

Advanced Training in Sterile Compounding Compliance and Inspection

This course will be held on the following dates:

- Thursday, November 6 Friday, November 7, 2025
- Tuesday, March 10 Wednesday, March 11, 2026
- Tuesday, July 21 Wednesday, July 22, 2026

Registration Deadline: fourteen (14) days before the event or when capacity is met

Course Description: This 22-hour advanced training program is designed to equip inspectors, accreditors, and surveyors with the essential knowledge and skills required to assess and ensure compliance within sterile compounding areas. Participants will gain a deep understanding of industry standards, regulations, and best practices for assessing compliance with USP Chapters <797> and <800>. Through a combination of theoretical knowledge and practical case studies, this course covers key areas such as regulatory guidelines, inspection protocols, risk assessment, documentation, and facility-specific practices. At the end of the program, participants will be proficient in performing thorough inspections, identifying potential risks, and ensuring that facilities meet standards to guarantee patient safety and compliance.

Target Audience: This course is developed to provide training for inspectors, accreditors, and surveyors of sterile compounding areas. This certificate-based course is ACPE accredited for Pharmacists and Pharmacy Technicians.

Participation Requirements: Successfully completing the 7-hour home study (includes: required reading, watching recorded lectures, and passing (with an 80% or higher) a Post-test) before attending the live, in-person class. The participant must physically be able to stand for a minimum of 2 hours.

Location of Event: The 15 hour in-person training will be at the Aseptic Compounding Experience (ACE) Lab, located in the University of South Carolina College of Pharmacy: 715 Sumter Street Columbia, SC 29208.

Program Faculty:

Richard Capps, PharmD	Carl E. Dunn, RPh
Pharmacy Manager	Training Instructor III, Clinical Instructor
Prisma Health Oconee Memorial Hospital	University of South Carolina, College of Pharmacy
Katie Olsen, PharmD, BCPS Clinical Pharmacy Specialist – Pharmacotherapy, Ambulatory Care Medical University of South Carolina Health	Tenissa Ray, CPhT Education and Compliance Technician Supervisor Prisma Health System
George Smith, PharmD, BCPS, BCSCP System Sterile Compounding Services Specialist Prisma Health	Eric Sparks, BS Cleanroom Certification Consultant
Krystal Brashears Stefanyk	
Director of Inspections	
North Carolina Board of Pharmacy	

Disclosure Statements:

George Smith and Krystal Brashears Stefanyk report the following disclosures: honoraria from ARL Bio Pharma, and honoraria from Pharmacy Purchasing Product Magazine. All other faculty, planners, reviewers, staff, and CPE committee report no financial or personal relationship with any ineligible company that produces, markets, resells, or distributes a product or service that appears in this program. There is no commercial support for this program.

Program Registration Fees, Cancellation and Refund Policies

Registration: To register, visit http://cop.sc.learningexpressce.com/

Registration Fees: \$1,400*T

*Please note that fees will show as "Learning Express" on your credit card statement.

^T includes a \$200 non-refundable course fee

Registration is limited and will be taken on a first come first served basis. Fee includes: training (home study and on-site), food (as mentioned below), digital versions of the educational materials, ACPE continuing education credit (CPE), and ACPE Certificate Program recognition with successful completion of the requirements.

For the two-day live training program breakfast, lunch, coffee, and snacks will be provided. Please inform us via the registration question and/or email if you have any dietary restrictions/lifestyles, or food allergies.

Travel Information:

- Registrants are responsible for any travel expenses. A list of nearby hotels is provided in the "Course Material(s)" section after registration.
- Columbia Metropolitan Airport (CAE) is the nearest airport.

Handouts/Slides: Will be available to all participants to download/print prior to the course in the "Course Material(s)" section when they are available (this section is only accessible after registration).

Cancellation/Refund Policy:

- Policy applies to self-pay, third-party billing (including NABP code), and voluntary transfers.
- To cancel the course and receive a refund (minus the \$200 non-refundable course fee), you must email
 the request to CE@cop.sc.edu on or before thirty (30) days before the live program date. All refund
 requests submitted after that deadline will be denied.
- If you enroll in the course after that deadline, you will <u>NOT</u> be eligible to receive a refund. Similarly, if you voluntarily transfer to a later course date, you will not be eligible to receive a refund.
- USC COP reserves the right to cancel the entire program. In the event of a conference cancellation, each participant will be notified via phone and/or email at least 14 days prior to the live program date and a full tuition refund will be made or transfer to a later course date.
- In the event of inclement weather, the decision to cancel a course will be made no later than 9:00 am Eastern time the day before the live program.

Registration transfers:

- Individuals attending the course in place of the registered individual will be honored if the request is made at least 7 days before the live program date. Email CE@cop.sc.edu to facilitate.
- Individuals wanting to transfer to a later date must email CE@cop.sc.edu at least 14 days prior to the live program date, no changes can be made less than 14 days.

Registration Deadline:

Registration will be accepted up to 14 days prior to the live program or when capacity is met.

Continuing Education Credit Requirements: To obtain continuing education credit, participants must successfully complete the home study and pass the post-test prior to arrival. Upon arrival, sign-in, have attendance verified, attend the program in its entirety, and successfully demonstrate certificate-based competencies using planned simulations, and competency test, along with fully completing the associated online evaluation before the deadline. Failure to complete the evaluation within 30 days of attendance may result in loss of credit. The NABP CPE Monitor will not accept credit submitted greater than 60 days from the date of attendance.

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Accreditation Information: The University of South Carolina College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This certificate-based activity has been approved for a total of 22 contact hours (2.2 CEUs), consisting of 15 hours of live education and 7 hours of home study continuing education credit,

ACPE # 0062-0000-25-136-B07-P/T and Certificate program # 0062-25-006-CP

Program Schedule: All times shown are Eastern (specifics are subject to change)

Day 1:

Time	Session
8:00 – 8:15a	Welcome, Introductions and Course Overview
8:15 – 9:00a	Review of Home Study
9:00 – 10:15a	Training & Competencies
10:15 – 10:30a	Break
10:30 – 12:30p	Training and Competencies (Lab) & Microbiological Environmental Monitoring
12:30 – 1:15p	Lunch
1:15 – 2:15p	What to Expect When Inspecting
2:15 – 4:30p	Observations of Compounding Process & Master Formulation & Compounding Records (with one 15 min break)
4:30 – 4:45p	Break
4:45 – 5:30p	Panel Discussion / Q&A

Day 2:

Time	Session
8:00 – 10:00a	BUD and Sterilization & Lab Demo
10:00 – 10:15a	Break
10:15 – 11:45a	Facilities Walk-Thru & Certification Report Review
11:45 – 12:00p	Facilities & Engineering Controls Q&A
12:00 – 12:30p	Lunch
12:30 – 1:00p	Final Assessment Preparation
1:00 – 4:00p	Final Assessment (with one 30 min break)
4:00 – 4:30p	Assessment Debrief & Wrap-up

Learning Objectives:

At the conclusion of this activity, the **pharmacist** and **pharmacy technician** will be able to:

- 1. Define sterile compounding
- 2. Identify enforceable aspects of USP Chapter <797> and <800>
- 3. Demonstrate best practices for sterile compounding area etiquette
- 4. Evaluate compliance with sterile compounding employee training and documentation requirements
- 5. Assess sterile compounding area compliance with site-specific standard operating procedures
- 6. Interpret room certification reports
- 7. Differentiate between inspecting hazardous and nonhazardous sterile compounding areas
- 8. Discuss compliance scenarios with a panel of experts

Please contact CE@cop.sc.edu or 803-777-9979 with any questions regarding registration!