State of Connecticut
Department of Consumer Protection
Drug Control Division
DCP.DrugControl@ct.gov

Sterile Compounding Inspection

Facility Information

Facility Name		Date	
Facility Address		Phone #	
Pharmacy Manager/Director		Fax #	
Manager/Director E-mail			

Licenses and Accreditation

CT Pharmacy License (PCY) #		CSP # (Hospital)		CT Manufacturer License # (CSM)	
DEA License #		DEA Type		FDA License #	
Other State Licenses and Accreditations					

A. Required Documentation

1. List of Pharmacists and Technicians that compound/enter clean room provided?	○ Yes	○ No	Comment	
2. Documentation for competency for the Pharmacist/technicians provided?	○ Yes	○ No	Comments	
3. List of all the States the pharmacy is licensed in besides Connecticut provided?	○ Yes	○ No	Comment	
4. Last two Certification Reports provided? (Please include the certification of the Primary Engineering Controls (PEC) including pre-filter changes)	○ Yes	○ No		
5. Documentation of last two Media Fill tests provided? (Provide information on the kits used)	○ Yes	○ No	Comment	
6. Documentation of last two Gloved Fingertip test provided? (Provide information on agar plates used)	○ Yes	○ No	Comment	

7. Copy of PCAB, Joint Commission accreditation or any other provided?	○ Yes	○ No	○ N/A	Comment	
8. Standard operating procedures (SOP) for the clean room, cleaning, and environmental testing provided?	○ Yes	○ No		Comments	
9. Is all of the cleaning of the compounding rooms performed by the pharmacy staff? (If no, please provide the name of the service/ department and arrange for their participation during the inspection)	○ Yes	○ No		Comments	
10. A list of all cleaning products used in the compounding room provided? (Please include the kill times and coverage of organisms)	○ Yes	○ No		Comments	
11. Documentation for all the environmental monitoring (EM) done by the hospital provided? (air sampler information)?	○ Yes	○ No	○ N/A	Comments	
12. Has the facility provided a temperature log including a range for the maximum/minimum?	○ Yes	○ No		Comments	
13. Has the facility provided a pressure log for all compounding areas?	○ Yes	○ No		Comments	
14. Has the facility provided a humidity log for all compounding areas?	○ Yes	○ No	○ N/A	Comments	
15. Has the facility provided documentation showing that the products used for garbing and cleaning are non-shedding or non-linting?	○ Yes	○ No			
16. Is there a representative available to discuss the heating, ventilation, air conditioning (HVAC) system at the time of the inspection?	○ Yes	○ No		Comments (areas surrounding compounding rooms)	
17. Has the facility provided a list of the facilities/outsourcing pharmacies that provide compounded product?	○ Yes	○ No	○ N/A	Comments	
18. Has the facility provided documentation of all work orders in the compounding areas for the past year?	○ Yes	○ No	○ N/A	Comments	

Personnel

1. Total # of pharmacists Compounding	

2. Total # of technicians compounding

3. Number of Sales Personnel

Pharmacy Questionnaire

1. How many sterile compounding areas are in the primary facility site?

2.How many satellite facilities do you have with sterile compounding? (Please list the facilities)

3. Type of compounding performed
- ☐ Low Risk
- ☐ Medium Risk
- ☐ High Risk

4. Top 2 products products/list of products compounded

5. What type of facilities are the compounded products provided to?

6. What states are the products distributed to?

7. Does the facility compound chemotherapy agents? ○ Yes ○ No

8. Does the facility compound patient specific medications? ○ Yes ○ No

9. Does the facility compound non-patient specific medications? ○ Yes ○ No

In the following questions pertaining to Beyond Use Date (BUD), please define your process low risk, medium risk and high risk including the storage type (refrigeration, freezing, etc.)

10. BUD's used for the types of risk level of the compounded products ○ Yes ○ No Comments

11. Does the pharmacy have appropriate compounding references including USP Chapter 797, injectable drug compatibility, hazardous materials references? ○ Yes ○ No Comments

12. Does the pharmacy distribute sterile compounded preparations to practitioners for office use? ○ Yes ○ No Comments

13. Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers? ○ Yes ○ No Comments

14. If the pharmacy compounds sterile preparations for animals, does the compounding meet the same standards as compounding for human patients? ○ Yes ○ No ○ N/A

