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

Though CriticalPoint’s Sterile Compounding eLearning curriculum is consistent with current and potentially with proposed USP standards, our eCurriculum primarily focuses on teaching CriticalPoint’s recommended best practices. Each organization must determine its own specific standard operating procedures (SOPs). The eLessons do not reflect state-specific requirements. It is the responsibility of each organization to know and comply with their state’s Pharmacy, Department of Health, or other applicable regulations.

The eCurriculum includes high-resolution images, video, and interactivity, which helps to create an engaging learning experience that we believe will result in improved knowledge learning. To stimulate the maximum transfer of the knowledge from this curriculum into your work setting (and thereby realize the best return on investment), CriticalPoint strongly recommends that these lessons NOT be assigned to be taken all at once within a given period. That approach results in less learning and merely checks the box. Break the curriculum into groups based on the compounding performed at your organization and the role each employee plays in your organization.

In CriticalPoint eLearning,
• procedures are broken down into steps that require user intervention.
• high definition videos demonstrate procedures in real work environments.
• learners’ attention and ability to use the information is checked during eLessons.
• eLessons and Post Tests are packaged together for user convenience.

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

The History of Compounding and USP Sterile Compounding Chapters (1 hour)
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 (2019).
• Describe the roles of the USP and the FDA concerning 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 compounding.

Determining Beyond-Use Dating (1 hour)
0761-9999-18-244-H07-P
0761-9999-18-244-H07-T

• Describe situations that are not considered compounding.
• Differentiate expiration from beyond-use dates.
• Explain the Immediate Use provision in USP 797 (2019).
• Discuss the conditions that influence the beyond-use date (BUD) assignment.

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Determining Beyond-Use Dating (continued)
- Define the two categories described in USP 797.
- Describe conditions that differentiate the storage conditions for each category.
- List the use and maximum beyond-use dating for conventionally manufactured products, and pharmacy prepared single-dose and multiple-dose containers.

Quality Releases and Final Checks of CSPs (1 hour)
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.
- Discuss the release inspections and testing per USP 797 (2019).

Labeling and Packaging (1 hour)
0761-9999-18-246-H07-P
0761-9999-18-246-H07-T
- Identify the 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 store and package the final CSP containers properly.

Master Formulation and Compounding Records (1 hour)
0761-9999-18-247-H07-P
0761-9999-18-247-H07-T
- Identify the key differences between a Master Formulation Record (MFR) and a Compounding Record (CR).
- Describe and explain the purpose of USP 797 (2019) requirements relative to compounding documentation.
- List the circumstances which require the use of an MFR based on USP 797 as well as best practice recommendations about MFRs.
- Develop a plan to implement this compounding documentation at your pharmacy.

Purpose and Effective Use Standard Operating Procedures (1 hour)
0761-9999-18-248-H07-P
0761-9999-18-248-H07-T
- Identify the characteristics of effective Standard Operating Procedures (SOPs).
- List the USP 797 (2019) requirements for SOPs.
- Discuss the content, format, and control of SOPs.

General Elements of Documentation (1 hour)
0761-9999-18-249-H07-P
0761-9999-18-249-H07-T
- List the purposes of documentation.

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General Elements of Documentation (continued)

- 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 (1 hour)
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.
- List USP 797 (2019) requirements on the use and proper placement of ACDs.

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

Primary Engineering Controls: Function, Use, Testing and Certification (2 hours)
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 of 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 hours)
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.
- Summarize the testing and certification standards/requirements for secondary engineering controls.
eCourse: Personnel Sampling Metrics (2 lessons/3 hours CE)

Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (2 hours)
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 compounded sterile preparations (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 (2019).
• 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 Competency Testing in Aseptic Manipulation (1 hour)
0761-9999-18-254-H07-P
0761-9999-18-254-H07-T

• Discuss the resources used for the development of training materials and how they relate to organizational SOPs.
• Describe the desired aseptic technique behaviors that relate to media-fill testing and requirements for observation in USP 797 (2019).
• List the requirements of USP 797 (2019) as they relate to media-fill testing and aseptic technique competency.
• Develop media-fill test documentation that meets or exceeds USP 797 (2019) requirements.

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Surface Sampling (continued)
- 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.

**eCourse: Cleaning Pharmacy Controlled Environments (3 lessons/3 hours CE)**

Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (1 hour)
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 (2019).
- 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 hour)
0761-9999-18-258-H07-P
0761-9999-18-258-H07-T
- Describe specific cleaning activities related to the types of PECs used at your facility.
- Differentiate between the agents used in PEC daily and monthly cleaning and disinfection versus hazardous drug (HD) decontamination versus the sIPA, which is used to remove residues and sanitize throughout 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.

Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (1 hour)
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.

**eCourse: Aseptic Technique and Work-Related Practices (5 lessons/5 hours CE)**

Overview of Quality and Responsibilities of Compounding Personnel (1 hour)
0761-9999-18-260-H07-P
0761-9999-18-260-H07-T
- Describe the requirements of a quality management system for pharmaceutical compounding.
- Differentiate between the term quality assurance and quality control.
- List the responsibilities of the designated person (DP) or persons as well as the responsibilities of compounding staff.

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Overview of Quality and Responsibilities of Compounding Personnel (continued)

- Describe required notification and recall of out of specification dispensed compounded sterile preparations (CSPs).
- List USP 797 (2019) requirements relative to complaint handling and adverse event reporting.

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

- Define material handling.
- Identify the potential consequences of improper material handling.
- List the USP Chapter 797(2019) 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 hour)
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 the 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.

Aseptic Technique and Conduct in Controlled Environments (1 hour)
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 Outside of SCAs and Cleanroom Suites (1 hour)
0761-9999-18-264-H07-P
0761-9999-18-264-H07-T

- State the definition of what is not compounding, also known as preparation per approved labeling.
- Define the differing use requirements for proprietary bag and vial systems assembled for immediate use and future use.
- List the six conditions which must be met for Immediate Use CSPs whereby Category 1 and Category 2 requirements are not required.

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Sterile Compounding Outside of SCAs and Cleanroom Suites (continued)

- 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 used when compounding occurs outside of ISO 5 conditions.

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

Sterility Testing Requirements of USP 71 and 797 (1 hour)
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.

Bacterial Endotoxin Testing (1 hour)
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 bacterial endotoxin testing is essential in sterile compounding.
- Identify sources of pyrogens.
- Recall information about Limulus Amebocyte Lysate (LAL).

Steam and Dry Heat Sterilization Methods (1 hour)
0761-9999-19-072-H07-P
0761-9999-19-072-H07-T

- Identify the critical concepts of terminal sterilization of compounded sterile preparations.
- Describe the process of steam 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.

Sterilization by Filtration (1 hour)
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.
eCourse: Requirements and Best Practices for Hazardous Drug Compounding
(3 lessons/5 hours CE)

Hazardous Drug Introduction and Overview (1 hour)
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.
- 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 hours)
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 hours)
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 USP 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 2018 through July 2020