

Sample Pharmacy
ORIENTATION, TRAINING AND COMPETENCY EVALUATION OF PHARMACY PERSONNEL
P-410.2

1.0 Definition and Purpose

The purpose of this policy is to provide a consistent process and mechanisms to measure and document the acquired skill sets necessary to operate the equipment and perform processes required pharmacy operations compounding sterile preparations.

2.0 Policy

- 2.1 The orientation, training and competency evaluation of compounding personnel is designed to ensure that staff are adequately skilled, educated, instructed and trained to correctly perform and document the critical activities in their sterile compounding duties.
- 2.2 A written description of specific training and a performance evaluation program for individuals involved in the use of aseptic techniques for the preparations of sterile product must be maintained by Pharmacy Leadership.
- 2.3 All pharmacists and technicians are required to pass the following: didactic coursework; practical skill assessments through competency evaluation; and media-fill testing both initially and on an ongoing basis.
- 2.4 Ongoing competency evaluation (Aseptic Technique F-410.b; Hand Hygiene and Garbing F-410.a and Cleaning and Disinfecting F0410.c) and media-fill testing must at a minimum be completed annually for employees working in pharmacies performing low/medium risk level compounding and semi-annually for pharmacies performing high risk level compounding.
- 2.5 Any employee handling, disposing or compounding Hazardous Drugs must successfully complete the Competency Assessment: Hazardous Drugs (F-700.b) prior to working with hazardous drugs and annually thereafter. Employees are not eligible to complete the Hazardous Drug Competency Assessment until they successfully complete the three base competencies mentioned in policy statement 2.4.
- 2.6 Personnel who fail written or media-fill tests, will be immediately reeducated and reevaluated by expert compounding personnel to ensure correction to all aseptic processes as well as demonstrate the ability to pass repeated written and/or media-fill tests.

3.0 Applicable Documents

- 3.1 *Competency Assessment: Hand Hygiene and Garbing; F-410.a*
- 3.2 *Competency Assessment: Aseptic Technique; F-410.b*
- 3.3 *Competency Assessment: Cleaning and Disinfecting; F-410.c*
- 3.4 *Training Roster; F-410.d*
- 3.5 *Competency Assessment: Material Handling; F-410.e*
- 3.6 *Competency Assessment: Environmental Monitoring; F-410.f*
- 3.7 *Competency Assessment: Secondary Engineering Controls; F-410.g*
- 3.8 *Competency Assessment: Primary Engineering Controls BSCs; F-410.h*
- 3.9 *Competency Assessment: Primary Engineering Controls CAIs/CACIs; F-410.i*
- 3.10 *Competency Assessment: Primary Engineering Controls LAFWs; F-410.j*
- 3.11 *Competency Assessment: Final Release Tests Sterility Testing Membrane Filtration; F-410.k*
- 3.12 *Competency Assessment: Final Release Tests Pyrogen Testing; F-410.l*

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- 3.13 *Competency Assessment: Final Release Tests Filter Integrity Testing; F-410.m*
- 3.14 *Competency Assessment: Automated Compounding Devices; F-410.n*
- 3.15 *Competency Assessment: Hazardous Drug Testing; F-700.b*
- 3.16 Quality Management and Environmental Sampling; P-204
- 3.17 *Facility and Personnel Environmental Sampling Action Report; F-204.b*
- 3.18 Personnel Media Fill and Process Verification; P-402
- 3.19 *Employee Gloved Fingertip Sampling and Media-Fill Results Log; F-402.a*
- 3.20 Gloved Fingertip Sampling; P-408
- 3.21 Hazardous Drug Employee Training and Safety Program; P-700