15. Does the pharmacy compound allergen extracts? ○ Yes ○ No

16. Does the pharmacy compound radiopharmaceuticals? ○ Yes ○ No

17. Does the pharmacy compound parenteral preparations? ○ Yes ○ No

18. Does the pharmacy compound ophthalmic preparations? ○ Yes ○ No

19. Does the pharmacy compound inhalation preparations? ○ Yes ○ No

14. Does the pharmacy compound parenteral suspensions? ○ Yes ○ No

15. Does the pharmacy compound preservative-free parenterals? ○ Yes ○ No

16. Does the pharmacy make a copy of an approved product? ○ Yes ○ No

17. Are products to be sterile compounded appropriately identified as hazardous? ○ Yes ○ No

18. Does the pharmacy make any compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)? ○ Yes ○ No

Number of BSC | Number of LAFW

Number of CAI | Number of CACI

19. Are camera's used for verification in the PECs? ○ Yes ○ No

A. Component Selection and Use

1. Are products to be compounded appropriately identified as low-risk? (Check all that apply)

- ☐ Not more than three sterile drug packages used
- ☐ Sterile equipment
- ☐ Compounded in an ISO Class 5 hood in an ISO Class 7 clean room (if ISO Class 5 hood NOT in ISO Class 7 clean room, max BUD 12 hours)
- ☐ Limited basic closed system aseptic transfers and manipulations

2. Are products to be compounded appropriately identified as medium-risk? (Check all that apply)

- ☐ Uses four or more sterile ingredients
- ☐ Complex aseptic manipulations other than single volume transfer
- ☐ Compounded sterile preparation (CSP) is to be administered to multiple patients or to one patient on multiple occasions
- ☐ Compounding process of unusually long duration (dissolution, homogeneous mixing)

3. Are products to be compounded appropriately identified as high-risk? (Check all that apply)

- ☐ Made with non-sterile ingredients, non-sterile devices, or non-sterile containers
- ☐ Prepared with sterile ingredients but exposed to <ISO Class 5 air
- ☐ Greater than a six-hour delay before sterilization
- ☐ Purity of components assumed but not verified

4. Are immediate use compounds appropriately identified? (Check all that apply)

- ☐ Aseptically compounded
- ☐ Simple transfer ≤ 3 commercially manufactured non-hazardous products
- ☐ Not > 2 entries into any container
- ☐ Administration begins ≤ 1 hour from start of compounding

B. High Risk Compounding

High Risk Compounding performed? (if no, skip this section) ○ Yes ○ No

1. Are certificates of analysis (COAs) obtained for all APIs? ○ Yes ○ No

1a. Are the COAs domestic or foreign? ○ Domestic ○ Foreign

1b. If the source is a foreign FDA facility, does the pharmacy obtain information on the last FDA inspection of that facility and a copy of the report? ○ Yes ○ No

2. Does the pharmacy perform any testing/analysis of APIs? ○ Yes ○ No

2a. If so, indicate how API is selected for testing, what tests are performed and if tested in-house or sent to an outside lab - indicate which lab in notes. ○ In-house ○ Outside lab

Comment (list lab(s))

3. Are USP- or NF-grade substances used, if available? ○ Yes ○ No

3a. If compendial quality components are not available, are chemically pure, analytical reagent grade or American Chemical Society-certified components used? ○ Yes ○ No ○ N/A

Comment

3c. Are other means used to establish purity and safety?	○ Yes	○ No	○ N/A	Comment	
4. Do any of the labels state "For Research Purposes Only" or "Not for Drug Use" or “Veterinary Use only” or similar?	○ Yes	○ No		Comment	
5. Do all substances and components have a complete label including a batch control or lot number, an expiration date, and are marked with the date of receipt?	○ Yes	○ No		Comment	
6. For substances without an expiration date assigned by the manufacturer or supplier, does the pharmacy have a procedure to assign a conservative expiration date and is it followed?	○ Yes	○ No		Comment	
7. Does the pharmacy repackage APIs into smaller containers for ease of use?	○ Yes	○ No		Comment	
7a. If so, how is the expiration date determined for the repackaged product?					
8. When manufactured products are used for compounding, do the labels contain a lot number and expiration date?	○ Yes	○ No		Comment	
9. Are any preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons?	○ Yes	○ No			
9a. How does the pharmacy determine this?					
10. Does the pharmacy compound its own stock solutions or components that are then used to compound a finished product?	○ Yes	○ No			
10a. If so, how are BUDs determined?					
10b. Are the compounded stock solutions prepared in batches that are exposed longer than 12 hours at 2-8°C (25-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before being sterilized?	○ Yes	○ No		Comment	
10c. Are all compounded stock solutions that will be used as a component of a finished product tested for sterility and stability?	○ Yes	○ No		Comments	

11. When using its own compounded stock solution, is it used without dilution in a final preparation (repackaged as-is into smaller or unit-of-use packages)? ○ Yes ○ No ○ N/A Comments

11a. If so, are these preparations given extended BUDs? ○ Yes ○ No

11b. How is the BUD determined?

12. When using its own compounded stock solution, is it used as a component of a preparation (made less concentrated by the addition of a diluent or other component)? ○ Yes ○ No

12a. If so, are these preparations given extended BUDs? ○ Yes ○ No

12b. How is the BUD determined?

