KPIC Aseptic Technique Training Program
Thursday, May 16 – Friday, May 17, 2019

Registration Deadline: Thursday, May 2, 2019, at 8:00 am or when program capacity has been met

Program Description: The KPIC Aseptic Technique Training Program is an intensive practice-based educational activity designed to equip pharmacists and technicians with immersive, hands-on training in the compounding of aseptic products. Learners will be provided training in aseptic technique and objective evaluations following the preparation of Compounded Sterile Products (CSPs) according to USP <797> regulations through the use of didactic training, observation, coaching and practical skill assessments. The live session provides hands-on skills training focused on the current requirements and situations most likely to be encountered in a sterile compounding environment. Learners must successfully demonstrate competency via hands-on simulations in the state of the art compounding facility.

As a pre-requisite to the practice-based activity, the participant must first complete a home study component that will prepare the student for the intensive hands-on training. This self-study activity provides comprehensive instruction in current compounding techniques, and standards of practice for successful sterile compounding.

By registering for this program, you understand and agree that you must complete the home study portion in order to attend the live portion of the program. Upon registering for this live event, the USC COP will enroll you in the home study program, and participant is responsible for purchasing the textbook (*Concepts in Sterile Preparations and Aseptic Technique by Pamela S. Ochoa and Jose A. Vega, Burlington, MA: Jones and Bartlett Learning; 2015*). Only upon successful completion of the entire home study program will you will be allowed to attend the live portion. Cut-off for successful completion of self-study will be no later than 11:59pm on Wednesday, May 15, 2019.

The home study pre-requisite portion of this program provides 7.5 hours of continuing pharmacy credit (0.75 CEUs) and the live portion of this program provides 16 hours of continuing pharmacy credit (1.6 CEUs). Participants who fully and successfully complete both portions may receive a maximum of 23.5 hours of continuing pharmacy credit (2.35 CEUs).

Target Audience: This course is targeted for Pharmacists and Pharmacy Technicians responsible for preparing sterile compounded preparations.   This course will provide core training for individuals new to sterile compounding or individuals seeking to review their knowledge and skills in sterile compounding and aseptic technique.

Participant Requirements: To receive continuing education credit for this program, participant must be a registered pharmacist or registered pharmacy technician. Participant must physically be able to stand for a minimum of 2 hour periods and must have manual dexterity to allow manipulation of needles, syringes and other products utilized to prepare sterile products. Participant must also have full range of motion to complete physical tasks required in the compounding processes.

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 in Columbia, SC.

Program Dates: May 16 and 17, 2019

Program Faculty

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Disclosure Statements:
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<u>Activity Staff Disclosures</u>: The planners, reviewers, staff and CPE committee who control content have no relevant financial relationships to disclose.
There is no commercial support for this program.

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: $695
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. For the two-day live training program; breakfast, lunch, and morning and afternoon snacks are provided.   Registrants are responsible for the purchase of the self-study textbook (Concepts in Sterile Preparations and Aseptic Technique, Burlington, MA: Jones and Bartlett

Learning; 2015), dinner, any travel expenses, and hotel accommodations. The textbook is available from multiple sources on-line.

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 start of the live component. Transfer participants must still complete the required pre-requisite self-study by the required cut-off date.

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.

Registration Deadline:

- **Registration will be accepted until <u>14 days prior to the start of the live practice based component</u> (Thursday, May 2, 2019 at 8:00 am) or until capacity has been reached.**

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. The KPIC Aseptic Technique Training Program has been accredited for **7.5 hours** of home study and **16 hours** of live programming for a total of **23.5 hours**.

- The pre-requisite home study activity must be completed prior to attending the live program.   In order to receive continuing education credit for the self-study activities, the participant will be required to complete each reading and video assignment along with

review questions and case studies, complete the pre and post-tests and on-line program evaluation. Post-test will be automatically graded, and you must receive a score of 70% or higher to be considered successful. This knowledge based activity has been approved for **7.5** hours of continuing education credit. **ACPE#: 0062-0000-17-117-H04-P/T**. Initial Release Date: 7/10/2017 Expiration Date: 7/10/2020

- 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# 0062-0000-18-018-L07-P/T**. Initial Release Date: 03/16/2018 Expiration Date: 03/16/2021

- Credit claimed will be automatically uploaded to CPE Monitor. Each participant is required to provide their NABP ePID and month and day of birth; CPE credit will not be issued to individuals that do not provide this information. ACPE now requires that all completed pharmacy continuing education credits must be processed and claimed *no later than 60 days* from the date of the live activity or completion of an on-demand activity.

