KENNEDY
PHARMACY INNOVATION CENTER

Practical Compliance with USP chapters <797> and <800>
Thursday, September 7 – Friday, September 8, 2023

Registration Deadline: Thursday, August 24th at 4:00 pm (ET)

Course Description: Practical Compliance with USP Chapters <797> and <800> is an updated course geared towards individuals who are responsible for ensuring compliance with the USP Compounding Standards. The course is based on the currently enforceable USP chapter <797>, and the revised USP Chapter <797> and USP Chapter <800> which will be enforceable November 2023.The course focuses on the practical application of the standards from the revised USP <797> and the new USP <800>. The target audience includes pharmacists, pharmacy technicians, and others who are practicing in a sterile compounding environment and/or who are designated as responsible for the performance of a sterile compounding facility. Participants who satisfactorily complete the program will receive a certificate of completion as well as 16 hours of live ACPE-accredited continuing pharmacy education credit.

Target Audience: Pharmacists, pharmacy technicians, and others who are practicing in a sterile compounding environment and/or who are designated as responsible for the performance of a sterile compounding facility.

Participation Requirements: It is a strong recommendation that attendees read and review USP chapters <797> and <800> prior to attending the course. The participant must physically be able to stand for a minimum of two hours. Participant must also have full range of motion to complete physical tasks required in the compounding process.

Location of Event: The training program will be offered at the Aseptic Compounding Experience (ACE) Lab, located at 715 Sumter Street, University of South Carolina College of Pharmacy Campus, Columbia, SC 29208.

Program Faculty:

Nancy Roberts, PharmD, MS Program Director, Sterile Compounding Training Kennedy Pharmacy Innovation Center, Columbia, SC RobertN3@kennedycenter.sc.edu	
Richard Capps, PharmD Pharmacy Manager Prisma Health Oconee Memorial Hospital, Seneca, SC	**Shay Garrison**, RPh, MPH Pharmacist Specialist Prisma Health Richland Hospital, Columbia, SC
Allen Welch, PharmD Senior Director of Compliance & Regulatory Services Comprehensive Pharmacy Services, White Pine, TN	**Eric Sparks,** BS Vice President, Business Development Technical Safety Services

Disclosure Statements:

Disclosures: Faculty, planners, reviewers, staff, and CPE committee report no financial or personal relationship with any commercial interest producing, marketing, reselling, or distributing 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: Pharmacists/Technicians: $950*
Please note that fees will show as "Learning Express" on your credit card statement.

Registration is limited and will be taken on a first come first served basis. Fee includes on-site training and continuing education credit. Registrants are responsible for any travel expenses. **For the two-day live training program breakfast, lunch, coffee, and snacks will be provided. Please inform us via registration question and/or email of any dietary restrictions, dietary lifestyles, or food allergies.**

Handouts/Slides: Will be made available to all participants to download/print prior to the course (on or around September 4th) via registration portal.

Cancellation Policy:

- Cancellations received in writing at least 30 days prior to program date via letter or email to CE@cop.sc.edu will receive a full refund minus a $200 cancellation fee.
- 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 program and a full tuition refund will be made.
- 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 program.

Registration transfers:

- Individuals attending the course in place of the registered individual will be honored as long as the request is made in advance of the registration deadline, which is 7 days prior to the event.

Refunds:

- Refund requests are subject to a $200.00 cancellation fee and must be received 30 days prior to the start of the live component. All registration cancellations must be submitted in writing or by e-mail to the Continuing Education Department at the following address: University of South Carolina College of Pharmacy Continuing Education, 715 Sumter Street, Room 314B, Columbia, SC 29208, Email: CE@cop.sc.edu
- Registrants may receive 100% of the program registration fees, less the $200.00 cancellation fee up to 30 days prior to start date of the live component. No refunds are offered for cancellations fewer than 30 days prior to the start date of the live component or for no shows.