13. Trace two preparations from API to finished product.

C. General Facility

1. Are both sterile and non-sterile compounding areas separated and distinct? ○ Yes ○ No ○ N/A

2. Is entry into the sterile compounding areas limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized personnel)? ○ Yes ○ No Comments

3. Does the ante-room have a line of demarcation or other separation of the dirty to the clean side? ○ Yes ○ No

4. Are carts used to bring supplies from the storeroom kept on the outside of the line of demarcation? ○ Yes ○ No

5. Are carts used in the clean room/buffer room kept on the clean side of the line of demarcation? ○ Yes ○ No

6. Are all surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating? ○ Yes ○ No Comments

7. Are walls painted with epoxy based paint or other impermeable surface, and are they seamless or have sealed seams where panels meet and corners with no cracks?
○ Yes ○ No Comments

8. Are the ceiling tiles composed of a vinyl surface, with the tiles caulked and sealed and are the seams where the walls meet the ceiling caulked and sealed?
○ Yes ○ No Comments

9. Is the floor overlaid with:
☐ Wide Sheet Flooring
☐ Seamless or heat welded seems
☐ Coving to the sidewall
☐ Sealed seam where the coving meets the side wall
☐ Other
Comments

10. Does the clean room or ante-room have dust collecting overhangs, such as ceiling utility pipes, or ledges?
○ Yes ○ No

10a. Are all sprinkler heads flush with the ceiling?
○ Yes ○ No

11. Are the exposed surfaces of the light fixtures smooth, mounted flush, and sealed?
○ Yes ○ No

12. Is there a sink with hot and cold running water located in the ante room or near the sterile compounding area that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands, and is there an eyewash station?
○ Yes ○ No

13. Is there a sink or a floor drain in the clean room/buffer room? (This is not allowed)
○ Yes ○ No

D. Heating, Ventilation and Air Conditioning (HVAC)

1. Are all air ducts controlling air flow into the sterile compounding area equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment?
○ Yes ○ No ○ N/A Comments

2. Are incoming air ducts through HEPA filters on or near the ceiling and are air return ducts low on the walls to facilitate turbulent air flow in the ante-room and clean room?
○ Yes ○ No ○ N/A Comments

3. Is there any particle generating equipment (computers, refrigerators, etc.) in the clean room/buffer room or anteroom?
○ Yes ○ No
Comments

3a. If there is particle generating equipment in the clean room or ante-room, is the equipment located by an air return so air flows over and out of the room taking particles with it, and has this air flow has been confirmed by smoke testing? View certification report for the room and specifically look at particle counts taken in the area of the equipment.
○ Acceptable ○ Unacceptable ○ Insufficient Information
Comments

4. Does the sterile compounding area have a fan?
○ Yes ○ No

4a. Has it been validated to not affect airflow in the ISO Class 5 PEC?
○ Acceptable ○ Unacceptable ○ Insufficient Information
Comments

5. Are coffee, water, chewing gum, candy, or food items prohibited by SOP or signage from the clean room/buffer area or ante-room?
○ Yes ○ No
Comments

6. Are sterile compounded products prepared with aseptic manipulations 6 inches within ISO Class 5 or better air quality hood or shielded laminar flow work area using only sterile ingredients, products, components, and devices?
○ Yes ○ No
Comments

7. Is the ISO Class 5 compounding area located within an ISO Class 7 clean room or buffer area?
○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A
Comments

8. Is the ISO 7 clean room positive pressure to the ISO 7 or 8 ante room? Record pressure differential.
○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A
Comments

9. Is the hazardous compounding room and hazardous drug storage area negative pressure to the ISO 7 ante room? Record pressure differential.
○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A
Comments

10. Is the ISO Class 7 or 8 ante room positive pressure to the general pharmacy areas? Record the pressure differential.
○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A
Comments

11. Are pressure differential monitoring procedures in place including an alarm or alert when there is an excursion? Verify by viewing daily logs and ensure a plan is in place if discrepancy is found.
○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A
Comments

12. If the clean room and anteroom are not fully enclosed, is the air flow measured across the openings? Record the air flow.

○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A Comments

13. Are air flow monitoring procedures in place including an alarm or alert if the air flow drops below the limit?

○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A Comments

14. Is the temperature of the compounding area controlled by a thermostat and an adequate air conditioning system (anteroom and cleanroom) maintained between 64-72°F (18-22°C)?

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

15. Is the humidity monitored daily and in the range of 35%-60% in the sterile compounding area?

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

16. Are the blowers on ISO 5 laminar airflow workbenches (LAFW) or barrier isolators operated continuously during compounding activity, including during interruptions of less than eight hours?

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

17. Are the doors into the ante-room from the general pharmacy area and from the anteroom into the clean room interlocked to prevent both being open at the same time?

