Sterile Compounding 2013

Fundamentals of Sterile Compounding (10 lessons/10 hours CE)

The History of Compounding and USP <797>
- 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

Overview of Quality and Responsibilities of Compounding Personnel
- 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
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Determining Beyond-Use Dating
- Explain the evolution of pharmacy compounding guidelines up to present day USP Chapter <797>
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- Exhibit increased awareness of pharmacy compounding guidelines as they impact your daily decisions while performing sterile compounding activities
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Use of Syringes, Needles, Vials, Ampules and Filters
- Explain the evolution of pharmacy compounding guidelines up to present day USP Chapter <797>
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Proper Material Handling
- 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
Quality Releases and Final Checks of CSPs
- 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
- 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

Batch Documentation and CSPs
- 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

Purpose and Effective Use of Policies and Procedures
- 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

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

Primary Engineering Controls: Function, Use, Testing and Certification
- 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
- 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

Facility and Personnel Environmental Sampling Metrics (5 hours CE/4 lessons)

Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (2 hours CE)
- 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
- 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

Volumetric Air Sampling
- 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
- 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

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

Overview of Cleaning and Disinfection of Pharmacy Controlled Environments
- 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

Cleaning and Disinfection of Primary Engineering Controls
- 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
- 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

Optional Compounding Practices (4 lessons/4 hours of CE)

Filtration and Sterility Testing
- 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
- 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
- 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

Automated Compounding Devices (ACDs)
- 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

Hazardous Drug Compounding (2 lessons/4 hours of CE)

Hazardous Drug Health Effects, Occupational Risk and Safe Handling
- 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 recommendations from OSHA, NIOSH, ASHP and USP for minimizing the risk of occupational exposure to HDs
- Demonstrate the specific administrative, environmental, personal protective equipment (PPE) and work practice controls that result in improved safety in handling HDs at your work setting

Specific Hazardous Drug Work Practices and Spill Cleanup
- Select the correct type of personal protective equipment (PPE) for sterile hazardous drug (HD) compounding
- Demonstrate proper work practices related to material transfer and organization of compounding work space
- Describe negative pressure compounding techniques used in HD sterile compounding
- Practice proper decontamination, containment and disposal procedures for trace and bulk HD waste
- List 2 systems used to train and verify the HD compounding competency of personnel
- Perform HD spill cleanup