Sterile Compounding eLearning Course Curriculum
28 lessons with 33 hours of CE

Fundamentals of Sterile Compounding (8 lessons/8 hours CE)

The History of Compounding and USP Sterile Compounding Chapters (1 hr)
• Explain the evolution of pharmacy compounding guidelines up to present day USP Chapter <797> Pharmaceutical Compounding - Sterile Preparations
• Describe the roles of the USP and the FDA with regard to standards and enforcement
• Exhibit increased awareness of pharmacy compounding guidelines as they impact your daily decisions while performing sterile compounding activities
• Describe relevant regulatory requirements associated with pharmacy sterile compounding

Determining Beyond-Use Dating (1 hr)
• Differentiate expiration date from beyond-use date (BUD).
• Discuss the two factors that determine the beyond-use date.
• List the five Compounding Sterile Preparation (CSP) Risk Levels and give examples of each.
• Describe the controlled storage conditions and BUD for each type of CSP risk level.
• List the maximum beyond-use dating for single-dose and multiple does containers as well as pharmacy bulk packaging

Quality Releases and Final Checks of CSPs (1 hr)
• Identify the purpose of quality release checks
• List the specific types of quality release checks
• Explain how to recognize a failed quality release check
• Describe how the environment and compounders can impact the quality of compounded sterile preparations (CSPs)

Labeling and Packaging (1 hr)
• Identify required elements of a final compounded sterile preparation (CSP) label
• Discuss the importance of standardization in labeling
• Explain considerations for positioning and adhering the label to the final CSP
• State when to perform final labeling
• Explain how to properly store and package the final CSP containers

Master Formulation and Compounding Records (1 hr)
• Define batch documentation
• Identify essential items found on a CSP compounding worksheet
• Explain the purpose and function of suggested elements found on a compounding worksheet
• Describe how batch documentation can be used in a quality management program
Fundamentals of Sterile Compounding (continued)

Purpose and Effective Use Standard Operating Procedures (1 hr)
• Identify the characteristics of effective policies and procedures (PnPs)
• List the Standard Operating Procedures (SOPs) that every compounding organization should have
• Discuss the content, format and control of PnPs

General Elements of Documentation (1 hr)
• List the purposes of documentation
• Identify elements of good documentation
• List documentation “Do's” and “Don'ts”
• Identify characteristics of effective forms
• Describe documentation audits

Use of Automated Compounding Devices (ACDs) (1 hr)
• Contrast the operation of gravimetric and volumetric Automated Compounding Devices (ACDs)
• Describe ACD daily set up, calibration and cleaning requirements
• Discuss concerns relative to tubing and source container changes
• Describe the importance of staff training and competency verification

Engineering Controls for Sterile Compounding (2 lessons/4 hours CE)

Primary Engineering Controls: Function, Use, Testing and Certification (2 hrs)
• Incorporate concepts fundamental to primary engineering controls into your everyday sterile compounding activities
• Describe the regulatory requirements and recommendations for all types engineering controls used in sterile compounding
• Describe the considerations for placement and general use of primary engineering controls
• Distinguish between different types of primary engineering controls based on their function, placement, venting and maintenance
• Summarize the testing and certification standards/requirements for primary engineering controls

Secondary Engineering Controls: Function, Use, Testing and Certification (2 hrs)
• Incorporate concepts fundamental to secondary engineering controls into your everyday sterile compounding activities
• List essential cleanroom design and build considerations of walls, ceilings, floors and pass-throughs
• Describe special considerations for hand drying and hazardous drug storage
• Describe the regulatory requirements including special considerations based on compounding risk level
• Summarize the testing and certification standards/requirements for secondary engineering controls
Personnel Sampling Metrics (2 lessons/3 hours CE)

Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (2 hrs)
• Describe why hand hygiene and garbing are important for reducing the risk of contamination to compounded sterile preparations (CSPs)
• Describe gloved fingertip sampling as required by USP Chapter <797> and why it is important
• Correctly perform hand hygiene, garbing and gloved fingertip sampling (GFS)
• Describe considerations for general attire and personal protective equipment (PPE)

Personnel Aseptic Media Fill and Competency Evaluation (1 hr)
• State the major learning processes for compounding sterile preparations
• List practical skills that compounding personnel need to master
• List the type and frequency of tests that compounding personnel need to successfully complete

Viable Facility Sampling Metrics (2 lessons/2 hours CE)

Volumetric Air Sampling (1 hr)
• Define Volumetric Air Sampling as part of an overall Environmental Sampling (ES) Plan including where and when it is performed
• List the steps in Volumetric Air Sampling in the correct sequence
• Describe how to read, interpret and document the results of air sampling
• List the steps to take when results of colony forming unit (CFU) counts are out of limit

Surface Sampling (1 hr)
• Define Surface Sampling including where and when it is performed
• List the steps to set up and begin Surface Sampling
• Explain the process of obtaining, processing and incubating the surface samples
• Describe how to read, interpret and document the results of surface sampling
• List the steps to take when the counts of colony forming units (CFUs) are beyond established Action Levels

Sanitization of Pharmacy Controlled Environments (3 lessons/3 hours CE)

Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (1 hr)
• Describe the purpose and general principles of cleaning
• Identify cleaning requirements outlined in USP <797>
• Adhere to principles related to the proper selection, preparation and use of cleaning agents and supplies
• Cite key considerations for personnel safety, training and competency
Sanitization of Pharmacy Controlled Environments (continued)

