Samford University
McWhorter School of Pharmacy

PRINCIPLES OF ASEPTIC COMPOUNDING

This home study continuing pharmacy education (CPE) activity is intended to educate pharmacists and pharmacy technicians in the concepts and principles of preparing compounded sterile preparations (CSPs) as set forth in USP-NF Chapter <797>: Pharmaceutical Compounding- Sterile Preparations. The activity is recognized by the Alabama Board of Pharmacy (ALBOP) as an educational training activity for receiving Sterile Product Certification for pharmacists (see below for more details).

Event will be delivered as asynchronous content in the Samford University Canvas Connect Learning Management System (LMS) (See technical specifications below). Participants will receive 6 hours (0.6 CEUs) of non-live, CPE credit upon successful completion.

Faculty*:
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*Faculty has no relevant conflict of interest to disclose

This is a knowledge-based CPE activity and appropriate for all pharmacists and pharmacy technicians. To obtain CPE credit, the participant must complete all activity modules and successfully complete the online, written exam (a score of 70% is required to successfully complete the written exam. Participants will have 2 attempts). Credit will be sent through the CPE Monitor within 30 days. **In order to receive Sterile Product Certification with the ALBOP, pharmacists must also complete the 2-credit hour CPE activity entitled "Application of the Principles of Aseptic Processing" (ACPE Program number: 0002-0000-21-005-L07-P) to demonstrate proficiency in aseptic technique.** Click here for initial ALBOP Sterile Products Certification requirements for pharmacists.

Activity ACPE Program numbers: 0002-0000-21-004-H07-P, 0002-0000-21-004-H07-T

Method of Delivery of Activity Content:
Upon course registration, the participant will be sent an online link to enroll in the Samford University Canvas Connect LMS activity site. After enrollment, the participant will receive further instructions for navigating the LMS. Content for the activity is intended to be self-paced. However, participants must successfully complete the content of this activity prior to being allowed to participate in the CPE activity entitled "Application of the Principles of Aseptic Processing."

Technical Specifications (Canvas Connect LMS):
Screen Size: Canvas is best viewed at a minimum of 1024x600, which is the average size of a notebook computer. If you want to view Canvas on a device with a smaller screen, we recommend

using the Canvas mobile app.
Browsers: Because it's built using web standards, Canvas runs on Windows, Mac, Linux, iOS, Android, or any other device with a modern web browser. Canvas supports the last two versions of every browser release. It is highly recommend updating to the newest version of whatever browser you are using as well as the most up-to-date Flash plug-in.
Operating Systems: Windows XP SP3 and newer, Mac OSX 10.6 and newer, or Linux – ChromeOS
Mobile Operating System Native App Support: iOS 7 and newer or Android 2.3 and newer
Computer Speed and Processor: Use a computer 5 years old or newer when possible, 1GB of RAM, and 2GHz processor
Internet Speed: Minimum of 512kbps

Pharmacist Learning Objectives:
Following the event, the participant should be able to:

- Summarize the historical events that have necessitated the current state and federal regulations related to sterile compounding.
- Describe the broad objective of USP <797> including the five (5) conditions that could cause harm to patients.
- List the medical personnel and medical settings that must adhere to USP <797> when preparing compounded sterile preparations (CSPs) and the dosage formulations that must be prepared and maintained under sterile conditions.
- Describe the general requirements and layout of the clean room and the activities that occur in the ante and buffer areas.
- Identify the various primary engineering controls (PECs) available for non-hazardous and hazardous sterile compounding and describe the mechanisms by which a laminar airflow workbench (LAFW) maintains the proper environment for sterile compounding.
- List the processes associated with compounding CSPs including items that must not be taken into the clean room, preparing compounding supplies, hand hygiene, donning personnel protective equipment (PPE), and proper cleaning/disinfecting practices in sterile compounding areas.
- Review the elements of aseptic technique essential to compounding CSP including recognition of critical sites, type and function of commonly used compounding supplies, placement of compounding supplies in the PEC, disposal of compounding waste.
- Describe the compounding risk levels/categories as described in USP<797> and assign a beyond-use dates (BUDs) for each compounding risk level/category at room, refrigerated, and freezer temperatures when presented a compounding scenario.
- Discuss the process for observing CSPs for visual defects and handling observed defects during finished CSP checking and the responsibilities of compounding personnel for ensuring the proper storage and use of CSPs after dispensing.
- Reproduce the process for creating a quality assurance (QA) plan to assure proper monitoring of responsible personnel.
- Recall the personnel requirement tests required for QA and what each represents as according to USP <797> including the protocols for gloved fingertip testing and media fill testing.
- Describe the environmental testing required for QA including surface sampling and non-viable/viable airborne particulate testing.
- Compare the requirements for preparation of non-hazardous CSP with those necessary to compound a hazardous CSP.

Pharmacy Technician Learning Objectives:
Following the event, the participant should be able to:

- Identify the historical events that have necessitated the current state regulations related to sterile compounding.
- State the purpose of USP <797> including the five (5) conditions that could cause harm to patients.
- Name the medical personnel and medical settings that must adhere to USP <797> when preparing compounded sterile preparations (CSPs) and the types of dosage formulations that must be prepared and maintained under sterile conditions.
- Identify the general layout of the clean room and the activities that occur in the ante and buffer areas.
- List the various primary engineering controls (PECs) available for non-hazardous and hazardous sterile compounding.
- Explain the processes associated with compounding CSPs including items that must not be taken into the clean room, preparing compounding supplies, hand hygiene, donning personnel protective equipment (PPE), and proper cleaning/disinfecting practices in sterile compounding areas.
- Identify the elements of aseptic technique essential to compounding CSP including recognition of critical sites, type and function of commonly used compounding supplies, placement of compounding supplies in the PEC, disposal of compounding waste.
- State the compounding risk levels/categories as described in USP<797> and recognize beyond-use dates (BUDs) for each compounding risk level/category at room, refrigerated, and freezer temperatures when presented a compounding scenario.
- List the process for observing CSPs for visual defects and handling observed defects during finished CSP checking and the responsibilities of compounding personnel for ensuring the proper storage and use of CSPs after dispensing.
- Overview the process for creating a quality assurance (QA) plan to assure proper monitoring of responsible personnel.
- Reproduce the personnel requirement tests required for QA and what each represents as according to USP <797> including the protocols for gloved fingertip testing and media fill testing.
- Recognize the environmental testing required for QA including surface sampling and non-viable/viable airborne particulate testing.
- State the requirements for preparation of a hazardous CSP.

Cost: $225 for pharmacists; $175 for pharmacy technicians (cost includes registration in Application of the Principles of Aseptic Processing)

Participants can register and enroll in the activity at any time. However, once the participant has enrolled in the LMS refunds cannot be granted.

To register: www.samford.edu/pharmacy/continuing-education or for more information call (205) 726-2722

This ACPE-accredited CPE activity is conducted without commercial support or influence of any kind.

Samford University McWhorter School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.