The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Health Professions Licensure

250 Washington Street, Boston, MA 02108



# Sterile Compounding Documents for Inspection

# Licenses/Registrations/Certifications:

* Massachusetts Drug Store Pharmacy License
* Massachusetts Controlled Substance Registration
* DEA Controlled Substance Registration Certificate
* Non-Resident Drug Store Pharmacy Licenses for all States Doing Business In
* Sterile Compounding License, as applicable
* Institutional Sterile Compounding License, as applicable
* Pharmacist, Pharmacy Intern, and Pharmacy Technician Licenses & Registration Cards
	+ Technician Trainee hours
* Other (DCP, FDA, etc.)

# Policy and Procedure Manual:

* Scope of Practice (e.g. Types of CSPs prepared; Roles and responsibilities of designated person(s).
* Personnel Monitoring and Evaluation (e.g. Aseptic Media Fills, Gloved Finger Tip Sampling, etc.)
* Personal Hygiene and Garbing
* Facility Design and Engineering Controls
* Certification and Recertification of Primary and Secondary Engineering Controls
* Microbiological Air and Surface Sampling
* Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% Isopropyl Alcohol
* Equipment
* Components
* Master Formulation Records and Compounding Records, including assignment of BUD
* Release Inspections and Testing (e.g. visual, pH, sterility, endotoxin, etc.)
* Labeling
* CSP Handling, Storage, Packaging, Shipping, and Transport
* Documentation
* Immediate Use Preparations, as applicable
* Blood/Biological Handling Procedures, as applicable
* Allergenic Extracts, as applicable
* Quality Assurance program including Out of Specification, RCA and CAPA
* Change control procedures
* Aseptic technique
* Patient monitoring and adverse event reporting, including recalls of CSPs.
* Proper waste handling and disposal including response to broken, spilled, damaged CSPs
* Hazardous Handling, as applicable

# Personnel Training, Competency, and Proficiency Tests:

* Training program design for new and veteran compounding personnel including didactic, observational, and return demonstration proficiency tests
* Aseptic manipulation proficiencies (e.g. Media Fill) for compounding personnel
* Gloved finger tip/thumb proficiencies for compounding personnel and external staff members (Initial and Ongoing)
* Hand Hygiene and Garbing competencies for compounding personnel and external staff members
* Cleaning and Disinfection competencies for compounding personnel and external staff members
* Environmental monitoring (Air and Surface) training for Pharmacy staff members conducting such testing

**Quality Related Documentation:**

* Environmental monitoring results including trending analysis, sampling map, and certificates of analysis for sampling media
* Certification report for compounding environment (PEC and SEC)
* Out of Specification reports for Environment, Personnel and Product including Root Cause Analysis (RCA) and Corrective Action Preventative Action CAPA.
* Defective Drug Logs and Quality Related Events documentation
* Safety Data Sheets (SDSs) and Certificates Of Analysis (COAs), as applicable
* Compounding Master Formulation Records and Individual Compounding Records
* Logs: Cleaning and Disinfection, Pressure Differentials, Temperature and Humidity, Incubator(s)
* Cleaning and Disinfection chemicals, activity, contact time, ready-to-use (RTU) or dilution (Instructions required)
* Sterility and Endotoxin Testing Report
* References and Resources utilized to determine formulation and assignment of BUD
* Extended Stability Analytical Testing Reports
* List of CSPs Produced and/or Outsourced
* List of CSPs Recalled, for any Reason