CriticalPoint
a trchealthcare brand

Sterile Compounding and Hazardous Drugs

(USP 797 and 800) Curricula

Though Critical Point's Sterile Compounding curriculum is consistent with current and potentially with proposed USP standards, our courses primarily focus on teaching Critical Point's recommended best practices. Each organization must determine its own specific standard operating procedures (SOPs). The content does 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.

In CriticalPoint content,

- 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 courses.
- Courses and post tests are packaged together for user convenience.

Introductory Sterile Compounding from Critical Point provides an affordable, high-quality, easy-to-access set of courses that provides a foundation for the new sterile compounder. It includes 12 hours of ACPE-accredited CE in the compounding category. Current course library includes:

- History of Sterile Compounding (1 hour of CE)
- USP 797 Primary Engineering Controls (2 hours of CE)
- USP 797 Secondary Engineering Controls (2 hours of CE)
- Hand Hygiene and Garbing for Sterile Compounding (2 hours of CE)
- Personnel Competency Testing in Aseptic Manipulation (1 hour of CE)
- Quality Management of Sterile Compounding (1 hour of CE)
- Best Practices for USP 797 Material Handling (1 hour of CE)
- Use of Supplies and Components (1 hour of CE)
- Aseptic Technique and Conduct for Sterile Compounding (1 hour of CE)

Intermediate Sterile Compounding from Critical Point provides an affordable, high-quality, easy-to-access set of courses that allows the sterile compounder to expand their expertise. It includes 10 hours of ACPE- accredited CE in the compounding category. Current course library includes:

- Quality Releases and Final Checks for Sterile Compounding (1 hour of CE)
- USP 797 CSP Handling: Staging through Transport (1 hour of CE)
- Master Formulation and Compounding Records for Sterile Compounding (1 hour of CE)
- Standard Operating Procedures for Sterile Compounding (1 hour of CE)
- General Elements of Documentation for Sterile Compounding (1 hour of CE)
- Use of Equipment and Integrating Technology for Sterile Compounding (1 hour of CE)
- Overview of Environmental Monitoring (1 hour of CE)
- Sterile Compounding Environments: Principles of Cleaning and Disinfection (1 hour of CE)
- Cleaning of Primary Engineering Controls for Sterile Compounding (1 hour of CE)
- Cleaning of Secondary Engineering Controls for Sterile Compounding (1 hour of CE)

Advanced Sterile Compounding from Critical Point provides an affordable, high-quality, easy-to-access set of courses that allows the experienced sterile compounder to expand their knowledge for more complex sterile compounding practices. It includes 7.5 hours of ACPE-accredited CE in the compounding category. Current course library includes:

- Determining USP 797 Beyond-Use-Dating (1 hour of CE)
- Viable Air and Surface Sampling (0.5 hours of CE)
- Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (1 hour of CE)
- Best Practices for Mixing Outside of ISO-Classified Conditions, USP 797 (1 hour of CE)
- Sterility Testing Requirements of USP Chapters 71 and 797 (1 hour of CE)
- Bacterial Endotoxin Testing for Sterile Compounding (1 hour of CE)
- Steam and Dry-Heat Sterilization Methods, USP 797 (1 hour of CE)
- Sterilization by Filtration of USP Chapters 71 and 797 (1 Hour of CE)

Hazardous Drugs from Critical Point provides an affordable, high-quality, easy-to-access set of courses that allows pharmacists and technicians to understand how to safely handle hazardous drugs in both sterile and nonsterile compounding environment. It includes 5 hours of ACPE-accredited CE. Current course library includes:

- Hazardous Drug Overview; USP 795 and 797 (1 hour of CE)
- Containment Primary and Secondary Engineering Controls (1 hour of CE)
- Personal Protective Equipment for HD Handling for USP 795 and 797b Compounding (1 hour of CE)
- HD Work Practice Strategies: Receiving Through Transport to Patients (1 hour of CE)
- HD Work Practice Strategies: Decontamination and Spill Management, USP 795 and 797 (1 hour of CE)

Sterile Compounding and Hazardous Drugs Combined Program: Contains all the above courses, totaling 32 courses with 34.5 hours of CE

Course Information by Topic

Topic: Fundamentals of Sterile Compounding (8 courses/8 hours CE)

History of Sterile Compounding (1 hour)
JA4008164-0000-24-3027-H07-P
JA4008164-0000-24-3027-H07-T

- Explain the evolution of pharmacy compounding guidelines up to present-day USP Chapter 797.
- Describe the roles of the USP and the FDA concerning standards and enforcement.
- Define ways to 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 USP 797 Beyond-Use Dating (1 hour)
JA4008164-0000-24-3005-H07-P
JA4008164-0000-24-3005-H07-T

- Describe situations that are not considered compounding.
- Differentiate expiration from beyond-use dates.