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

18. Are the inside and outside doors of a pass-through interlocked to prevent both being open at the same time?

○ Acceptable ○ N/A ○ Unacceptable ○ Insufficient Information Comments

E. LAFW NOT located in ISO Class 7 buffer area:

Does the facility have a LAFW Not located in ISO Class 7 buffer area? (If no, skip this section)

○ Yes ○ No

1. Is compounding restricted to low-risk preparations with a maximum BUD of 12 hours?

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

2. Are all garbing requirements adhered to?

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

3. Is the LAFW located in an area that is maintained under sanitary conditions physically located in a low traffic area?

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

4. Does the location contain any unsealed windows or doors? (If unacceptable, describe surrounding areas)

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

5. Is the sink separated from the immediate area of the ISO Class 5 workbench (not adjacent)? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

F. CAI or CACI NOT located in ISO Class 7 buffer area

Does the facility have CAI or CACI Not located in ISO Class 7 buffer area? ○ Yes ○ No

1. Does the CAI/CACI maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP? NOTE: for certification, particle counts must be sampled 6 to 12 inches upstream of the critical exposure site. ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

2. Does the pharmacy have documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

3. Is the CAI or CACI located in an area that is maintained under sanitary conditions and utilized only for sterile compounding? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

4. For hazardous compounding in a CACI that is NOT located in a buffer area, is the CACI located in a physically separated area that maintains a negative pressure of 0.01” water column pressure to adjacent areas and a minimum of 12 ACPH? ○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A Comments

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G. Garbing

1. Is garbing performed from the dirtiest to the cleanest starting with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed? ○ Acceptable ○ Unacceptable Comment

1a. Does garbing then progress to head and facial hair covers and masks? ○ Acceptable ○ Unacceptable Comments

2. Is hand cleaning performed in the ante-room for at least 30 seconds from finger tip to forearm and does it include use of a nail pick? ○ Acceptable ○ Unacceptable Comments

2a. Are hands and arms then dried with a non-linting disposable towel? ○ Acceptable ○ Unacceptable ○ N/A Comments

2b. Are hands and arms dried using a hand dryer? ○ Yes ○ No ○ N/A Comments

2c. If yes to 2b, has the hand dryer been validated by a certification company to not disrupt laminar air flow? ○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A Comments

3. Is the gown non-shedding? ○ Acceptable ○ Unacceptable

4. Is all bare skin covered on the arms and the legs? ○ Acceptable ○ Unacceptable Comments

5. Prior to donning sterile gloves, is a waterless alcohol based surgical hand scrub with **persistent activity** used and are hands allowed to dry? ○ Acceptable ○ Unacceptable Comments

6. Upon leaving the sterile product compounding area, are gowns taken off and disposed of? ○ Yes ○ No Comments

6a. If gowns are not disposed of, are they left in the ante-room and not reused for longer than one shift or to gown manufacturers expiration? ○ Acceptable ○ Unacceptable Comments

6b. If gowns are not disposed of, are the chemo and I.V. gowns physically separated on hangers in the ante-room? ○ Acceptable ○ Unacceptable Comments

7. Do pharmacists or any other personnel enter the ante-room and cross the line of demarcation without proper garb? ○ Acceptable ○ Unacceptable Comments

8. Is there documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? Must be zero CFUs/plate on any testing ○ Acceptable ○ Unacceptable Comments

9. Is there documentation that compounding personnel have passed an annual (every six months for those performing high risk compounding) observed gowning procedure and gloved fingertip sampling test? Must be 3 or less CFU/plate upon re-validation ○ Acceptable ○ Unacceptable Comments

10. Is there documentation that a media fill test procedure is performed for each compounding employee at least **annually** for individuals that compound **low or medium risk-level products**. The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product.

○ Acceptable ○ Unacceptable Comments

11. Is there documentation that a media fill test procedure is performed for each compounding employee at least **semi-annually** for individuals that compound **high risk-level products**. The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product.

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

12. Do the media-fill testing procedures include: (all must be selected to be acceptable)

☐ media selection
☐ fill volume
☐ incubation time and temperature
☐ inspection of filled units
☐ documentation
☐ interpretation of results
☐ action levels with the corrective actions required
☐ Not Applicable

Comments

13. Are personnel prohibited from entering the clean room or ante room if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection?

○ Acceptable ○ Unacceptable Comments

13a. Is there a SOP in place for personnel with rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection to be prohibited from accessing the compounding areas?