- **NOTE:** ***For participants that complete the entire program, Certificates of Completion will be provided.***

Required Computer Hardware/Software

Activity Requirement: Internet connectivity and Adobe Acrobat Reader are required for participation in this activity.
Please ensure the computer system you plan to use meets the following minimum requirements:

- *Operating System:* Windows XP SP2 or later, Windows Vista, Windows 7, Mac OS X 10.5 or later
- *Internet Browser (Mac &/ Windows):* Internet Explorer 7 or later, Firefox 3.5 or later, Safari 4
- *Broadband Internet connection:* Cable, High-speed DSL & any other medium that is internet accessible
- *Peripherals:* Computer speakers or headphones
- *Monitor Screen Resolution:* 320 x 480 or higher
- *Media Viewing Requirements:* For some components, the most up-to-date version of Adobe Flash may be required.   To obtain the free Flash plug-in, go to http://get.adobe.com/flashplayer/.

COURSE GUIDE AND LEARNING OBJECTIVES

LIVE COMPONENT

The goal of this course is to provide training followed by objective evaluations of preparers of Compounded Sterile Products (CSPs) according to USP <797> regulations through the use of didactic training, written competence assessments, observations, coaching and practical skill assessments.

The live practice based component will be held over 2 days and will provide 16 hours of live ACPE approved credit for pharmacists and pharmacy technicians:

KPIC Aseptic Technique Training Curriculum Schedule

Day 1

Time	Session	Format
8:00-8:15am	Registration, welcome, introductions	
8:15-9:15am	Introduction to Sterile Compounding	Lecture
9:15–10:15am	Overview of USP<797>	Lecture
10:15-10:30am	Break	
10:30-11:15	Hand Hygiene, Personal Protective Equipment, Garbing	Lecture
11:15-1200 pm	Dirty Fingertip Sampling, Hand Hygiene, Garbing Demo	Interactive Demo Lab classroom
12:00-12:45 pm	Lunch	
12:45-1:45pm	Overview of supplies and equipment necessary for sterile compounding	Lecture/Demo
1:45-2:45pm	Primary and Secondary Engineering Controls LAFW; Cleaning/Disinfecting LAFW	Lecture/Demo
2:45-3:00pm	Break	
3:00 – 5:30pm	*Exercise 1:* Garbing, hand hygiene competency Gloved fingertip sample competency Cleaning/Disinfecting LAFW competency *Demo* Smoke Test Demo Particle Generation Demo --- *Exercise 2:* Gather supplies for hands on training and review of relevant calculations for sterile compounded products	Lab Lab classroom & CLS 010

Day 2

Time	Session	Format
8:00-9:30am	Discussion of Aseptic technique and Low/Medium risk sterile compounding	Lecture/demo and hands on CLS 010
9:30– 12:30pm	*Exercise 1:* Hands on training of Low/Medium risk sterile compounding & aseptic technique *(15 min break as participants finish exercises)* _____ *Exercise 2:*	Lab Lecture/Demo

	Compatibility/stability, BUDs, Documentation, QA and QC for CSP	
12:30-1:15pm	Lunch	
1:15-2:30pm	Environmental Cleaning/Disinfection Documentation Requirements	Lecture
2:30-5:15pm	Review of Fingertip Sample preliminary results and remediation (if needed) *Exercise 1:* Assessment of Student Skills in Low/Medium Risk Sterile Compounding and Aseptic Technique (Media Fill) *Exercise 2*: Demo of Environmental cleaning products, processes, surface and air sampling *(15 min break as participants finish 1st exercise)*	Lab Lab classroom

Live Practice Based Learning Objectives:

After completion of this activity, the **pharmacy technician** *will be able to:*

- Explain the need for sterile products and the importance of aseptic compounding
- Describe the advantages and disadvantages of different parenteral routes
- Identify USP<797> requirements for the training and evaluation of preparers of CSPs as well as the responsibilities of personnel
- Discuss the difference between primary and secondary engineering controls
- Define ISO classifications 5, 7, and 8
- Describe the layout of a typical clean room, define ante area and buffer area
- Examine supplies used for CSPs and identify factors that influence selection
- Explain manipulations for accommodating positive and negative pressure
- Apply understanding of critical sites and airflow in sterile compounding
- Perform the steps for proper transfers and handling of sterile preparations
- Demonstrate proper techniques to aseptically attach needle to syringe, withdraw contents from vial and ampule, reconstitute vial, and inject into IV bag following all USP <797> guidelines and utilizing appropriate aseptic technique
- Demonstrate proficiency in aseptic technique as it relates to the preparation of different CSPs
- Demonstrate proper garbing procedure, hand hygiene and proper cleaning/disinfecting processes
- Demonstrate accuracy in basic calculations related to the preparation of different CSPs
- Conduct a media fill test to assess ability to aseptically compound sterile preparations
- Discuss 3 types of contamination: microbial, chemical and physical
- Differentiate between QA and QC and analyze as it relates to personnel, facilities and monitoring
- Describe special considerations and requirements with preparation of chemotherapy and hazardous drugs including exposure risks and how to minimize them

