CE Activity Announcement

Compounded Sterile Preparations Certificate for Pharmacists

ACPE Activity Number: 0204-0000-19-739-H07-P thru to 0204-0000-19-754-H07-P
Release Date: April 24, 2019
Expiration Date: April 24, 2022
Activity Type: Application-based
CE Credits: 38.00 hours *(no partial credit)*

Accreditation for Pharmacists

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Target Audience

This program is intended for pharmacists managing and developing cleanroom personnel and/or compliant compounding facilities.

Activity Overview

The program provides 38 hours of ACPE continuing education for pharmacists, incorporating recorded presentations, readings, video demonstrations, and exercises in curricular modules. The program covers sterile product preparation practice standards and regulations, pharmacy calculations, facilities and engineering controls, environmental monitoring, cleanroom personnel behaviors, sterile compounding components and procedures, stability and sterility, beyond-use date assignment, nonsterile to sterile compounding, hazardous drugs, managing products until final check or disposal, patient care, and overall quality management. After completing all of the modules, participants should be proficient in both basic compounding techniques and advanced skills required to lead and manage safe and compliant sterile product preparation in a cleanroom environment.

Learning Objectives and Schedule of Activities

Activity CE Information	Title, Description, Faculty, and Learning Objectives
ACPE # 0204-0000-19-739-H07-P **CE Hours:** 2.5 **Activity Type:** Application	**Title: Introduction to Sterile Product Preparation for Pharmacists** This activity discusses sterile compounding guidelines, best practices, standards, and regulations and the impact these different provisions have on many aspects of practice to ensure safe sterile product preparation. **Faculty:** Ryan A. Forrey, Pharm.D., M.S., FASHP **Learning Objectives:** • Identify factors contributing to the development of sterile compounding guidelines, best practices, standards, and regulations in the United States. • Describe lessons learned from major patient safety events involving sterile compounded preparations. • List the standards of practice that apply to sterile compounding in the United States. • Identify best practices to ensure sterile compounding safety. • Differentiate between sterile compounding standards, guidelines, and best practices.

	• Describe the role of the United States Pharmacopeia (USP) in sterile compounding. • Discuss provisions of the Pharmaceutical Quality, Security and Accountability Act (DQSA). • Distinguish other federal mechanisms to influence sterile compounding practice. • Contrast the role of the Food and Drug Administration (FDA) to the role of the states in sterile compounding regulation. • Identify other regulations related to workplace safety. • Compare USP <797> standards to the noncompliance findings from FDA Form 483 inspection reports. • Analyze corrective and preventive action (CAPA) plans. • Explain the role of the compounder in assuring the safety of compounded sterile preparations.
ACPE # 0204-0000-19-740-H07-P **CE Hours:** 1.75 **Activity Type:** Application	**Title: Calculations for Pharmacists** This activity covers calculations routinely used by pharmacy personnel when compounding sterile preparations. **Faculty:** DeeAnn Wedemeyer-Oleson, Pharm.D., CPHQ **Learning Objectives:** • Calculate doses in both weight and volume using ratios, proportions, and concentrations. • Practice conversions commonly used in sterile compounding calculations. • Apply the alligation method to calculate parts of two solutions with different concentrations to compound a solution with a different desired concentration. • Calculate infusion times in mL/hr and mL/min. • Select quantity of dosage units required to supply an order for a specified number of days or weeks.
ACPE # 0204-0000-19-741-H07-P **CE Hours:** 2.25 **Activity Type:** Application	**Title: Overview of Compounding Facilities and Engineering Controls for Pharmacists** This activity discusses the design, construction, and maintenance of compounding facilities including the role primary and secondary engineering controls and ancillary compounding equipment have in sterile product preparation. **Faculty:** Elaine Strauss, Pharm.D., M.S. **Learning Objectives:** • Describe sterile compounding facility requirements. • Differentiate between primary engineering controls and secondary engineering controls. • Analyze principles of design, construction, and material selection for compounding environments. • Propose a downtime plan for ongoing secondary engineering control and primary engineering control maintenance.