- Explain the immediate-use provision in USP 797.
- 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 for Sterile Compounding (1 hour)
JA4008164-0000-24-3013-H07-P
JA4008164-0000-24-3013-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.

USP 797 CSP Handling: Staging through Transport (1 hour)
JA4008164-0000-24-3055-H07-P
JA4008164-0000-24-3055-H07-T

- Explain how to properly stage components and supplies in preparation for compounding a CSP.
- Discuss the importance of proper handling, packaging, and transport of the final CSP containers.
- Discuss the importance of standardization and identify the required elements of a final compounded sterile preparation label.
- Explain when to perform final labeling and the consideration for positioning and adhering it to the CSP.
- Review the disposal of components and CSPs (sharps, pharmaceutical waste, etc.).

Master Formulation and Compounding Records for Sterile Compounding (1 hour)
JA4008164-0000-24-3014-H07-P
JA4008164-0000-24-3014-H07-T

- Identify the key differences between a master formulation record and a compounding record.
- Describe and explain the purpose of USP 797 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.
- Outline steps needed to develop a plan to implement this compounding documentation at your pharmacy.

Standard Operating Procedures for Sterile Compounding (1 hour)
JA4008164-0000-24-3017-H07-P
JA4008164-0000-24-3017-H07-T

- Identify the characteristics of effective standard operating procedures (SOPs).
- List the USP 797 for SOPs.
- Discuss the content, format, and control of SOPs.

General Elements of Documentation for Sterile Compounding (1 hour)
JA4008164-0000-24-3015-H07-P
JA4008164-0000-24-3015-H07-T

- Review the required documentation elements of USP 797.
- List the purposes of documentation.
- Identify elements of good documentation.
- List documentation "Dos" and "Don'ts."
- Identify characteristics of effective forms.
- Describe documentation audits.

Use of Equipment and Integrating Technology for Sterile Compounding (1 hour)
JA4008164-0000-24-3018-H07-P
JA4008164-0000-24-3018-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 requirements on the use and proper placement of ACDs.
- Review the different IV technologies available for sterile compounding and identify the effect it has on current sterile compounding procedures.

Topic: Engineering Controls for Sterile Compounding (2 courses/4 hours CE)

USP 797 Primary Engineering Controls (2 hours)
JA4008164-0000-24-3024-H07-P
JA4008164-0000-24-3024-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.

USP 797 Secondary Engineering Controls (2 hours)
JA4008164-0000-24-3025-H07-P
JA4008164-0000-24-3025-H07-T

- Identify concepts fundamental to secondary engineering controls (SECs) for 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.

Topic: Personnel Sampling Metrics (2 courses/3 hours CE)

Hand Hygiene and Garbing for Sterile Compounding (2 hours)
JA4008164-0000-24-3023-H07-P
JA4008164-0000-24-3023-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 and thumb sampling (GFT) as required by USP Chapter 797.
- Correctly outline the steps required for hand hygiene, garbing, and gloved fingertip and thumb sampling.

Personnel Competency Testing in Aseptic Manipulation (1 hour)
JA4008164-0000-24-3029-H07P
JA4008164-0000-24-3029-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.
- List the requirements of USP 797 as they relate to media-fill testing and aseptic technique competency.
- Describe media-fill-test documentation that meets or exceeds USP 797 requirements.

Topic: Viable Facility Sampling Metrics (3 courses/2.5 hours CE)

Overview of Environmental Monitoring (1 hour)
JA4008164-0000-24-3019-H07-P
JA4008164-0000-24-3019-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)
JA4008164-0000-24-3009-H07-P
JA4008164-0000-24-3009-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)
JA4008164-0000-24-3006-H07-P
JA4008164-0000-24-3006-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.
- Outline general concepts of investigating and remediating a microbial excursion.