Cleaning and Disinfection of Primary Engineering Controls (1 hr)
- Describe specific cleaning activities related to primary engineering controls (PECs)
- Differentiate between the agents used in PEC daily cleaning versus those used in ongoing disinfection of the PEC that occurs periodically during the compounding day
- Properly sequence the activities involved in cleaning PECs
- Explain the rationale for the sequence of cleaning activities
- Contrast the differences in cleaning activities based on the type of PEC being used
- Identify critical mistakes in cleaning activities

Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (1 hr)
- Describe specific daily and monthly cleaning activities for a sterile compounding facility
- Properly sequence the specific activities involved in daily and monthly cleaning
- Explain the rationale for the sequence of daily and monthly cleaning activities
- Identify common misconceptions about cleaning practices that may lead to increased bioburden

Aseptic Technique and Work Related Practices (5 lessons/5 hours CE)

Overview of Quality and Responsibilities of Compounding Personnel (1 hr)
- Explain the evolution of pharmacy compounding guidelines up to present day USP Chapter <797>
Pharmaceutical Compounding - Sterile Preparations
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Proper Material Handling (1 hr)
- Define material handling
- Identify potential consequences of improper material handling
- List the USP Chapter <797> requirements and best practice recommendations for material handling activities that occur before compounding
- Identify the optimal sequence of events relative to material procurement during the compounding phase
- List the USP Chapter <797> requirements and best practice recommendations for material handling activities that occur after compounding has been completed

Use of Syringes, Needles, Vials, Ampules and Filters (1 hr)
- Explain the evolution of pharmacy compounding guidelines up to present day USP Chapter <797>
Pharmaceutical Compounding - Sterile Preparations
- Describe the roles of the USP and the FDA with regard to standards and enforcement
- Exhibit increased awareness of pharmacy compounding guidelines as they impact your daily decisions while performing sterile compounding activities
- Describe relevant regulatory requirements associated with pharmacy sterile compounding
Aseptic Technique and Conduct in Controlled Environments (1 hr)
• Conduct yourself properly in ISO controlled sterile compounding environments
• Prepare components for entry into the ISO controlled environments and specifically for entry into the ISO Class 5 environment
• Discuss the importance of the location and direction of first air in primary engineering controls
• Position components, supplies and gloved hands properly when performing aseptic manipulations

Sterile Compounding on Patient Units (for nursing and medical staff) (1 hr)
• Perform sterile drug preparation according to the best practice recommendations presented and in accordance with professional association standards in the instances when sterile drug preparation occurs on patient units.
• Describe safe injection, infusion and medication vial practices.
• Demonstrate best practice infection prevention procedures related to hand hygiene, garbing, material handling, cleaning and aseptic technique.
• List the requirements for labeling of nurse mixed sterile solutions.

Filtration and Sterility Testing (1 hr)
• Explain the critical concepts of sterility/sterilization and filtration
• Describe how to perform filter integrity testing
• Explain why sterility testing is necessary
• Describe the sterility testing process

Moist and Dry-Heat Sterilization (1 hr)
• Identify the critical concepts of sterilization
• Describe the process of moist heat sterilization
• Describe the process of dry heat sterilization
• Explain how to verify the effectiveness of a terminal sterilization cycle through the use of Biological Indicators (BIs)

Bacterial Endotoxin (Pyrogen) Testing (1 hr)
• Define terminology and concepts relevant to Bacterial Endotoxin testing (BET)
• List the requirements of USP Chapters <85> and <797> relative to BET
• Explain why BET is important in sterile compounding
• Identify sources of pyrogens
• Recall information about Limulus Amebocyte Lysate (LAL) gel clot pyrogen testing
Requirements and Best Practices for Hazardous Drug Compounding (3 lessons/5 hours CE)

Introduction and Overview
• List the adverse health risks of occupational exposure to hazardous drugs (HDs)
• Describe the occupational sources of HD contamination that may result in exposure of workers
• Compare the key strategies described by OSHA, NIOSH, ASHP and USP for minimizing the risk of occupational exposure to HDs
• Develop a plan to identify HDs used at your organization including an assessment of risk
• Demonstrate the specific administrative, environmental, personal protective equipment (PPE) and work practice controls that result in improved safety
• Describe the recommended environmental and medical surveillance

Engineering Controls and Personal Protective Equipment
• Describe the types of compliant HD primary and secondary engineering controls for both sterile and non-sterile compounding
• Discuss considerations relevant to the use of pass-throughs in HD applications
• Analyze the allowable but suboptimal designs of HD secondary engineering controls
• Select the correct type of personal protective equipment (PPE) for hazardous drug compounding and other handling scenarios
• List the proper sequence and methods of donning and doffing HD PPE

Hazardous Drug Work Practice Strategies
• Demonstrate proper work practices essential to containment of HD residues from receipt of inventory, material transfer, storage, compounding, labeling and packaging of final compounded preparations and their transport to patients.
• Contrast negative pressure compounding techniques used in HD sterile compounding with the use of CSTDs
• Properly sequence and perform decontamination, cleaning and disinfection in HD handling environments
• Design an effective spill management program that meets the requirements of Chapter <Chapter <800> as well as addresses the logistical and practical challenges often encountered managing spills
• Describe strategies for the development and maintenance of effective written policies and procedures (standard operating procedures), initial and ongoing training as well as documentation.

ACPE-Approved Continuing Education is valid from August 1, 2016 through July 31, 2018.