USP <797> and USP <800> Gap Analysis - Primary Engineering Controls

Protection for your patients and compounding personnel begins with selecting and implementing the right Primary Engineering Controls (PECs) for your pharmacy. Labconco's gap analysis assesses your pharmacy's PEC readiness for all requirements per the finalized version of USP <797> published November 1st, 2022.

Have a specific question or concerns? Contact one of our pharmacy experts, or visit labconco.com for information on PECs and to access helpful articles on USP <797> and USP <800> compliance.

Email: compounding@labconco.com **Website:** labconco.com/pharmacy **Phone:** (800) 821-5525

Appropriate PECs - Sterile Hazardous & Sterile Non-Hazardous Products

Criteria	Comply?	Comment
Are PECs used for non-hazardous sterile compounding either Laminar Airflow Workstations (LAFWs) or Compounding Aseptic Isolators (CAIs)?	☐	
Are containment PECs (C-PECs) used for hazardous sterile compounding either Class II BSCs (Type C1, A2, or B2) or Compounding Aseptic Containment Isolators (CACIs)? Are Class II BSCs/CACIs externally vented?	☐	
Do PECs provide unidirectional ISO 5, HEPA-filtered airflow during dynamic conditions? Is airflow confirmed in smoke visualization studies?	☐	
If using a piece of equipment within the PEC (e.g. compounder, IV verification/gravimetric system, etc.), is uniform airflow maintained?	☐	
If using a CAI or CACI, has PEC's abiliity to maintain ISO 5 air quality under dynamic conditions been documented?	☐	
Are PECs constructed of materials that are compatible with cleaning/disinfection agents used in the pharmacy? Are polycarbonate/acrylic windows being cleaned with ammonia-free agents?	☐	

Location of PECs - Category 1 Compounded Sterile Products (CSPs)

Criteria	Comply?	Comment
For non-hazardous Category 1 CSPs, are PECs located in a Segregated Compounding Area (SCA)?	☐	
For hazardous Category 1 CSPs, are C-PECs located in a Containment Segregated Compounding Area (C-SCA)?	☐	

Location of PECs - Category 1 Compounded Sterile Products (CSPs) (Continued)

Criteria	Comply?	Comment
Is the C-SCA externally vented, with a minimum of 12 Air Changes Per Hour (ACPH) and negative pressure (between 0.01 and 0.03" of water column)?	☐	
Are PECs placed within a SCA or C-SCA located away from areas of turbulent airflow (e.g. doors)?	☐	
Is the SCA or C-SCA located away from sources of contamination (e.g. windows, high-traffic areas, restrooms, etc.)?	☐	
Is the PEC appropriately sized for the room? PECs should not cause excessive air currents within the SCA or C-SCA.	☐	
Are CSPs prepared in the SCA or C-SCA assigned BUD dates of 12 hours or less (24 hours or less if refrigerated)?	☐	

Location of PECs - Category 2 & Category 3 Compounded Sterile Products (CSPs)

Criteria	Comply?	Comment
For non-hazardous Category 2 & Category 3 CSPs, are PECs (LAFWs, CAIs) placed in a (+) ISO 7 Buffer Room that is entered through an ISO 8 (or better) ante-room?	☐	
For hazardous Category 2 & Category 3 CSPs, are PECs (Class II BSCs, CACIs) placed in a (-) ISO 7 Buffer Room that is entered through an ISO 7 (or better) ante-room?	☐	
Do ISO 7 Rooms (both (+) and (-)) have a minimum of 30 ACPH? Do ISO 8 Rooms have a minimum of 20 ACPH? Are ACPH sufficient to maintain room classifications during dynamic conditions?	☐	
Are PECs placed within a (+) or (-) ISO 7 Buffer Room located away from areas of turbulent airflow (e.g. doors)?	☐	
If preparing Category 2 or Category 3 CSPs from non-sterile starting ingredients, are pre-sterilization procedures carried out in ISO 8 (or better) conditions? Are procedures carried out in a C-PEC such as a CVE, BSC, or CACI?	☐	

Ventilation of C-PECs - Hazardous CSPs

Criteria	Comply?	Comment
Are all C-PECs used to produce CSPs externally vented?	☐	
If Class II, Type A2 or C1 BSCs are used, are they canopy connected to the exhaust system, with a canopy alarm installed?	☐	
If Class II, Type B2 BSCs are used, are they connected to a exhaust system with redundant blowers?	☐	
If Class II, Type B2 BSCs are used, are they connected to a single exhaust blower and single duct run per each B2 BSC?	☐	
If a hard-ducted Class II, Type A/3B3 BSC is used, does a plan exist to remove the BSC per USP <800> and NSF/ANSI Standard 49?	☐	
If using a CACI, are (3) pairs of gloves being used? Glove liner, gloves on sleeves/gauntlets, gloves over top of sleeve/gauntlet gloves.	☐	
If a PEC(s) is providing a portion of a room's minimum air changes (C-SCA = 12 ACPH, ISO 7 Buffer Room = 30 ACPH), is it left on continuously?	☐	
If a PEC(s) is providing a portion of the minimum 30 ACPH, is the room HVAC providing at least 15 of the ACPH?	☐	

Certification of PECs

Criteria	Comply?	Comment
Is the certification professional(s) servicing your cleanroom properly trained? CETA Sterile Cleanroom Certified, NSF Accredited, etc?	☐	
Do all PECs used to prepare CSPs have a current certification within the last 6 months?	☐	
Are PECs used to prepare CSPs scheduled to receive a certification every 6 months after initial certification?	☐	

Certification of PECs (Continued)

Criteria		Comply?	Comment
Are PECs missing any parts (diffusers, bolts, etc.)?		☐	
Do HEPA filter(s) within the PECs have any visual discoloration or damage? If yes, does a plan exist to have the filter(s) replaced and re-certified?		☐	
For older PECs, does the manufacturer still have available replacement parts?		☐	
Do programs exist for the monitoring of total airbone particles, viable airbone particles, and surfaces within all PECs used for CSPs?		☐	
Do certification reports for your PECs include:			
Certification Testing Components	Airflow Testing (Face Velocity (LAFW, CAI, CACI) or Inflow/Downflow (Class II BSC)?	☐	
	HEPA Filter Integrity Testing?	☐	
	Total Particle Count Testing?	☐	
	Dynamic Airflow Smoke Pattern Testing?	☐	
Are certification reports for PECs understood by the Pharmacy Director/Pharmacist-In-Charge? Compounding Personnel?		☐	

PEC Personnel Training

Criteria	Comply?	Comment
Do formal SOPs exist for all compounding activities involving PECs? Compounding, cleaning, certification, etc.	☐	
Do compounding personnel have a basic understanding of how each PEC used in the pharmacy works? Controls, airflow, etc.	☐	
Have all compounding personnel that prepare CSPs performed an initial media fill test, followed by a competency test every 6 months thereafter (Category 1 and Category 2 CSPs), or 3 months thereafter (Category 3 CSPs)?	☐	

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