	• List the secondary engineering control elements of the cleanroom environment. • Contrast work behaviors in the secondary engineering control contributing to reduction of contamination. • Describe the primary engineering controls used in compounding facilities. • Explain the principles of generating a laminar airflow environment in the primary engineering control. • Contrast appropriate use of ancillary compounding equipment. • Explain proper steps for equipment calibration and maintenance documentation.
ACPE # 0204-0000-19-742-H07-P **CE Hours:** 1.5 **Activity Type:** Application	**Title: Cleanroom Personnel Basics for Pharmacists** This activity describes the necessary behaviors and competencies cleanroom staff must master to minimize contamination in cleanroom facilities. **Faculty:** Elaine Strauss, Pharm.D., M.S. **Learning Objectives:** • Identify sources of contamination within the cleanroom environment. • Distinguish necessary behaviors for cleanroom staff. • Assess personnel for appropriate hand hygiene technique. • Evaluate garbing sequence for non-hazardous and hazardous compounding. • Contrast the components and performance characteristics of garb and gloves for non-hazardous drug and hazardous compounding. • Describe the testing requirements to assess personnel for appropriate garbing technique. • Develop a training and assessment program to ensure mastery of core competencies by aseptic processing personnel.
ACPE # 0204-0000-19-743-H07-P **CE Hours:** 3.25 **Activity Type:** Application	**Title: Compounding Materials, Equipment, and Resources for Sterile Product Preparation for Pharmacists** This activity covers supplies, critical sites, equipment, labels, and references essential for sterile product preparation. **Faculty:** Ashley M. Duty, Pharm.D., M.S. **Learning Objectives:** • Recognize basic compounding supplies. • Differentiate between the critical sites and non-critical sites on syringes, needles, vials, and bags. • Assess a vial's medication label to determine number of doses and ingredients. • Select appropriate compounding materials based on review of medication order. • Identify the different types of automated compounder pumps used in sterile product preparation. • Choose the appropriate compounding equipment needed for various situations.

	• Interpret several types of patient medication labels. • Produce a Master Formulation Record and a Compounding Record. • Use tertiary resources to find necessary drug information.
ACPE # 0204-0000-19-744-H07-P **CE Hours:** 1.5 **Activity Type:** Application	**Title: Getting Started in Sterile Product Preparation for Pharmacists** This activity describes dosage forms, small and large volume parenterals, routes of administration, parenteral nutrition, high alert medications, and general considerations for automated compounding devices. **Faculty:** Ashley M. Duty, Pharm.D., M.S. **Learning Objectives:** • Describe the dosage forms, preparation requirements, and routes of administration. • Differentiate between small and large volume parenterals. • Recognize appropriate routes of administration for compounded sterile preparations. • Explain the components and role of parenteral nutrition. • Evaluate parenteral nutrition orders and processes. • Propose strategies to mitigate risk of high alert medications. • Assess automated compounding devices for safety, interoperability, and overall functionality.
ACPE # 0204-0000-19-745-H07-P **CE Hours:** 2.5 **Activity Type:** Application	**Title: Stability and Sterility: Assigning Beyond Use Dates for Pharmacists** This activity discusses the factors that influence the stability and sterility of sterile product preparations, considerations when assigning or extending beyond-use dates, and quality control testing. **Faculty:** Kevin N. Hansen, Pharm.D., M.S., BCPS **Learning Objectives:** • List factors that influence beyond-use date assignments for compounded sterile preparations. • Describe physical and chemical compatibility criteria for components. • Apply USP <797> risk categories to assigning a proper beyond-use date for compounded sterile preparations. • Recommend beyond-use date for a final compounded sterile preparation using evidence-based information. • Differentiate conditions under which sterility, potency, and endotoxin testing are required. • Identify requirements for quality control testing. • Interpret results of quality control testing. • Apply USP standards to properly extend a beyond-use date.
ACPE # 0204-0000-19-746-H07-P **CE Hours:** 2.75 **Activity Type:** Application	**Title: Aseptic Techniques for Compounding Non-Hazardous Preparations for Pharmacists**

	This activity explains "first air," aseptic technique in horizontal and vertical airflow, reconstituting powders, and appropriate compounding behaviors to prevent or minimize sharps injuries. **Faculty:** Lynda Kiliany, B.S.Pharm., Pharm.D. **Learning Objectives:** • Define the concept of "first air." • Illustrate the location of the direct compounding area in horizontal and vertical airflow. • Describe proper methods for disinfecting critical sites on commonly used sterile components. • Distinguish workflow steps and best practices associated with compounding in a laminar airflow workbench and a compounding aseptic isolator. • Describe techniques for reconstituting sterile powders. • Demonstrate placement of hands to prevent disruption of airflow to critical sites when reconstituting powders and withdrawing diluent or medication from vials. • Restate various strategies used to prevent the potential for coring vial stoppers. • Recommend compounding techniques and behaviors that should be used to prevent and address a sharps injury.
ACPE # 0204-0000-19-747-H07-P **CE Hours:** 2.5 **Activity Type:** Application	**Title: Small Volume Parenterals and Other Non-Hazardous Preparations for Pharmacists** This activity covers techniques and procedures associated with compounding medication cassettes and other "specials" including epidural, intrathecal, and ophthalmic preparations. **Faculty:** Lynda Kiliany, B.S.Pharm., Pharm.D. **Learning Objectives:** • Describe techniques for compounding medication cassettes. • Practice calculations commonly used with medication cassettes. • Interpret procedures to accurately measure components using principles of volumetric accuracy. • Describe techniques for compounding 'specials' including epidural, intrathecal, and ophthalmic preparations. • Differentiate situations when sterile filtration and/or preservative-free ingredients must be utilized when compounding special administration medications.
ACPE # 0204-0000-19-748-H07-P **CE Hours:** 1 **Activity Type:** Application	**Title: Nonsterile to Sterile Compounding for Pharmacists** This activity describes the general requirements and considerations associated with nonsterile to sterile compounding. **Faculty:** Mala Crossley, Pharm.D. and Marc Stranz, Pharm.D. **Learning Objectives:**

