STATE OF CONNECTICUT

Department of Consumer Protection
Drug Control Division

Sterile Compounding Pharmacy Inspection

Please provide the following documents for inspection:

1. List of Pharmacists and Technicians that compound/enter clean room

2. Provide documentation for competency for the Pharmacist/technicians

3. List of all areas of sterile compounding within the hospital (i.e. cancer centers) or off site.

4. Provide a copy of one year's worth of Certification Reports for each compounding area in the facility

    a. Including certification of the Primary engineering controls (PEC)

    b. Provide documentation of pre-filter changes for the PEC's

5. Provide documentation of last two Media Fill tests

    a. Provide information on the kits used to administer Media fill tests

6. Provide documentation of last two Gloved Fingertip tests.

    a. Provide information on the plates used to administer gloved fingertip tests

7. Provide Standard operating procedures (SOP) pertaining to the compounding rooms such as cleaning, gowning procedures, and environmental testing.

8. Provide the documentation for cleaning of PEC, buffer areas, and ante room—daily and monthly for the last year.

    a. If the cleaning is being done by Environmental services (ES), please provide the training documentation for the cleaners.

        i. Please have a representative from ES available (in person or by phone) to provide information that may be needed.

    b. Provide a list of cleaning products used on the buffer/ante/PEC's/walls/ceilings including coverage of organisms and kill time.

9. Provide the documentation for all the environmental monitoring done by the hospital for the compounding rooms

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a. Provide information related to media utilized in the test

b. Provide information on air sampling device utilized by the facility

10. Provide Temperature log (all compounding areas)

a. Provide the range for max/min set up

11. Provide Humidity log (when monitored)

12. Provide Pressure log for Ante/Chemo/Buffer room (all compounding areas)

13. Provide documentation showing that the products used (for garbing and cleaning such as mops and wipes) are non-shedding or non-linting.

14. Information will be needed regarding HVAC systems specific to the compounding areas. Therefore a representative from facilities/building services available for information (in person or by phone)

a. Identify all the areas surrounding the compounding rooms including above and below.

b. Have knowledge of how the HVAC systems are set up i.e fully ducted, partial ducted, plenum based

c. Provide documentation of pre-filter changes to the HVAC system

15. Provide a list of the name and address of the facilities/outsource pharmacies the hospital purchases compounded product (i.e. chemotherapy, TPN)

16. Provide all work orders related to the compounding rooms for the past year

17. Provide a list of the standard beyond use dates (BUD) for LOW, MEDIUM and HIGH risk compounded products.

18. If compounding high risk products, please provide all information on ACTIVE PHARMACEUTICAL INGREDIENTS (API), BUD used with supporting data, methods of sterilization, and other supporting documentation as required.

19. If compounding high risk products, please prepare the documentation for the most recent lot of the two most compounded HIGH RISK products from API to distribution.

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