CONNECTICUT DEPARTMENT OF
CONSUMER PROTECTION
DRUG CONTROL DIVISION

Sterile Compounding Complex Inspection Checklist

	1. List of pharmacists and pharmacy technicians (include credentials)that enter the sterile compounding complex
	2. Documentation of each pharmacist and pharmacy technician's sterile compounding observational competency for the past two years
	3. List of all sterile compounding complexes within the pharmacy.
	4. Certification reports for the past 2 years, including primary engineering controls (PECs), for each sterile compounding complex within the pharmacy.
	5. Documentation of PEC pre-filter changes for the past 2 years
	6. Documentation of the last two Media Fill tests, including the kits used to administer the Media Fill tests, dates of incubation, temperature logs during incubation & certificates of analysis (COAs)
	7. Documentation of the last two years for Gloved Fingertip tests (GFT), including the plates used to administer the GFT, COAs, incubation procedures, & temp incubation logs
	8. Standard Operating Procedures (SOPs) for the sterile compounding complex as identified in USP <797>.
	9. Documentation of cleaning the PECs, buffer area, and ante room on a daily basis for the past two years
	10. Documentation of cleaning the PECs, buffer area, and ante room on a monthly basis for the past two years.
	11. List of cleaning products, including organism coverage and kill times, used to clean the buffer area, ante room, PECs, floors, walls, ceilings, surfaces, etc
	12. Documentation of all environmental monitoring performed for each sterile compounding complex within the pharmacy. Include : a.)Chain of Custody, COAs, finalized in-house results, finalized lab results, sampling diagram, air sampling device certification report, dates of incubation, temperatures logs of incubation, staff training records for sampling if sampling is performed in-house
	13. Temperature logs, including minimum and maximum range, for all compounding areas (i.e. buffer area, ante room, and chemotherapy) for each sterile compounding complex within the pharmacy for the past two years
	14. Humidity logs including minimum and maximum range, for all compounding areas (i.e. buffer area, ante room, and chemotherapy) for each sterile compounding complex within the pharmacy for the past two years
	15. NIST certification reports for temperature,humidity, pressure monitoring devices for all compounding areas (i.e. buffer area, ante room, and chemotherapy) for each sterile compounding complex within the pharmacy for the past two years (including incubators used for in-house incubation of media plates/growth media)

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	16. Pressure logs for all compounding areas (i.e. buffer area, ante room, and chemotherapy room) for each sterile compounding complex within the pharmacy for the past two years
	17. Documentation that products used within each sterile compounding complex within the pharmacy are non-shedding or non-linting (i.e. garbing, mops, and wipes, etc.)
	18. Manufacturer specification for sterile gloves, sterile chemotherapy gloves & chemotherapy garb
	19. Information regarding HVAC system for each sterile compounding complex within the pharmacy:
	a. HVAC system's "as built" schematics that are specific to the sterile compounding complex and clearly indicate supplied air, exhausted air, and returned air
	i. Note the set-up of each HVAC system (i.e. fully ducted, partially ducted, or plenum based) for each sterile compounding complex within the pharmacy
	ii. Confirm if Air Handling Unit is dedicated to the sterile compounding complex(s)
	1. if not dedicated - list other areas it services
	b. Documentation of HVAC pre-filter changes for the past 2 years
	20. List of manufacturers & outsource pharmacies, including name and address, from whom the pharmacy purchases compounded sterile products (i.e. TPN, chemotherapy, etc, if applicable)
	21. Work orders for the past two years related to each sterile compounding complex within the pharmacy
	22. List of standard beyond use dates (BUDs) for low risk compounded products
	23. List of standard BUDs for medium risk compounded products
	24. List of BUDs for high risk compounded products
	a. List of Active pharmaceutical ingredients (APIs)
	b. Supporting data for BUDs
	c. Sterilization methods
	d. Supporting documentation, if applicable
	e. Documentation from APIs to distribution for the two most common and most recently compounded high risk products