RSVP Information and cut-off date:

- **Registration will be accepted until 14 days prior to the start of the program (Thursday, August 24th at 4:00pm ET) or until capacity has been reached.**

Continuing Education Credit Requirements: To obtain continuing education credit, participants must sign in upon arrival, have attendance verified, attend the program in its entirety, and fully complete the associated online evaluation. 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.

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. For successful completion for the live certificate-based activity, participants will be required to attend the accredited program in its entirety, successfully demonstrate certificate-based competencies using planned simulations, and complete speaker and program evaluations. This certificate-based activity has been approved for **16 contact hours (1.6 CEUs) of live continuing education credit, ACPE #0062-0000-22-171-L07-P/T** and **Certificate program #0062-22-004-CP.**

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

Day 1:

Time	Session
8:00 – 8:30a	Welcome, Introductions and Course Overview
8:30 – 9:45a	USP Chapter <797> Introduction and Requirements for Training Evaluation of Preparers of CSPs, SOPs, CR & MFR
9:45 – 10:00a	Break
10:00 – 11:30a	Sterile Compounding Categories/Level Establishing BUDs
11:30a – 12:30p	Facilities and Engineering Controls for Non-Hazardous drugs
12:30 – 1:15p	Lunch
1:15 – 2:45p	Environmental Cleaning/Disinfection, Hand Hygiene, PPE, Garbing, and Gloved Fingertip Test
2:45 – 3:45p	Environmental Monitoring (Air/Surface Sampling)
3:45 – 4:00p	Break
4:00 – 5:30p	Demos: Hand Hygiene, PPE, Gloved Fingertip Sampling Ex. Particle Counts, Smoke Test, Cleaning, Microbial Air and Surface Sampling

Day 2:

Time	Session
8:00 – 8:30a	Introduction to USP Chapter <800 >
8:30 – 9:30a	Facilities Design and Engineering Controls for Hazardous Drugs
9:30 – 9:45a	Break
9:45a – 12:30p	Other topics per USP <800
12:30 – 1:15p	Lunch
1:15 – 3:15p	Hood and Room Certification per <797> and <800>
3:15 – 3:30p	Break
3:30 – 5:30p	Certification Reports per <797> and <800>

Learning Objectives for Pharmacists and Pharmacy Technicians:

At the conclusion of this program, pharmacists and pharmacy technicians will be able to:

1. Assess the USP <797> requirements for facilities and engineering controls

2. Evaluate the types and placement of primary engineering controls (PEC) for non-hazardous sterile compounding

3. Implement a microbial air and surface monitoring program based on requirements for viable and non-viable sampling, including proper incubation periods

4. Analyze microbial air and surface sampling results to identify potential issues related to cleaning activities and other sources of contamination

5. Analyze the introduction of equipment and supplies into the cleanroom suite and PEC in order to minimize particle generation and risk of contamination to the cleanroom environment and sterile compounds

6. Evaluate personnel performing hand hygiene, garbing, gloved fingertip and media fill sampling according to USP <797> requirements

7. Analyze the elements of an effective cleaning and disinfectant program that complies with USP <797>

8. Analyze a recertification report to identify the critical elements to ensure the environmental controls in the classified areas meet the minimal requirements of USP <797> or <800>

9. Differentiate between the three categories of compounded sterile preparations as defined in USP <797>

10. Evaluate sterilization methods for compounded sterile preparations prepared with nonsterile components or nonsterile supplies

11. Evaluate aseptic process and sterilization methods as discussed in USP <797>

12. Examine the personal protective equipment (PPE) requirements of USP <800>

13. Analyze USP <800> requirements for deactivating, decontaminating, cleaning, and disinfecting

14. Assess the USP <800> requirements for facilities and engineering controls

15. Evaluate the types and placement of containment primary engineering controls (C-PEC) for hazardous compounding

16. Examine the elements of hazardous risk based on USP <800> involved in creating an assessment of risk for your formulary

17. Demonstrate spill management and disposal of hazardous drug waste

18. Examine the role and accountabilities of the designated person per USP

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