KENNEDY
PHARMACY INNOVATION CENTER

# Update on compliance with standards for sterile compounding with emphasis on USP chapters <797> and <800>

**Tuesday, April 30 – Wednesday, May 1**

***Registration deadline: Tuesday, April 16 at 8:00 am***

**Course Description:** This is a management level course for individuals who oversee sterile compounding facilities and are responsible for ensuring compliance with current minimum practice standards. The course will focus on the practical application of the "musts" and the "shoulds" from USP chapters <797> and <800> through the use of tools and best practice recommendations.

**Target Audience**: Pharmacists, pharmacy technicians, and other individuals who are practicing and/or responsible for compliance with sterile compounding standards.

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

**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, President of BioTech Balancing**
    - Eric is a United States Air Force veteran and certified metrologist 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#0062-0000-18-009-L07-P/T**. Initial Release Date: 2/23/2018 Expiration Date: 2/23/2021

## 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: $750
**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 14 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 14 days prior to the start of the program (Tuesday, April 16 at 8:00 am) or until capacity has been reached.**

## Program Schedule and Learning Objectives

**Program Schedule:**

**Day 1:**

| Time | Session | Format |
|---|---|---|
| 8:00 – 8:30 | Welcome | Lecture |
| 8:30-9:30 | Introduction, Compounding/Manufacturing, DQSA, 503A/503B, FDA 483s | Lecture/Interactive Exercises |
| 9:30-9:45 | Break | |
| 9:45-10:45 | SOPs, Training, Competencies, Documentation, PI, Documentation/Records per USP <797> and <800> | Lecture/Interactive Exercises |
| 10:45:11:45 | Facility Design and Engineering Controls per USP <797> | Lecture |
| 11:45-12:45 | Lunch | |
| 12:45-1:45 | Cleaning, PPE and Environmental Monitoring per USP <797> (Part 1) | Lecture |
| 1:45 -2:45 | Cleaning, PPE and Environmental Monitoring USP <797> (Part 2) | Interactive Exercises (Lab) |
| 2:45-3:45 | Hood and Room Certification per USP <797> and <800> | Demo (Lab) |
| 3:45-4:00 | Break | |
| 4:00-5:30 | Certification Reports per USP <797> and <800> | Lecture |

**Day 2:**

| Time | Session | Format |
|---|---|---|
| 8:00 – 10:00 | Risk Level Differences, BUDs, High Risk: Equipment, Testing, Training, and Competencies | Lecture |
| 10:00-10:15 | Break | |
| 10:15-10:45 | Intro to <800> | Lecture |
| 10:45-12:15 | Facility Design and Engineering Controls per USP <800> | Lecture |
| 12:15-1:15 | Lunch | |
| 1:15-3:15 | Assessment of Risk | Lecture/Interactive Exercises |
| 3:15-3:30 | Break | |
| 3:30-5:30 | Other Topics per USP <800>: Environmental QC, PPE, Cleaning, Receiving, Storage, Spill Kit, Disposal, Hazard Communication Program (HCP), Medical Surveillance, and Drug Shortage | Lecture |

**Learning Objectives for Pharmacists and Pharmacy Technicians:**

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

1. Develop training for compounding personnel based on the competencies, documentation, and requirements outlined in USP <797> and <800>.
2. Adhere to the minimum standards operating procedures (SOPs) required by USP <797> and USP <800>.
3. Employ performance improvement, quality assurance (QA) and quality control (QC) methods.
4. Evaluate the operation and function of primary and secondary engineering controls and assess how they work together to ensure a proper environment for sterile compounding.
5. Implement environmental monitoring and an environmental sampling plan.
6. Analyze environmental sampling results to identify potential issues related to cleaning activities and other sources of contamination.
7. Analyze material handling and personnel processes in a cleanroom in order to minimize particle generation and risk of contamination to the cleanroom environment and sterile compounds.
8. Evaluate personnel performing hand hygiene, garbing, and gloved fingertip sampling according to USP <797> and USP <800> requirements.
9. Develop and implement a cleaning program that complies with USP <797> and USP <800> requirements.
10. Analyze a certification report to identify key components, to effectively utilize the information to maintain the cleanroom environment, and to ensure the PECs and SECs are functioning as designed.
11. Differentiate between the three risk levels for sterile compounding.
12. Evaluate the limitations of the three primary methods of sterilization for high risk compounding.
13. Demonstrate proper use and limitations of bubble point testing equipment.
14. Interpret key components of a Certificate of Analysis.
15. Develop a process for quality release testing, batch testing, and assigning a beyond use date for sterile compounds.
16. Examine the requirements of USP <800> related to containment, personal protective equipment (PPE), and cleaning/deactivation/decontamination of PECs and SECs used for compounding hazardous drugs.
17. Evaluate the types of containment primary engineering controls that are acceptable for sterile hazardous drug compounding as defined in USP Chapter 800.
18. Assess the facility requirements for compounding sterile hazardous drugs as defined in USP Chapter 800.
19. Develop and implement the components of a Hazard Communication Plan.
20. Conduct an Assessment of Risk.
21. Educate others on resources for identification of hazardous drugs and their exposure risks.
22. Demonstrate spill management and disposal of hazardous drug waste.
23. Conduct medical surveillance.
24. Implement environmental controls for minimizing exposure to hazardous drugs: storage, general handling, labeling and transport.
25. Develop strategies for managing drug shortages and the challenges they pose to sterile compounding.

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