KENNEDY
PHARMACY INNOVATION CENTER

Practical Compliance with USP chapters <797> and <800>
August 12-13, 2021

Course Description: The course is geared towards individuals who are responsible for ensuring compliance with the USP Compounding Standards. The training is based on USP 797 (2019) version and current best practices. Where applicable, the training program provides a comparison of the differences between the currently enforceable version of USP 797 (2008) and the (2019) version whose publication was postponed due to appeals. The course focuses on the practical application of the standards from the revised USP <797> and the new USP <800>.

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.

Location of Event: The program will be Virtually

Program Faculty:

- **Richard Capps, PharmD, DPLA; Pharmacy Manager at Oconee Memorial Hospital (Greenville Health System) in Seneca, SC**
  - Richard Capps has over twenty-five years' experience in pharmacy management and has been a Pharmacy Manager with the Greenville Health System since 2000. Richard is currently the Pharmacy Manager of Oconee Memorial Hospital, a 160 bed community hospital. Before transferring to Oconee, Richard designed and opened an off-site compounding pharmacy to support seven GHS hospitals. The compounding pharmacy is registered with the FDA and DEA as a manufacturer and employs two RIVA robots for sterile compounding. The compounding pharmacy has an extensive environmental monitoring plan and performs its own end product sterility testing in compliance with USP <71>. The compounding pharmacy also repackages oral medications to support the health system. Before opening the compounding pharmacy, Richard was the Pharmacy Manager of the Greenville Memorial Hospital Pharmacy. In that role, he transitioned the pharmacy from a completely manual distribution system to a fully automated barcode assisted dispensing system. Richard was also responsible for overseeing Omnicell medication cabinets; the Alaris drug library, corporate compliance, and controlled substance diversion monitoring.
  - Richard is a graduate of The Citadel, The Military College of South Carolina. He received his Doctorate of Pharmacy from Mercer University Southern School of Pharmacy in Atlanta and completed an American Society of Health-system Pharmacy accredited Pharmacy Practice Residency at Emory University Hospital. In 2010, Richard graduated from the ASHP Foundation Pharmacy Leadership Academy and the ASHP Foundation Leaders Innovation Masters Series in 2013. Richard is an active member with ASHP's Section on Pharmacy Informatics and Technology and the Regulatory Committee for the South Carolina Society of Health-system Pharmacy. Richard authored the chapter Primary Engineering Controls in ASHP's *Compounding Sterile Preparations,* 4th ed.
- **Shay Garrison, RPh, MPH, Pharmacist Specialist at Palmetto Health Richland Hospital in Columbia, SC (*specializing in sterile compounding, USP <797>, and USP <800>*)**
  - Shay received a B.S. in Microbiology from Clemson University in 1978. He furthered his career with a B.S. degree in pharmacy from the Medical University of South Carolina School of Pharmacy in 1981 followed later in 1992 with a Masters in Public Health Administration from the University of South Carolina.
  - Shay has over 30 years of experience in hospital pharmacy practice, the majority at Palmetto Health Richland Hospital in Columbia, South Carolina as a manager. In Shay's 25 plus years experience in pharmacy administration he has spent working the majority of his time maintaining direct and in-direct oversight over the oncology and sterile product components. During this time, he was directly involved with the new construction and/or renovation of several sterile compounding areas in the Palmetto Health facilities and most recently with the establishment of a robotic sterile processing facility. In the past, Shay has also held adjunct teaching functions for Midlands Technical College Pharmacy Technician Program and currently lectures in sterile compounding as part of the Kennedy Pharmacy Innovation

Center of the University of South Carolina. He also works in an advisory role on the Compounding Committee for the South Carolina Board of Pharmacy.

