Sterile Compounding eLearning Course Curriculum
29 lessons with 34 hours of CE

CriticalPoint's Sterile Compounding eLearning curriculum is written by industry experts and covers both Chapter <797> and <800>. All content is current and updated to reflect industry standards and CriticalPoint's best practice recommendations. These lessons include high resolution images and interactivity. The format of our eLearning creates an engaging learning experience that we believe will result in improved knowledge transfer as well as change of performance in the work setting.

Our eLearning includes:

- Individual procedures broken down into interactive steps
- Videos demonstrating actual procedures
- Interactive exercises that check learners' knowledge
- Lessons and Post Tests packaged together

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

The History of Compounding and USP Sterile Compounding Chapters (1 hr)
0761-9999-18-243-H07-P
0761-9999-18-243-H07-T

- 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)
0761-9999-18-244-H07-P
0761-9999-18-244-H07-T

- 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.

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Quality Releases and Final Checks of CSPs (1 hr)
0761-9999-18-245-H07-P
0761-9999-18-245-H07-T

- 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 CSPs.

Labeling and Packaging (1 hr)
0761-9999-18-246-H07-P
0761-9999-18-246-H07-T

- Identify required elements of a final 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)
0761-9999-18-247-H07-P
0761-9999-18-247-H07-T

- 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)
0761-9999-18-248-H07-P
0761-9999-18-248-H07-T

- Identify the characteristics of effective standard operating procedures (SOPs).
- List the SOPs that every compounding organization should have.
- Discuss the content, format and control of SOPs.

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General Elements of Documentation (1 hr)
0761-9999-18-249-H07-P
0761-9999-18-249-H07-T

- 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)
0761-9999-18-250-H07-P
0761-9999-18-250-H07-T

- 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)
0761-9999-18-251-H07-P
0761-9999-18-251-H07-T

- Incorporate concepts fundamental to primary engineering controls (PECs) 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 PECs.
- Distinguish between different types of PECs based on their function, placement, venting and maintenance.
- Summarize the testing and certification standards/requirements for PECs.

Secondary Engineering Controls: Function, Use, Testing and Certification (2 hrs)
0761-9999-18-252-H07-P
0761-9999-18-252-H07-T

- 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.

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Personnel Sampling Metrics (2 lessons/3 hours CE)

Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (2 hrs)
0761-9999-18-253-H07-P
0761-9999-18-253-H07-T

- Explain why hand hygiene and garbing are important for reducing the risk of contamination to CSPs.
- Discuss the considerations for general attire and personal protective equipment (PPE).
- List the performance elements of hand hygiene, garbing and gloved fingertip sampling (GFS) as required by USP Chapter <797>.
- Analyze best practice recommendations made in this lesson for hand hygiene, garbing and gloved fingertip sampling and decide if you will apply them to your pharmacy.
- Correctly perform hand hygiene, garbing and gloved fingertip sampling.

Personnel Aseptic Media Fill and Competency Evaluation (1 hr)
0761-9999-18-254-H07-P
0761-9999-18-254-H07-T

- 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)
0761-9999-18-255-H07-P
0761-9999-18-255-H07-T

- Define Volumetric Air Sampling as part of an overall Environmental Sampling Plan (ESP) 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 above the action level.

Surface Sampling (1 hr)
0761-9999-18-256-H07-P
0761-9999-18-256-H07-T

- Define Surface Sampling including where and when it is performed.
- List the steps to set up and begin Surface Sampling.
- Identify the correct steps for 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.

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Cleaning Pharmacy Controlled Environments 3 lessons/3 hours CE)

Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (1 hr)
0761-9999-18-257-H07-P
0761-9999-18-257-H07-T

- 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)
0761-9999-18-258-H07-P
0761-9999-18-258-H07-T

- Describe specific cleaning activities related to 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)
0761-9999-18-259-H07-P
0761-9999-18-259-H07-T

- 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.

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

Overview of Quality and Responsibilities of Compounding Personnel (1 hr)
0761-9999-18-260-H07-P
0761-9999-18-260-H07-T

- State the goal of a quality system.
- List ISO designations relevant to sterile compounding.
- Describe how particulates can affect ISO air quality and actions to reduce particulates.
- Define USP <797> risk levels.
- Explain desired quality assurance program components.

Proper Material Handling (1 hr)
0761-9999-18-261-H07-P
0761-9999-18-261-H07-T

- 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)
0761-9999-18-262-H07-P
0761-9999-18-262-H07-T

- Define syringe, needle, vial, ampule and filter.
- Identify parts of a syringe, needle, vial and ampule.
- Identify the appropriate syringe based on volume of solution.
- Explain the sequence of activities when attaching a needle to a syringe.
- Explain the sequence of activities when removing drugs from a vial or an ampule.
- State the critical handling tips for each device.

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Aseptic Technique and Conduct in Controlled Environments *(1 hr)*
0761-9999-18-263-H07-P
0761-9999-18-263-H07-T

- 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 (1 hr)
0761-9999-18-264-H07-P
0761-9999-18-264-H07-T

- 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 care areas such as inpatient units, office practices, emergency departments and operating suites.
- 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 sterile drugs mixed outside of controlled pharmacy environments.

Nonsterile to Sterile Compounding Practices (4 lessons/4 hours CE)

Sterility Testing Requirements of USP <71> and <797>
0761-9999-19-070-H07-P
0761-9999-19-070-H07-T

- Identify when sterility testing must be performed
- Explain the critical concepts of sterility testing
- Discuss why sterility testing is necessary
- Understand the requirements of sterility testing per USP <71>
- Describe the sterility testing process

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Bacterial Endotoxin Testing

0761-9999-19-071-H07-P

0761-9999-19-071-H07-T

- Define terminology and concepts relevant to Bacterial Endotoxin Testing (BET)
- List the requirement 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)

Moist and Dry Heat Sterilization Methods

0761-9999-19-072-H07-P

0761-9999-19-072-H07-T

- Identify the critical concepts of terminal sterilization of compounded sterile preparations (CSPs)
- 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)

Sterilization by Filtration

0761-9999-19-073-H07-P

0761-9999-19-073-H07-T

- Discuss important concepts about the limitations of sterilization by filtration
- Explain the required information needed to select the correct filter
- State the correct procedure for using a filter to sterilize a solution intended for a compounded sterile preparation (CSP)
- Describe when and how to perform filter integrity testing as well as required elements of documentation

Requirements and Best Practices for Hazardous Drug Compounding (3 lessons/5 hours CE)

Hazardous Drug Introduction and Overview (1 hr)

0761-9999-18-268-H07-P

0761-9999-18-268-H07-T

- 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.

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- 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 hrs)
0761-9999-18-269-H07-P
0761-9999-18-269-H07-T

- 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 hrs)
0761-9999-18-270-H07-P
0761-9999-18-270-H07-T

- 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, 2018 through July 31, 2020.

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