2020–2022 Sterile Compounding eLearning Curriculum
32 eLessons with 34.5 hours of CE

Though CriticalPoint's Sterile Compounding eLearning curriculum is consistent with current and potentially with proposed USP standards, our eCourses primarily focus 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 its state's Board of 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 knowledge from this curriculum into your work setting (and thereby realize the best return on investment), CriticalPoint strongly recommends these eCourses be assigned in a logical sequence. Assigning a new employee to take the complete curriculum at one time (or in a given period, say the first week or two of employment) makes it impossible to adequately learn the material. People need to take specific eLearning and then practice what they've learned and apply it in their work. Assigning the entire curriculum all at one time results in less learning and merely checks the box. Break the curriculum down by eCourses or even groups within the eCourses. Group all didactic training based on the role each person will play in your organization. Allow them to learn the information in manageable "chunks," and then observe how each is played out at your pharmacy.

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 abilities to use the information are checked during eLessons.
- eLessons and Post Tests are packaged together for user convenience.

---

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

The History of Compounding and USP Sterile Compounding Chapters (1 hour)
0761-9999-20-133-H07-P
0761-9999-20-133-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)
0761-9999-20-134-H07-P
0761-9999-20-134-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.
- 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)
0761-9999-20-135-H07-P
0761-9999-20-135-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 compounded sterile preparations (CSPs).
- Discuss the release inspections and testing per USP 797 (2019).

Labeling and Packaging (1 hour)
0761-9999-20-136-H07-P
0761-9999-20-136-H07-T

- Identify the 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 hour)
0761-9999-20-137-H07-P
0761-9999-20-137-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 that 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 of Standard Operating Procedures (1 hour)
0761-9999-20-138-H07-P
0761-9999-20-138-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)
0761-9999-20-139-H07-P
0761-9999-20-139-H07-T
- Review the required documentation elements of USP 797 (2019).
- 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 (1 hour)
0761-9999-20-140-H07-P
0761-9999-20-140-H07-T
- Contrast the operation of gravimetric and volumetric automated compounding devices (ACDs).
- Describe ACD daily setup, 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.

---

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

Primary Engineering Controls: Function, Use, Testing, and Certification (2 hours)
0761-9999-20-141-H07-P
0761-9999-20-141-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 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 hours)
0761-9999-20-142-H07-P
0761-9999-20-142-H07-T
- Incorporate concepts fundamental to secondary engineering controls (SECs) into your everyday sterile compounding activities.
- List essential cleanroom design and build considerations of walls, ceilings, floors, and pass-throughs.

(continued on next page)

Secondary Engineering Controls: Function, Use, Testing, and Certification *(continued)*

- 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 eLessons/3 hours CE)

Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (2 hours)
0761-9999-20-143-H07-P
0761-9999-20-143-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 eLesson 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)
0761-9999-20-144-H07-P
0761-9999-20-144-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.

---

eCourse: Viable Facility Sampling Metrics (3 eLessons/2.5 hours CE)

Overview of Environmental Monitoring (1 hour)
0761-9999-20-145-H07-P
0761-9999-20-145-H07-T

- Define environmental monitoring, and explain its importance to sterile compounding pharmacies.
- List the essential components of an environmental monitoring program.
- Explain the difference between alert and action levels and why they are essential to a compliant program.
- Identify the correct steps for processing, incubating, and reading viable air and surface samples.

Viable Air and Surface Sampling (0.5 hours)
0761-9999-20-146-H07-P
0761-9999-20-146-H07-T

- Define viable air and surface sampling as part of an overall environmental monitoring (EM) program.
- Describe the difference between volumetric and gravimetric air sampling.
- List the steps for viable air and surface sampling in the correct sequence.

Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (1 hour)
0761-9999-20-147-H07-P
0761-9999-20-147-H07-T

- List the necessary steps to take in the event of an exceeded action level.
- Describe the key elements that must be part of the documentation associated with the investigation.
- Identify common microorganisms recovered in sterile compounding environments and their typical source.
- Apply general concepts of investigating and remediating a microbial excursion to your own organization.

