



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