4.0 Procedures

- 4.1 Each employee will receive a comprehensive orientation to the company and to their specific job role. Orientation consists of didactic training experiences (written information, distance learning applications, CD-ROM based training and/or video/DVD programs) as well as hands on practical training and mentorship by qualified experts.
- 4.2 As new processes and equipment are introduced at the compounding facility, employees require ongoing training in order to properly use such new equipment or processes. Employees are required to demonstrate knowledge and skill in select procedures or tasks before they can independently perform those procedures in real life production.
- 4.3 A qualified staff member must observe all newly learned skills or procedures and staff able to return demonstrate the skill/knowledge independently (without prompting).
- 4.4 The following competencies are required to be completed upon hire and regularly thereafter as stated in policy 2.4 per USP Chapter <797>.
 - 4.4.1 *Competency Assessment: Hand Hygiene and Garbing; F-410.a*
 - 4.4.2 *Competency Assessment: Aseptic Technique; F-410.b*
 - 4.4.3 *Competency Assessment: Cleaning and Disinfecting; F-410.c*
- 4.5 Depending upon the operation, the organization may require certain additional competencies such as:
 - 4.5.1 *Competency Assessment: Material Handling; F-410.e*
 - 4.5.2 *Competency Assessment: Environmental Monitoring; F-410.f*
 - 4.5.3 *Competency Assessment: Secondary Engineering Controls; F-410.g*
 - 4.5.4 *Competency Assessment: Primary Engineering Controls BSCs; F-410.h*
 - 4.5.5 *Competency Assessment: Primary Engineering Controls CAIs/CACIs; F-410.i*
 - 4.5.6 *Competency Assessment: Primary Engineering Controls LAFWs; F-410.j*
 - 4.5.7 *Competency Assessment: Final Release Tests Sterility Testing Membrane Filtration; F-410.k*
 - 4.5.8 *Competency Assessment: Final Release Tests Pyrogen Testing; F-410.l*
 - 4.5.9 *Competency Assessment: Final Release Tests Filter Integrity Testing; F-410.m*
 - 4.5.10 *Competency Assessment: Automated Compounding Devices; F-410.n*
 - 4.5.11 *Competency Assessment: Hazardous Drug Testing; F-700.b*

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- 4.6 The orientation and training program must include, but is not limited to:
 - 4.6.1 An orientation to pharmacy activities.
 - 4.6.2 An orientation to facility activities of other departments.
 - 4.6.3 View demonstrations of aseptic technique.
 - 4.6.4 View demonstration of the preparation of all types/classes of medications compounded.
 - 4.6.5 Demonstrate adequate knowledge in and ability to perform psychomotor skills related to:
 - 4.6.5.1 Materials Staging
 - 4.6.5.2 Hand Hygiene and Garbing
 - 4.6.5.3 Facility Cleaning and Disinfection
 - 4.6.5.4 Environmental Sampling
 - 4.6.5.5 Media- fill Testing
 - 4.6.5.6 Use of all Automated Compounding Devices
 - 4.6.5.7 Use of Primary and Secondary Engineering Controls
 - 4.6.5.8 Pressure Gradient Monitoring
 - 4.6.5.9 Temperature and Humidity Monitoring
 - 4.6.5.10 Final Release Checks
 - 4.6.5.11 Labeling
 - 4.6.5.12 CSP Packaging for Delivery
 - 4.6.6 Completion of required coursework.
 - 4.6.7 Information about viable and non-viable particulate and microbial contamination.
 - 4.6.8 Information about applicable pharmaceutical and medical technology and abbreviations.
 - 4.6.9 Review all pharmacy policies and procedures.
 - 4.6.10 Pharmaceutical calculations.
 - 4.6.11 Review operating principles of the facility, equipment and maintenance procedures.
 - 4.6.12 Demonstrate a thorough understanding of the completing and using all company forms and documentation.
 - 4.6.13 Review of the organization's performance improvement program and quality management initiatives.
 - 4.6.14 Participate in product delivery if deemed required.
 - 4.6.15 Participate in intradepartmental visits/meetings as needed.
 - 4.6.16 Refer to policy P-700 for information on training relative to Hazardous Drug compounding.

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5.0 Documentation

- 5.1 All occurrences of training whether during initial orientation or ongoing training must be documented.
- 5.2 Written competency assessment forms must be developed for any competencies required by the organization and used to document competency testing.
- 5.3 Media-fill testing and Gloved Fingertip sampling must be documented on the *Employee Gloved Fingertip Sampling and Media-Fill Results Log (F-402.a)*.
- 5.4 Should the employee fail Media-Fill Testing or Fingertip Sampling, this must be documented on the *Facility and Personnel Environmental Sampling Action Report (F-204.b)*.
- 5.5 See Personnel Media Fill and Process Verification (P-402) and Gloved Fingertip Sampling (P-408) for specific information.
- 5.6 The *Training Roster (F-410.d)* must be used to document instances of ongoing inservice training not documented elsewhere (i.e., in distance learning modules).

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