Topic: Sanitization of Pharmacy Controlled Environments (3 courses/3 hours CE)

Sterile Compounding Environment Principles of Cleaning & Disinfection (1 hour)
JA4008164-0000-24-3016-H07-P
JA4008164-0000-24-3016-H07-T

- Describe the purpose and general principles of cleaning.
- Identify cleaning requirements outlined in USP 797.
- Explain principles related to the proper selection, preparation, and use of cleaning agents and supplies.
- Cite key considerations for personnel safety, training, and competency.

Cleaning of Primary Engineering Controls for Sterile Compounding (1 hour)
JA4008164-0000-24-3020-H07-P
JA4008164-0000-24-3020-H07-T

- Describe specific cleaning activities related to the types of primary engineering controls (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 sterile isopropyl alcohol (sIPA).
- 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 of Secondary Engineering Controls for Sterile Compounding (1 hour)
JA4008164-0000-24-3021-H07-P
JA4008164-0000-24-3021-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.

Topic: Aseptic Technique and Related Work Practices (5 courses/5 hours CE)

Quality Management of Sterile Compounding (1 hour)
JA4008164-0000-24-3026-H07-P
JA4008164-0000-24-3026-H07-T

- Describe the requirements of a quality management system for pharmaceutical compounding.
- Differentiate between the terms quality assurance (QA) and quality control (QC).
- List the responsibilities of the designated person (DP) or persons as well as responsibilities of compounding staff.
- Describe required notification and recall of out-of-specification (OOS), dispensed compounded sterile preparations (CSPs).
- List USP 797 requirements relative to complaint handling and adverse-event reporting.

Best Practices for USP 797 Material Handling (1 hour)
JA4008164-0000-24-3028-H07-P
JA4008164-0000-24-3028-H07-T

- Define material handling.
- Identify the potential consequences of improper material handling.
- List the USP Chapter 797 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 Supplies and Components (1 hour)
JA4008164-0000-24-3030-H07-P
JA4008164-0000-24-3030-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 for Sterile Compounding (1 hour)
JA4008164-0000-24-3022-H07-P
JA4008164-0000-24-3022-H07-T

- Explain how to conduct yourself properly in ISO controlled sterile compounding environments.
- Identify how to 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.
- Determine the proper position of components, supplies, and gloved hands when performing aseptic manipulations.

Best Practices for Mixing Outside of ISO-Classified Conditions (USP 797) (1 hour)
JA4008164-0000-24-3007-H07-P
JA4008164-0000-24-3007-H07-T

- State the definition of what is not compounding, also known as preparation per approved labeling.
- Define the different use requirements for proprietary bag and vial systems assembled for immediate use and future use.
- List the seven conditions that must be met for immediate-use CSPs whereby Category 1, 2, and 3 requirements are not required.
- Describe safe injection, infusion, and medication vial practices.
- Outline 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.

Topic: Nonsterile-to-Sterile Compounding Practices (4 courses/4 hours CE)

Sterility Testing Requirements of USP Chapters 71 and 797 (1 hour)
JA4008164-0000-24-3008-H07-P
JA4008164-0000-24-3008-H07-T

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

Bacterial Endotoxin Testing (1 hour)
JA4008164-0000-24-3010-H07-P
JA4008164-0000-24-3010-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)
JA4008164-0000-24-3011-H07-P
JA4008164-0000-24-3011-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 using biological indicators.

Sterilization by Filtration (1 hour)
JA4008164-0000-24-3012-H07-P
JA4008164-0000-24-3012-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.

Topic: Requirements and Best Practices for Hazardous Drug Compounding

(5 courses/5 hours CE)

Hazardous Drug Overview (USP 795 and 797) (1 hour)
JA4008164-0000-24-3000-H07-P
JA4008164-0000-24-3000-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 an index of frequently used NIOSH-listed hazardous drugs.
- Discuss specific administrative, environmental, and work practice controls and personal protective equipment (PPE) that result in improved safety.

