COMPETENCY AND TRAINING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797> (2008) Requirements

Competency		
Low and Medium Risk: All training shall be completed and documented before any compounding personnel begin to prepare CSPs.		
Type of Competency	**Test**	**Frequency**
Written Test	Pharmaceutical calculations and terminology Aseptic technique Quality Assurance procedures Skills necessary to perform the assigned tasks	Initially, then at least every 12 months
Demonstration/ Observation	Hand hygiene & Garbing procedures, aseptic technique, achieving and maintaining ISO Class 5 environment, cleaning and disinfection procedure	Initially, then at least every 12 months
Process Validation	Media Fill testing	Initially, then at least every 12 months, or whenever the QA program yields an unacceptable result
	Gloved Fingertip Testing - Garbing: Immediately after donning all garb without disinfection gloves with 70% alcohol	3 sets initially, then one set at least every 12 months, or whenever the QA program yields an unacceptable result Action level - Greater than 0 CFU
	Gloved Fingertip Testing - Aseptic Technique: Immediately after completing the media-fill preparation	1 set initially, then at least every 12 months, or whenever the QA program yields an unacceptable result Action level - Greater than 3 CFU
High Risk: All training shall be completed and documented before any compounding personnel begin to prepare CSPs.		
Written Test	Pharmaceutical calculations and terminology Aseptic technique Quality Assurance procedures Skills necessary to perform the assigned tasks Sterilization technique	Initially, then at least every 12 months
Demonstration/ Observation	Hand hygiene & Garbing procedures, aseptic technique, achieving and maintaining ISO Class 5 environment, cleaning and disinfection procedure Sterilization techniques	Initially, then at least **every 6 months**
Process Validation	Media Fill Testing	Initially, then at least **every 6 months**, or whenever the QA program yields an unacceptable result
	Gloved Fingertip Testing - Garbing: Immediately after donning all garb without disinfection gloves with 70% alcohol	3 sets initially, then one set at least **every 6 months,** or whenever the QA program yields an unacceptable result Action level - Greater than 0 CFU
	Gloved Fingertip Testing - Aseptic Technique: Immediately after completing the media-fill preparation	1 set initially, then at least **every 6 months,** or whenever the QA program yields an unacceptable result Action level - Greater than 3 CFU

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. The tool is not a fixed compliance assessment that must be followed and should not be construed as legal advice or used to resolve legal problems.

Last Revised 9/17/18

TRAINING REQUIREMENTS	
Training	**Comments**
Hand hygiene and gloving	• Training includes theoretical principles and practical skills • Must complete didactic training, pass written competency and skills assessment (observation audit, GF testing, and media fill) before any compounding personnel begin to prepare/ handle CSPs • Media fill – simulates most challenging/ complicated condition/procedure actually encountered, and contains same amount of volume transferred. Verifies capability of compounding environment, aseptic technique and processes to produce sterile preparations
Procedure for Gloved Fingertip Sampling	
Order of Garbing procedures	
Aseptic work practices/technique (avoid touch contamination)	
Sterilization procedures for high risk compounding (if applicable)	
Pharmaceutical calculations & terminology	
Sterile compounding documentation (Compounding Log, Master Formula Record, Labelling, BUD, etc.)	
Quality assurance procedures	
Process validation using media fill tests	
General conduct in the controlled area	
Container, equipment and closure system selection	
Safe handling and compounding of CSPs (including hazardous drugs if applicable)	
Procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding	
Procedures for evaluating, maintaining, certifying, cleaning, disinfecting the facility/environment	
Achieving/maintaining ISO 5 (disinfect gloves and surfaces)	
Written training program	
Policy & Procedures	
Spill Management (pharmacy, nursing & other personnel)	
Train other support services (e.g. housekeeping) on hand hygiene, garbing, cleaning & disinfecting procedures	
Training documentation retained	

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