○ Acceptable ○ Unacceptable Comments

14. Are personnel required to wear dedicated clothing before entering compounding areas?

○ Acceptable ○ Unacceptable Comments

15. Are personnel required to remove all hand and wrist jewelry, and all visible jewelry or piercings?

○ Acceptable
○ Unacceptable

Comments

16. Are personnel prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed?

○ Yes ○ No Comments

H. Cleaning and Disinfection

1. Are all personnel that perform cleaning activities in the compounding areas appropriately trained (including housekeeping or other outside personnel if used for cleaning)?	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
2. Are all personnel performing cleaning appropriately garbed?	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
3. Is the sterile compounding area equipped with appropriate non-shedding cleaning equipment and supplies? All cleaning tools, such as wipers, sponges, and mops, must be non-shedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
4. If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area and are buckets inverted to prevent moisture accumulation?	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
5. Are tools appropriately labeled to prevent them from being used inappropriately? For example, a mop used for the floors cannot also be used for the ceilings and walls.	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
6. Are there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use and is the preparation of cleaning supplies documented?	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
7 Are cleaning and sanitizing agents appropriately labeled including expiration dates?	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
8. Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores? Indicate how often a sporicidal agent is used. List products used in note.	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
9. Are sanitizing agents rotated?	○ Yes	○ No			
9a. If yes, how often					
10. Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	
11. Does the cleaning of the ISO 5 PEC include cleaning with sterile water and sanitizing with sterile 70% IPA using a non-linting wipe?	○ Acceptable	○ Unacceptable	○ Insufficient Information	Comments	

12. Does daily cleaning and sanitizing include counters and easily cleanable work surfaces? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

13. Does daily cleaning include the floors starting from the clean room and working outwards? Floor cleaning is not to occur during compounding. ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

14. Are fatigue mats used? ○ Yes ○ No

14a. If fatigue mats are used, is there documentation showing that they are appropriate for use? ○ Acceptable ○ Unacceptable Comments

14c. If fatigue mats are used, is there an SOP specific to cleaning and drying the mats? ○ Acceptable ○ Unacceptable Comments

15. Is a tacky mat used? ○ Yes ○ No

15a. If a tacky mat is used, is there an SOP regarding the frequency it is changed or replaced? ○ Acceptable ○ Unacceptable Comments

15b. If a tacky mat is used, is is appropriately located? ○ Acceptable ○ Unacceptable Comments

16. Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

17. Is enough time allocated for cleaning activities? ○ Acceptable ○ Unacceptable Comments

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I. Compounding Equipment

1. Is appropriate equipment available and in good working order including equipment for handling hazardous materials? View maintenance and calibration logs. ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

2. Are scales, balances, and other equipment used for measuring or weighing calibrated at least annually? ○ Acceptable ○ Unacceptable Comments

3. Are any Automated Compounding Devices (ACDs) used? ○ Yes ○ No

3a. Are there SOP for the use, daily calibration and maintenance of the ACD? ○ Acceptable ○ Unacceptable

3b. Is there documentation of the ACD tubing being changed every 24 hours? ○ Acceptable ○ Unacceptable

3c. Is the ACD used when performing media fill testing? ○ Acceptable ○ Unacceptable

4. If compounding with non-sterile APIs, does the pharmacy have appropriate equipment to sterilize the finished product? List sterilizing equipment used in notes (filters, autoclave, etc.). ○ Acceptable ○ Unacceptable ○ Insufficient Information

5. Does the pharmacy have a lyophilizer? ○ Yes ○ No

5a. If so, note the volume or percent of products per week produced using the lyophilizer

5b. Is the lyophilizer is part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures. ○ Acceptable ○ Unacceptable

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J. Compounding Procedure

1. Are all procedures performed in a manner designed to minimize the risk of touch contamination? ○ Acceptable ○ Unacceptable Comments

2. Are gloves and critical sites sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA) spray and a non-linting wipe? ○ Acceptable ○ Unacceptable Comments

3. Are objects that shed particles prohibited? ○ Acceptable ○ Unacceptable Comments

4. Are supplies properly decontaminated prior to introduction to the ISO classified area? ○ Acceptable ○ Unacceptable Comments

5. Are compounding employees using appropriate aseptic technique? ○ Acceptable ○ Unacceptable Comments

6. Are supplies stored on the appropriately in the ISO classified area? ○ Acceptable ○ Unacceptable Comments

7. Is there a pre-compounding check or ingredients by the compounding personnel? ○ Acceptable ○ Unacceptable Comments

8. Are appropriate sanitization processes followed for vials and ampules prior to use? ○ Acceptable ○ Unacceptable Comments

9. Is every CSP visually inspected for thorough mixing and for the presence of particulate matter, evidence of incompatibility, or other issues?

○ Acceptable ○ Unacceptable

Comments

10. Are opened or needle punctured **single-dose** containers (bags, bottles, syringes, or vials) that are opened or punctured in **worse** than ISO Class 5 air used within one (1) hour and the remaining contents discarded?

○ Acceptable ○ Unacceptable

Comments

10a. How are **single-dose** opened/punctured in worse than ISO Class 5 air identified for expiration?

○ Acceptable ○ Unacceptable

Comments

11. Are single-dose vials exposed to ISO Class 5 or cleaner air used within six (6) hours of the initial puncture and any remaining contents discarded?

○ Acceptable ○ Unacceptable

Comments

11a. How are **single-dose** opened/ punctured in ISO Class 5 air or cleaner identified for expiration?

