CONNECTICUT
Consumer Protection

Drug Control Division

Sterile Compounding Complex Inspection Documents

- ☐ Electronic copy of the Standard Operating Procedures (SOPs) specific to the sterile compounding program as identified in USP Chapter <797>.
- ☐ List of all personnel that enter the sterile compounding complex, including credentials for pharmacists and pharmacy technicians.
- ☐ The name of the designated pharmacist and documentation of the required 30-hour designated pharmacist training.
- ☐ List of all states the sterile compounding pharmacy is licensed in, including credentials.
- ☐ Documentation of observational competency for all personnel associated with tasks within the sterile compounding complex (staff that participate in compounding, staff that oversee compounding, cleaning personnel, etc.) for the past two years.
- ☐ *Complete* certification reports for the past two years, including environmental sampling reports.
- ☐ *Complete* documentation of the past two years of media fill tests for all compounders and staff who have direct oversight of compounding.
- ☐ *Complete* documentation of the past two years of competency in garbing and hand hygiene for all personnel that enter the sterile compounding complex, including gloved fingertip testing.
- ☐ Documentation of daily and monthly cleaning of the sterile compounding complex for the past two years.
- ☐ List of cleaning products used in the sterile compounding complex, including organism coverage and kill/dwell times.
- ☐ *Temperature*, *humidity*, and *pressure* logs for the sterile compounding complex for the past two years.
- ☐ NIST certification reports for temperature, humidity, and pressure monitoring devices for the sterile compounding complex for the past two years. Include incubators used for in-house incubation of media plates/growth media.
- ☐ Documentation to show that products used within the sterile compounding complex are low-linting (i.e. garb, mops, wipes, etc.).
- ☐ Manufacturer specifications for sterile gloves (and sterile chemotherapy gloves and chemotherapy garb, if applicable).
- ☐ Documentation of HVAC pre-filter changes for the past two years.
- ☐ Invoices for compounded sterile preparation (CSP) components for the past 6 months.
- ☐ Work orders related to the sterile compounding complex for the past two years.
- ☐ List of standard beyond-use dates (BUDs) for CSPs.
- ☐ Copy of a Master Formulation Record and Compounding Record.
- ☐ Copy of a CSP prescription label.

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