CONNECTICUT DEPARTMENT OF
CONSUMER PROTECTION
DRUG CONTROL DIVISION

Sterile Compounding Complex Inspection Checklist

	1. List of pharmacists and pharmacy technicians that enter the sterile compounding complex
	2. Documentation of each pharmacist and pharmacy technician's sterile compounding competency
	3. List of all sterile compounding complexes within the pharmacy, hospital, and any off-site locations (i.e. cancer centers)
	4. Certification reports for the past 365 days, including primary engineering controls (PECs), for each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers)
	5. Documentation of PEC pre-filter changes for the past 365 days
	6. Documentation of the last two Media Fill tests, including the kits used to administer the Media Fill tests
	7. Documentation of the last two Gloved Fingertip tests, including the plates used to administer the Gloved Fingertip tests
	8. Standard Operating Procedures (SOPs) for the sterile compounding complex, including cleaning, gowning procedures, and environmental monitoring (EM)
	9. Documentation of cleaning the PECs, buffer area, and ante room on a daily basis for the past 365 days If daily cleaning is performed by an outside contractor, a. Documentation of training for the outside contractor b. Outside contractor must be available in person or by telephone to provide any additional information that may be needed
	10. Documentation of cleaning the PECs, buffer area, and ante room on a monthly basis for the past 365 days If monthly cleaning performed by an outside contractor, a. Documentation of training for the outside contractor b. Outside contractor must be available in person or by telephone to provide any additional information that may be needed
	11. List of cleaning products, including organism coverage and kill times, used to clean the buffer area, ante room, PECs, walls, and ceilings
	12. Documentation of all environmental monitoring performed for each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers) a. Information related to media utilized for environmental monitoring b. Information related to air sampling device utilized for environmental monitoring
	13. Temperature logs, including minimum and maximum range, for each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers)
	14. Humidity logs, if monitored

450 Columbus Boulevard, Suite 901, Hartford, Connecticut 06103
Phone: (860) 713-6065 Fax: (860) 713-7242 Email: dcp.drugcontrol@ct.gov
Internet Web Site: http://www.ct.gov/dcp/dcd

	15. Pressure logs for all compounding areas (i.e. buffer area, ante room, and chemotherapy room) for each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers)
	16. Documentation that products used within each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers) are non-shedding or non-linting (i.e. garb, mops, and wipes)
	17. Information regarding HVAC system for each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers)
	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
	b. Representative from building/facility services must be available in person or by telephone to provide information
	i. Identify all areas, including above and below, that surround each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers)
	ii. Explain the set-up of each HVAC system (i.e. fully ducted, partially ducted, or plenum based) for each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers)
	iii. Documentation of HVAC pre-filter changes
	18. List of facilities and outsource pharmacies, including name and address, from whom the hospital purchases compounded product (i.e. chemotherapy, TPN)
	19. Work orders for the past 365 days related to each sterile compounding complex within the pharmacy, hospital, and any off-site locations (i.e. cancer centers)
	20. List of standard beyond use dates (BUDs) for low risk compounded products, if applicable
	21. List of standard BUDs for medium risk compounded products, if applicable
	22. List of BUDs for high risk compounded products, if applicable
	a. 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