○ Acceptable ○ Unacceptable

Comments

12. Are the remaining contents of opened single-dose ampules discarded immediately?

○ Yes ○ No

Comments

13. Are **multiple-dose** vials assigned a BUD of 28 days or the manufacturer's specific BUD (whichever is less) after the initial entry or puncture?

○ Acceptable ○ Unacceptable

Comments

13a. How are **multi-dose** vials opened/punctured identified for expiration?

○ Acceptable ○ Unacceptable

Comments

14. Is the compounding record complete?

- ☐ Official or assigned name, strength and dosage form of the preparation
- ☐ Names, lot numbers and expiration dates of all components
- ☐ Total quantity or number of units compounded
- ☐ Person compounding the preparation
- ☐ Person performing the quality control procedures
- ☐ Person who approved the preparation
- ☐ Date of compounding
- ☐ Assigned internal identification number or prescription number
- ☐ Assigned BUD and reference if extended beyond USP guidelines
- ☐ Duplicate label
- ☐ Sterilization method (if applicable)
- ☐ Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if appropriate.

Comments

15. Is there an SOP for in-process checks performed by a pharmacist and is the procedure followed?

○ Acceptable ○ Unacceptable

Comments

16. Do labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include identifiers for the persons preparing and performing the final verification and appropriate packaging and labeling of hazardous materials?

○ Acceptable ○ Unacceptable Comments

17. Do any of the finished products inspected show any evidence of particulates?

○ Acceptable ○ Unacceptable Comments

18. Are BUDs greater than 24 hours documented with justification based on USP guidelines, testing or literature?

○ Acceptable ○ Unacceptable Comments

19. Are BUDs assigned that are longer than the USP Chapter 797 guidelines?

- ☐ Low Risk > 48 hours room temp
- ☐ Low Risk > 14 days refrigerated
- ☐ Low Risk > 45 days frozen
- ☐ Medium Risk > 30 hours room temp
- ☐ Medium Risk > 9 days refrigerated
- ☐ Medium Risk > 45 days frozen
- ☐ High Risk > 24 hours room temp
- ☐ High Risk > 3 days refrigerated
- ☐ High Risk > 45 days frozen

Comments

19a. Is there adequate documentation to support the extended BUDs in questions 19

○ Acceptable ○ Unacceptable ○ N/A Comments

Compounding Procedure - High Risk

20. Are appropriate sterilization methods used and documented? Ensure P&Ps in place that address determining the appropriate type of sterilization method, equipment to be used, documentation to be kept and testing to be performed.

○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

21. Does the pharmacy use non-sterile empty vials and vial stoppers or closures and terminally sterilize them with on on-site autoclave?

○ Acceptable ○ Unacceptable ○ Insufficient Information ○ N/A Comments

22. Filter Sterilization
Is there documentation that:

- ☐ The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP
- ☐ Filtering is completed rapidly without filter replacement
- ☐ Confirmation of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration
- ☐ Single use filters are only used once
- ☐ The CSP and the CSP volume are appropriate for filter used

23. Steam sterilization
Is there documentation that:

- ☐ The autoclave has been validated for the exposure time and mass of the items to be sterilized
- ☐ Ensures live steam contacts all ingredients and surfaces to be sterilized by load patter validation documetation
- ☐ Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization
- ☐ Heated filtered air is evenly distributed throughout the chamber with a blower
- ☐ That the CSP will not be adversely affected by the steam and heat
- ☐ The description of steam sterilization includes conditions and duration for specific CSPs

24. Dry heat sterilization
Is there documentation that:

- ☐ Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture
- ☐ Sufficient space is left between materials to allow for air circulation
- ☐ The description of dry heat sterilization includes conditions and duration for specific CSPs
- ☐ That the effectiveness of steam sterilization is verified each time using appropriate biological indicators
- ☐ Oven is equipped with a system for controlling temperature and exposure period

25. Depyrogenation by dry heat
Is there documentation that:

- ☐ Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes
- ☐ The description of the cycle and duration for specific load items
- ☐ The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs)
- ☐ Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins

Finished Preparation Release Checks and Tests

26. Is there a process in place to sample prepared products for potency and/or contamination? and recall actions to take if discrepancies are found? For suspensions, is the particle size measured?	○ Acceptable	○ Unacceptable	Comments	
26a. Is there a process for recall actions should the prepared products fail specifications in question 26?	○ Acceptable	○ Unacceptable	Comments	
26b. Is the particle size for suspension within specification?	○ Acceptable	○ Unacceptable	Comments	
27. Are products checked for particulates or other foreign matter against both a light and a dark colored background?	○ Acceptable	○ Unacceptable	Comments	
28. Are there checks for container and closure integrity?	○ Acceptable	○ Unacceptable	Comments	
29. Is compounding accuracy documented by verification of steps?	○ Acceptable	○ Unacceptable	Comments	
30. Are ingredient identity and quantity verified?	○ Acceptable	○ Unacceptable	Comments	
30a. Is there a reconciliation of components?	○ Acceptable	○ Unacceptable	Comments	
31. Are labels verified as being correct?	○ Acceptable	○ Unacceptable	Comments	
31a. Is a copy of the label included in the record?	○ Acceptable	○ Unacceptable	Comments	

32. Is sterility testing performed for each batch of CSPs that have extended BUDS, are prepared in batches of more than 25 identical containers, or are exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized?