Containment Primary and Secondary Engineering Controls (USP 795 and 797) (1 hour)
JA4008164-0000-24-3001-H07-P
JA4008164-0000-24-3001-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.

Personal Protective Equipment for HD Handling for USP 795 and 797 Compounding (1 hour)
JA4008164-0000-24-3002-H07-P
JA4008164-0000-24-3002-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.

HD Work Practice: Receiving through Transport to Patients (1 hour)
JA4008164-0000-24-3003-H07-P
JA4008164-0000-24-3003-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.
- 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 compounded sterile preparations.

HD Work Practice: Decontamination and Spill Management (USP 795 and 797) (1 hour)
JA4008164-0000-24-3004-H07-P
JA4008164-0000-24-3004-H07-T

- Properly sequence and explain 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 addressing 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 credit is valid from August 2024 through July 2026

Credit for Pharmacists and Pharmacy Technicians

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, TRC Healthcare/NetCE is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Statement of Participation/Course Completion
Credit will be awarded to participants who take the course, successfully complete the quiz with at least 80%, submit a course evaluation, and have provided an accurate NABP e-Profile ID and DOB. Participants who have successfully completed this course AND have provided accurate NABP e-Profile information, including month and day of birth, will have their CE credits submitted to CPE Monitor.

It is the participant's responsibility to verify credit is accurately posted to CPE Monitor. Participants who have questions about their credits or do not see their credits on CPE Monitor 20 days after their participation should contact TRC. Requests received after day 30 may not receive credit. Official statements of credit are only available from CPE Monitor.

Credit can't be claimed twice and will not be awarded to anyone who previously completed this course from CriticalPoint, RxAdvanced, Simplifi, or any TRC offering.

State Approvals: Most states accept courses that offer ACPE credit and do not need to formally review or approve courses. In unique cases where a state requires a formal review and approval process for a particular topic, those approvals will be listed here: AL BOP (didactic renewal training).

CriticalPoint/TRC Healthcare Faculty, Editors, & Staff

Patricia Cipoletti
Quality Control Manager
Flora Harp, PharmD
Editor
Latousha Jackson, PharmD, BCPS
Editor
Adam West, RCP-SCF, NSF-49 accreditation
Environmental Monitoring and Training Specialist

Disclosures

The editors of this activity and its publisher, TRC Healthcare/NetCE (TRC), have no relevant financial interests related to the products or services covered by this activity. TRC does not receive any commercial support and does not accept any advertising for its educational activities. It is completely independent and is supported entirely by subscriptions. In support of ACCME's Standards for Integrity and Independence, individuals declaring financial relationships with commercial interests (ineligible companies) are detailed below. When no financial relationship is listed, the individual has nothing to disclose. All relevant financial relationships, when present, have been mitigated. TRC focuses on delivering completely objective, unbiased drug information and advice for the benefit of subscribers. Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical or legal judgments. Information and Internet links in this activity were current as of the date of release.

Software/Hardware Requirements

TRC makes every effort to test and support the most recent version. This activity can be viewed on any device with an internet connection using one of the following browsers:

- Google Chrome, most recent stable version. No configuration recommendations.
- Mozilla Firefox, most recent stable version. No configuration recommendations.
- Apple Safari, most recent stable version. No configuration recommendations.

NOTE: For all browsers, you must have JavaScript and cookies enabled. To view PDFs, you will need a PDF-capable browser or standalone PDF viewer.

Your Privacy

In order to provide you with continuing education, Therapeutic Research obtains information such as your name, address, email address, phone number, payment information, etc. We treat this information as confidential and use it to provide you with the best service possible. TRC Healthcare has NEVER released any of this information to any outside organization for such organization's own commercial or marketing use and has a policy against doing so. We do not engage in renting out, selling, or trading names of subscribers or any information about any subscriber.

To provide you with valuable services, we will occasionally employ third parties to meet your needs. In such cases, only the information needed to meet your need will be shared with the outside organization. TRC Healthcare only employs third parties that have similarly protective privacy policies. We do not allow any other organization to send you unsolicited emails about any products or services. We might send you information about your subscription, your continuing education credits, or our own drug information services. We do not gather data or track your web usage of any websites other than our own. For further information see our Privacy Policy or submit a request at https://trchealthcare.com/privacyofficer/.