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)
- 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

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) – Previously named: 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 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) – Previously named: 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

Use of Automated Compounding Devices (ACDs) (1 hr) – Previously located under the Course: Optional Compounding Practices
• 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)

Previously named: Facility and Personnel Environmental Sampling Metrics

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) – New Topic

Volumetric Air Sampling (1 hr) Previously located under the Course: Facility and Personnel Environmental Sampling Metrics
- 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) Previously located under the Course: Facility and Personnel Environmental Sampling Metrics
- 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)

Previously named: Cleaning of Pharmacy Controlled Environments

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

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) Previously named: 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

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

Overview of Quality and Responsibilities of Compounding Personnel (1 hr) Previously located under the Course: Fundamentals of Sterile Compounding
• 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
Proper Material Handling (1 hr) Previously located under the Course: *Fundamentals of Sterile Compounding*

- 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) Previously located under the Course: *Fundamentals of Sterile Compounding*

- 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) New Lesson

- 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) New Lesson

- 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)

Previously named: Hazardous Drug Compounding

Introduction and Overview (1 hr) – Updated lesson Hazardous Drug Health Effects, Occupational Risk and Safe Handling to incorporate new Chapter <800>

• 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 (2 hr) – New HD Lesson

• 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 (2 hr) – Updated lesson Specific Hazardous Drug Work Practices and Spill Cleanup to incorporate new Chapter <800>

• 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.