○ Acceptable ○ Unacceptable Comments

33. Are the appropriate quantities of units for each batch tested? (View records to confirm appropriate number tested. View records of products failing tests including investigation and action taken.)

a. For small volumen parenterals

☐ Less than 100, test 10% or four units, whichever is greater
☐ 100 up to 500, test 10 units
☐ More than 500, test 2% or 20 units, whichever is less

Comments

b. For large volume parenterals: 2% or 10 containers, whichever is less.

☐ 2% or 10 containers, whichever is less Comments

c For non-parenterals (eye drops, inhalation, etc.

☐ Less than 200 containers, test 5% or 2 containers, whichever is greater
☐ 200 or more containers, test 10 containers
☐ If products are packaged in unit doses, refer to 33a

34. Are items dispensed or distributed prior to sterility testing completion?

○ Yes ○ No Comments

34a. If yes, is there a SOP requiring daily observation of media?

○ Yes ○ No Comments

34b. Is there a SOP for immediate recall upon evidence of growth?

○ Yes ○ No Comments

34c. Is there a SOP for notifying prescribing practitioners and patients for potential risk related to a contaminated CSP?

○ Yes ○ No Comments

35. Are all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials), or in multiple dose vials for administration to multiple patients, or exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized tested to ensure that they do not contain excessive bacterial endotoxins? View results of testing and indicate number or percentage of units tested.

○ Acceptable ○ Unacceptable Comments

36. Are products tested for purity and potency?

○ Yes ○ No

36a. How are the products selected for testing?

37. Have products that failed sterility, endotoxin, purity or potency testing been dispensed or distributed and not recalled? ○ Yes ○ No Comments

37a. How are 'inconclusive' results handled?

38. Does the pharmacy have its own lab to perform testing? ○ Yes ○ No

38a. If so, what testing is performed in house?

39. Does the pharmacy send samples to an outside lab to perform testing? ○ Yes ○ No

39a. If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.

K. Training

1. Is there documentation that all compounding personnel have passed an initial and subsequent annual written exams for quality assurance procedures for the appropriate risk level and including hazardous drugs? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

2. Is there documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of **aseptic compounding skills** including handling hazardous drugs? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

3. Are pharmacists and technicians performing compounding using hazardous drugs appropriately trained in the safe handling, garbing, cleaning, and disinfection procedures and waste disposal of hazardous drugs and materials? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

4. Does training include operation of any equipment that may be used when preparing compounded sterile products? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

5. Does the pharmacy use relief personnel from outside agencies to perform sterile compounding? ○ Yes ○ No

5a. How are training and certifications verified? ○ Acceptable ○ Unacceptable ○ Insufficient Information Comments

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L. Environmental Monitoring

1. Have all cleanrooms, laminar airflow workbenches, BSCs, CAIs, CACIs, and barrier isolators been certified?	○ Acceptable	○ Unacceptable		Comments	
2. Does the pharmacy have an ISO Class 5 shielded laminar workflow area built in to the room?	○ Acceptable	○ Unacceptable	○ N/A	Comments	
3. Is certification performed at least every six months and whenever a device or room is moved or major work is done to the space?	○ Acceptable	○ Unacceptable		Comments	
4. Are certification reports available?	○ Acceptable	○ Unacceptable		Comments	
4a. Note the date(s) of certification failures and obtain copies of the action plans for each failure.					
5. Is the person/parties responsible for overseeing the certification reports familiar with what testing is required and interpretation of results, have action levels have been identified, and are these further customized based on trended data of performance? (List responsible person/parties)	○ Acceptable	○ Unacceptable		Comments	
6. Is certification to the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is it noted on the report? If not, indicate the standards used as indicated on the report. (Environmental monitoring to CETA CAG-009-00 Viable Environmental Sampling and Gowning Evaluation may also be listed)	○ Acceptable	○ Unacceptable		Comments	
7. Is the equipment used by the certifier calibrated and is the calibration in date?	○ Acceptable	○ Unacceptable		Comments	
8. Does each test on the certification report have a clear indication of pass or fail?	○ Acceptable	○ Unacceptable		Comments	
9. Are the HEPA filtered air changes per hour (ACPH) measured for the compounding rooms?	○ Acceptable	○ Unacceptable		Comments	
10. Is the ISO Class 7 non-hazardous sterile compounding room certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources?	○ Acceptable	○ Unacceptable		Comments	