	• Explain the requirements under section 503A of the Drug Quality and Safety Act that apply to bulk drug ingredients. • Interpret the requirements under USP <797> for nonsterile to sterile compounding. • Discuss the facility and environmental requirements for nonsterile to sterile compounding. • Evaluate product release requirements for nonsterile to sterile compounding. • Assess the critical quality attributes that must be within limits to guarantee a quality compounded sterile preparation from non-sterile components. • Describe the installation and operational validation process for sterilization equipment. • Distinguish components of quality control.
ACPE # 0204-0000-19-749-H07-P **CE Hours:** 2.25 **Activity Type:** Application	**Title: Maintaining the Cleanroom Environment for Pharmacists** This activity discusses the important elements of cleaning and environmental monitoring required to maintain the cleanroom environment. **Faculty:** Elaine Strauss, Pharm.D., M.S. **Learning Objectives:** • Identify important considerations for designing a facility cleaning plan. • Describe the process to clean and disinfect classified areas. • Discuss how to build environmental control / monitoring skills into a compounded sterile preparation training program. • Contrast the required supplies and cleaning/disinfecting agents used in laminar airflow systems. • Differentiate cleaning a primary engineering control and a hazardous biological safety cabinet. • Explain how environmental conditions are measured and maintained. • Illustrate how to properly perform volumetric air sampling. • Recommend an appropriate action plan based on personnel and environmental monitoring reports.
ACPE # 0204-0000-19-750-H07-P **CE Hours:** 2 **Activity Type:** Application	**Title: Handling Hazardous Drugs for Pharmacists: Part 1** This activity covers the scope and requirements associated with USP chapter <800>, developing Assessments of Risk, and how to evaluate your organization's current compliance. **Faculty:** Patricia C. Kienle, B.S.Pharm., M.P.A., FASHP **Learning Objectives:** • Describe the key requirements of USP <800> Hazardous Drugs – Handling in Healthcare Settings, including limiting risk to personnel, facility design, and safe work practices. • Explain the scope of USP <800>. • Categorize the handling of hazardous drugs in your organization to determine their eligibility for inclusion in your Assessment of Risk.

	• Create or review an acknowledgement of risk document. • List questions relevant to your organization after reviewing USP <800>. • Assess your organization's current compliance with USP <800>. • Evaluate the organization's storage and compounding areas. • List the three types of containment primary engineering controls used for compounding hazardous drugs. • List the two types of containment secondary engineering controls used for storage and compounding hazardous drugs. • Analyze your organization's most recent certification report. • Interpret pressure gradients, air flow direction, and air changes per hour.
ACPE # 0204-0000-19-751-H07-P **CE Hours:** 2.5 **Activity Type:** Application	**Title: Handling Hazardous Drugs for Pharmacists: Part 2** This activity describes the key responsibilities of the Designated Person, organizing training materials and checklists, and appropriate hazardous drug work practices. **Faculty:** Patricia C. Kienle, B.S.Pharm., M.P.A., FASHP **Learning Objectives:** • Organize your organization's training materials. • List the key responsibilities of the Designated Person. • Differentiate personal protective equipment used in hazardous drug compounding from that used in non-hazardous compounding. • Describe work practice from receiving through compounding. • Design a policy and procedure for handling spills. • Apply appropriate strategies to achieve compliance identified in gap analyses. • Create a checklist that can be used for daily, monthly, and annual monitors for facilities and personnel.
ACPE # 0204-0000-19-752-H07-P **CE Hours:** 3.5 **Activity Type:** Application	**Title: Managing the Product until Final Check or Disposal for Pharmacists** This activity discusses the appropriate movement of drugs and supplies used in sterile product preparation from receipt through final check or disposal. **Faculty:** Joshua S. Ilenin, Pharm.D., M.S. **Learning Objectives:** • Illustrate the appropriate movement of drugs and supplies into an ISO classified cleanroom environment. • Analyze storage conditions for drugs and supplies to determine compliance with USP <797> and manufacturer recommendations. • