				
Identify Hazardous Drugs & compounding volumes current/future				
Hazardous drugs are received and stored separately from other inventory in a space that is negative pressure of at least 0.01" WC to adjacent spaces, is exhausted to the outside, and has at least 12 air changes per hour (ACH)				
The ISO Class 5 Biological Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI) is externally vented, placed in an ISO Class 7 area, physically separated and not less than 0.01-inch water column negative pressure to adjacent ISO Class 7 Ante-Room				
A pressure indicator is installed that can be readily monitored for correct room pressurization				
Cleanrooms (Compounding Areas and/or Buffer area) are supplied with the proper amount of HEPA-filtered air, have at least 30 ACH and meet ISO Class 7				
Ante areas meet ISO Class 8 or 7 and have at least 30 ACH of HEPA filtered supply air				
Environmental quality of air atmospheres and surfaces are verified by monitoring (*Viable and Nonviable Environmental Sampling (ES) Testing*).				
Entry to HD Prep Room through positive pressure buffer (non-HD Prep) room				
All HEPA filters should be integrity/leak tested as part of the semi-annual certification process				
Surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in a classified area or in a segregated compounding area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants can accumulate				
The buffer area does not contain sources of water (sinks) or floor drains				
A CETA registered Cleanroom Certified Professional for Sterile Compounding Facilities and a NEBB/TABB certified Test & Balance Technician together provide certification services				
Action Levels of Microbial Contamination are agreed upon, by the Compliance Team, indicating elevated levels of microbial growth				
All cleaning and disinfecting practices and policies, agreed upon by the Compliance Team				

Terminology/Definitions

CSP – Compounded Sterile Preparations. Mixed Drugs

BUD – Beyond Use Date. Drug stability/degradation

C-SCA - Containment Segregated Compounding Area. Cleanroom

CACI - Compounding Aseptic Containment Isolator: A specific type of CAI that is designed for compounding of sterile HDs. Exhaust air from the isolator shall be appropriately removed by properly designed building ventilation.

CAI - Compounding Aseptic Isolator: An isolator specifically designed for compounding sterile, non-hazardous pharmaceutical ingredients or preparations. A CAI shall not be used for the manipulation of HDs.

C-PEC - Containment Primary Engineering Control: A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants. Examples of C-PECs include Class I, II, or III BSCs, CACIs, and CVE (e.g., powder hood). C-PECs used for nonsterile compounding do not need to have ISO Class 5 air quality. C-PECs used for sterile compounding shall have ISO Class 5 air quality.

C-SEC - Containment Secondary Engineering Control: The C-SEC is the room in which the C-PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room (e.g., restricted access, barriers, special construction technique, ventilation, and room pressurization are components of the secondary control strategy).

C-SCA - Containment Segregated Compounding Area: A type of C-SEC with nominal airflow (12 ACPH) and room pressurization requirements (negative pressure between 0.01 – 0.03 inches of water column) as they pertain to HD compounding. The C-SCA is limited for use with a BSC or CACI when preparing low or medium-risk level CSPs with 12-hour or less BUDs or preparing nonsterile HDs in a C-PEC.

Anteroom: Transition area between the general area and the room containing the C-PEC. Hand hygiene, garbing, staging of components, order entry, and other particle-generating activities are performed in the anteroom. For sterile compounding, the anteroom shall meet ISO Class 7 and also provides assurance that pressure relationships between rooms are constantly maintained. Line of demarcation separates the designated clean and dirty areas.

Beyond-Use Date (BUD): The date or time after which a compounded preparation shall not be used, stored, or transported.

Buffer Room: Part of the HD compounding area under negative pressure where the C-PEC is physically located. Activities that occur in this area are limited to the preparation and staging of components and supplies used when compounding HDs.

Containment Ventilated Enclosure (CVE): A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants (through HEPA filtration) and prevent their release into the work environment (e.g., powder hood).

Nonsterile Compounding

*Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I BSC or CVE. A Class II BSC or a CACI may also be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned and disinfected before resuming sterile compounding in that C-PEC.

Sterile Compounding

*All C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides Class 5 or better air quality, such as a Class II or III BSC, or CACI. Class II BSC types A2, B1 or B2 are all acceptable. For most known HDs, type A2 cabinets offer a simple and reliable integration

with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile components.

*The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room (preferred) or an unclassified containment segregated compounding area (C-SCA). If the CPEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared must be limited to 12 hours or less.

*The C-PEC may be placed in an ISO Class 7 buffer room that has a negative pressure between 0.01 and 0.03 inches of water column and has a minimum of 30 ACPH of HEPA filtered supply air. HD CSPs prepared in an ISO Class 7 buffer room may use the BUDs described, based on the categories of CSP, sterility testing and storage temperature.

*The C-PEC may be placed in an unclassified C-SCA that has a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent spaces and has a minimum of 12 ACPH of HEPA-filtered supply air. Only low and medium risk HD CSPs may be prepared in a C-SCA.

What's Your Next Step?

To further help you identify and minimize your risk under UPS 787 and 800, CEPro has developed a 30-minute **USP Risk Consultation** which we conduct over the phone with you and your top staff/team members.

What we accomplish in this fast-paced, zero-nonsense session is:

-Review your current facility environments
-Identify and quantify your risk
-Outline a plan for minimizing your risk

Please be assured that this consultation will not be a thinly disguised sales presentation;
it will consist of the best intelligence we can supply in a 30-minute time span.

There is no charge for the call, but please be advised that the call must be strictly limited to 30 minutes.

To secure a time for this consultation, you may do one of the following…

Go to URL
Email ADDRESS
Call NUMBER

We look forward to working with you.