11. Is the ISO class 7 ante-room certified as having a minimum of 30 ACPH?	○ Acceptable	○ Unacceptable		Comments	
12. Are the ISO class 8 ante-room ACPH measured? A minimum of 20 ACPH is commonly referred to by the FDA and others.	○ Acceptable	○ Unacceptable	○ N/A	Comments	
13. Is the ISO class 7 hazardous sterile compounding room certified as having a minimum of 30 ACPH?	○ Acceptable	○ Unacceptable		Comments	
14. If a CACI is used, is the room in which it is located certified to maintain a minimum of 12 ACPH?	○ Acceptable	○ Unacceptable		Comments	
15. Was air pattern analysis using smoke testing performed?	○ Acceptable	○ Unacceptable		Comments	
15a. is the smoke flow described in the report for the various tests such as turbulent, sluggish, smooth, etc.?	○ Acceptable	○ Unacceptable		Comments	
16. Was air pattern analysis conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under **dynamic** conditions?	○ Acceptable	○ Unacceptable		Comments	
17. Was air pattern analysis conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs?	○ Acceptable	○ Unacceptable		Comments	
18. Was air pattern analysis conducted around particle generating equipment while the equipment was in operation to confirm air flow?	○ Acceptable	○ Unacceptable		Comments	
19. Was differential pressure or displacement airflow measured?	○ Acceptable	○ Unacceptable	○ N/A	Comments	
20. Was the differential pressure measured to be at least 0.02 water column positive from the cleanroom to the ante-room and between the ante-room and all adjacent spaces with the doors closed?	○ Acceptable	○ Unacceptable		Comments	

21. Was the displacement airflow (for low and medium-risk non-hazardous rooms only) measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the ante-room. Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.	○ Acceptable	○ Unacceptable	○ N/A	Comments	
22. Were particle counts measured? Greater than or equal to 0.5 mm.	○ Acceptable	○ Unacceptable		Comments	
23. Were all particle counts taken during dynamic conditions as noted on certification reports?	○ Acceptable	○ Unacceptable		Comments	
24. Are ISO Class 5 areas and hoods certified as having less than 3,520 particles per cubic meter of air?	○ Acceptable	○ Unacceptable		Comments	
25. Are ISO Class 7 areas certified as having less than 352,000 particles per cubic meter of air?	○ Acceptable	○ Unacceptable		Comments	
26. Are ISO Class 8 areas certified as having less than 3,520,000 particles per cubic meter of air?	○ Acceptable	○ Unacceptable		Comments	
27. Was HEPA filter testing performed?	○ Acceptable	○ Unacceptable		Comments	
27a. List the number of HEPA filters					
28. Were all room HEPA filters leak tested?	○ Acceptable	○ Unacceptable		Comments	
28a. If leaks were identified were they repaired?	○ Acceptable	○ Unacceptable		Comments	
28b. Was a smoke study performed in front of the repaired area?	○ Yes	○ No		Comments	
29. Were viable air and surface sampling tests conducted?	○ Acceptable	○ Unacceptable		Comments	
30. Is appropriate growth media used that supports both bacterial and fungal growth? List media used in note.	○ Acceptable	○ Unacceptable		Comments	
31. Was viable air sampling by active impaction using a volumetric air sampling device? NOTE: Passive air sampling is not compliant with USP Chapter <797>.	○ Acceptable	○ Unacceptable		Comments	

32. Was each air sample taken in the ISO areas/PECs at least 1000 liters in volume? If no, statistical analysis must be performed.	○ Acceptable	○ Unacceptable	Comments	
33. Was viable surface sampling performed on all direct compounding areas (inside of ISO 5 rooms or hoods), in each room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc., performed?	○ Acceptable	○ Unacceptable	Comments	
34. Did any of the viable samples exceed the USP recommended microbial action levels (or internal action levels if more restrictive)? Note: CFUs are TOTAL of bacterial plus fungal/mold plates.	○ Acceptable	○ Unacceptable	Comments	
35. Were all CFUs detected analyzed to determine the organism down to the genus? All CFUs detected must be identified even if the number of CFUs does not exceed an action level.	○ Acceptable	○ Unacceptable	Comments	
36. Were any mold, yeast, coagulase positive staphylococcus, or gram negative rods detected?	○ Acceptable	○ Unacceptable	Comments	
36a. If yes, was immediate remediation performed and was the root cause investigation conducted?	○ Acceptable	○ Unacceptable	Comments	
37. Did the testing report indicate that it included growth promotion testing and sterility quality control testing of the media plates? Positive and negative control tests important to validate results of viable testing.	○ Acceptable	○ Unacceptable	Comments	
38. Did the testing results report include media lot numbers and expiration dates and a signature of the laboratory analyst and/or reviewer?	○ Acceptable	○ Unacceptable	Comments	