- **Eric Sparks, Key Account Manager for Technical Safety Services**
  - Eric is a United States Air Force veteran and certified meteorologist with more than 20 years of experience in the certification, calibration and quality field. He holds a bachelor's degree in marketing from Thomas Edison State University with a background in electrical engineering technology. His current certifications include; CETA/CNBT Certified Professional for Testing USP <797> Sterile Compounding Facilities, NSF Accredited for Testing and Certification of Class II Biosafety Cabinet, and NEBB (TAB) Testing, Adjusting and Balancing Technician.
  - Eric has a vast knowledge of every aspect of a sterile environment in relation to certification and air balancing. Throughout his career, he has managed many projects for major pharmaceutical manufacturers and sterile pharmacies. These projects include construction, air balancing, microbial sampling, calibration and certification within cleanrooms. He has also managed several software development projects which handles the throughput of data collected during the cleanroom certification process.

Disclosure: 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.

Course 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 2 hours. Participant must also have full range of motion to complete physical tasks required in the compounding process.

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 practice based activity, participants will be required to attend the accredited program in its entirety, successfully demonstrate practice based competencies using planned simulations, and complete speaker and program evaluations. This practice-based activity has been approved for **16 contact hours (1.6 CEUs) of live continuing education credit, ACPE#0062-0000-19-163-L07-P/T**. Initial Release Date: 9/5/2019 Expiration Date: 9/5/2022

Program Registration Fees, Cancellation and Refund Policies

Registration: To register, visit http://cop.sc.learningexpressce.com/ and select the appropriate course (Pharmacists or Technicians).

Registration Fees: Pharmacists/Technicians: $850
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 serve basis. Fee includes on-site training and continuing education credit. Breakfast, lunch, and morning and afternoon snacks are provided. Participants will be responsible for their own dinner, travel, and hotel accommodations if required.

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 314C, 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 7 days prior to the start of the program (Thursday, August 5 at 4:00pm) or until capacity has been reached.**

Program Schedule:

Day 1:

Time	Session
8:00 – 9:30a	Welcome and Introduction to the 2019 Version of USP <797>
9:30 – 9:45a	Break
9:45 – 11:30a	Facilities and Engineering Controls for Non-Hazardous drugs
11:30a – 12:15p	Lunch
12:15 – 1:45p	Elements to Create an Effective Cleaning and Disinfectant Program PART 1
1:45 – 2:00p	Break
2:00 – 3:30p	Elements to Create an Effective Cleaning and Disinfectant Program PART 2
3:30 – 5:30p	Establishing Beyond -Use Dates Sterilization and Bubble Point Testing

Day 2:

Time	Session
8:00 – 8:30a	Introduction to USP Chapter <800 >
8:30 – 10:00a	Assessment of Risk
10:00 – 10:15a	Break
10:15 – 11:45a	Facilities and Engineering Controls for Hazardous Drugs
11:45a – 12:30p	Lunch
12:30 – 2:00p	Other topics per USP <800
2:00 – 3:30p	Hood and Room Certification and Certification Reports per <797> and <800> Part 1
3:30 – 3:45p	Break
3:45 – 5:30p	Hood and Room Certification and Certification Reports per <797> and <800> Part 2

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. Develop and implement a cleaning and disinfectant program that complies with USP <797> requirements for proper product use and frequency.
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 two categories of compounded sterile preparations as defined in USP <797>.
10. Establish Beyond-Use Dates for Category 1 and Category 2 compounded sterile preparations.
11. Evaluate sterilization methods for compounded sterile preparations prepared with nonsterile components or nonsterile supplies.
12. Demonstrate procedures for conducting a post-use bubble point test after sterilization by filtration.
13. Examine the personal protective equipment (PPE) requirements of USP <800>.
14. Analyze USP <800> requirements for deactivating, decontaminating, cleaning, and disinfecting.
15. Assess the USP <800> requirements for facilities and engineering controls.
16. Evaluate the types and placement of containment primary engineering controls (C-PEC) for hazardous compounding.
17. Create a Master Formulation and Compounding Record which meets all USP requirements.
18. Conduct an assessment of risk.
19. Demonstrate spill management and disposal of hazardous drug waste.
20. 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!