---

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

Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (1 hour)
0761-9999-20-148-H07-P
0761-9999-20-148-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)
0761-9999-20-149-H07-P
0761-9999-20-149-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 that 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)
0761-9999-20-150-H07-P
0761-9999-20-150-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 eLessons/5 hours CE)*

Overview of Quality and Responsibilities of Compounding Personnel (1 hour)
0761-9999-20-151-H07-P
0761-9999-20-151-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.
- 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)
0761-9999-20-152-H07-P
0761-9999-20-152-H07-T

- Define material handling.
- Identify the potential consequences of improper material handling.
- List the USP Chapter 797 (2019) requirements as well as CriticalPoint 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.
- State the USP Chapter 797 requirements as well as CriticalPoint best practice recommendations for material-handling activities that occur after compounding has been completed.

Use of Syringes, Needles, Vials, Ampules, and Filters (1 hour)
0761-9999-20-153-H07-P
0761-9999-20-153-H07-T

- Define the terms syringe, needle, vial, ampule, and filter.
- Identify parts of a syringe, needle, vial, and ampule.
- Select the appropriate syringe based on the volume of solution.
- Explain the sequence of activities when attaching a needle to a syringe.
- Identify 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)
0761-9999-20-154-H07-P
0761-9999-20-154-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)
0761-9999-20-155-H07-P
0761-9999-20-155-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 that must be met for immediate-use CSPs whereby Category 1 and Category 2 requirements are not required.
- 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 eLessons/4 hours CE)

Sterility Testing Requirements of USP Chapters 71 and 797 (1 hour)
0761-9999-20-156-H07-P
0761-9999-20-156-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)
0761-9999-20-157-H07-P
0761-9999-20-157-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 important in sterile compounding.
- Identify sources of pyrogens.
- Recall information about limulus amebocyte lysate (LAL).

Steam and Dry-Heat Sterilization Methods (1 hour)
0761-9999-20-158-H07-P
0761-9999-20-158-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)
0761-9999-20-159-H07-P
0761-9999-20-159-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

(5 eLessons/5 hours CE)

Introduction and Overview (1 hour)
0761-9999-20-160-H07-P
0761-9999-20-160-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 recommendations from OSHA, NIOSH, ASHP, and USP for minimizing the risk of occupational exposure to HDs.
- Develop a list of NIOSH-listed hazardous drugs handled at your organization.
- Discuss specific administrative, environmental, and work practice controls and personal protective equipment (PPE) that result in improved safety.

Primary and Secondary Engineering Controls (1 hour)
0761-9999-20-161-H07-P
0761-9999-20-161-H07-T

- Describe the types of compliant HD primary and secondary engineering controls for both sterile and nonsterile compounding.
- Analyze the allowable and allowable-but-suboptimal designs of HD SECs.
- Discuss considerations relevant to the use of pass-throughs in HD applications.

Use of Personal Protective Equipment (1 hour)
0761-9999-20-162-H07-P
0761-9999-20-162-H07-T

- Discuss the rationale for the types of personal protective equipment (PPE) required and recommended for hazardous drug handling.
- Select the correct type of PPE for HD compounding and other handling and spill scenarios.
- List the proper sequence and method of donning and doffing HD PPE.

Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (1 hour)
0761-9999-20-163-H07-P
0761-9999-20-163-H07-T

- Differentiate between the traditional and CriticalPoint-proposed receiving paradigm relative to actions needed to ensure containment of hazardous drug residues.
- List the requirements for storing active pharmaceutical ingredients (APIs) and antineoplastic drugs that require manipulation.

(continued on next page)

Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport *(continued)*

- Describe the necessary elements and strategies for developing an assessment of risk for eligible drugs.
- Outline required and best work practices for storage, compounding, labeling, packaging, and transport of HD components and final HD CSPs.

Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (1 hour)
0761-9999-20-164-H07-P
0761-9999-20-164-H07-T

- Properly sequence and perform decontamination in addition to other required elements of 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 in managing spills.
- List considerations for trace and bulk hazardous drug disposal.
- Outline requirements for initial and ongoing training, competency assessment, and documentation for a hazardous drug compounding practice.

ACPE-Approved Continuing Education is valid from August 2020 through July 2022