SELF STUDY COMPONENT
Must be completed prior to attendance at the live program

The goal of this course is to provide training followed by objective evaluations of preparers of Compounded Sterile Products (CSPs) according to USP <797> regulations through the use of didactic training, written competence assessments, observations, coaching and practical skill assessments.

The self-study component is a pre-requisite to the practice based live activity and provides 7.5 hours of knowledge based CE credit for pharmacists and pharmacy technicians using the textbook: *Concepts in Sterile Preparations and Aseptic Technique,* Burlington, MA: Jones and Bartlett Learning; 2015.

Self-study Learning Objectives:
After completion of this activity, the **pharmacy technician** *will be able to:*

- Define parenteral preparations and the role of safety, accuracy and attitude in risk prevention
- Discuss United States Pharmacopeia chapters applicable to pharmaceutical compounding of sterile products
- Define the role of the pharmacist and the responsibilities pertaining to sterile compounding
- Describe supplies and equipment used in sterile compounding and the safety considerations
- Summarize the microbiological considerations in sterile compounding and the responsibilities of personnel in preventing contamination
- Classify sterile preparations as low-, medium- or high risks and determine appropriate BUDs
- Differentiate between primary and secondary engineering controls and the role they play in maintenance of sterile environment for sterile compounding
- Describe the critical steps in proper aseptic technique and compounding manipulations
- Distinguish between quality control and quality assurance for sterile compounding
- Identify the key areas for monitoring for environment, personnel and end-product testing for a sterile compounding program

Participants will review the textbook and complete the following prior to attending the hands on portion of the course:

1. Chapter 1: Pages 1-15 and complete review questions on page 14-15
2. Chapter 2: Pages 17-62 and complete review questions and case studies on page 62
3. Chapter 4: Pages 107-135 and completer review questions and case study on pages 135-137.
4. Chapter 5: Pages 141-171 and complete review questions and case study on pages 171-172. View required video for Chapter 5:

   - on Page 148: Cleaning the HLFW (Video length 3:58)

5. Chapter 6: Pages 175-220 and complete review questions and case studies on pages 220-222. View required videos for Chapter 6:

   - Page 177: Hand Washing (Video length 6:09)
   - Page 181: Personal Protective Equipment – Garbing (Video length 0:44)
   - Page 181: Personal Protective Equipment-Sterile Gloves (Video Length 1:16)
   - Page 189: Attach Needle to Syringe and Remove Cap of Needle (Video Length 0:43)
   - Page 190: Enter Vial (Video length 1:02)

- Page 192: Withdraw Contents-equal pressure Milking (Video length 0:53)
- Page 192: Withdraw Contents Reverse Milking(Video length 0:36)
- Page 197: Removal of Air Bubbles (Video length 0:54)
- Page 199: Ampule Breaking (Video length 0:59)
- Page 199: Using A filter needle (1:28)
- Page 199: Using a filter straw (1:31)
- Page 206: Reconstituting Medications for Parenteral Administration (Video length 2:15)
- Page 208: Uncapping and Recapping Needles (Video length 0:38)
- Page 209: Capping a Syringe (Video length 0:51)
- Page 210: Priming an Infusion Set (Video length 2:41)
- Page 211: Positive Pressure (Video length 1:12)
- Page 212: Negative Pressure (Video length 0:50)
- Page 218: Workflow Process (Video length 2:12)

6. Chapter 11: Pages 347-367 and complete review question and case study on pages 367-369. View required video for Chapter 11:

- Page 361: Gloved Fingertip Test (Video length 1:06)

After completing the above, the participant must complete the online test at http://cop.sc.learningexpressce.com and a program evaluation prior to credit being awarded. This must be completed prior to attending the live program!

Contact Information: If you have questions about this CPE activity, please contact the CE office at 803-777-9979 or CE@cop.sc.edu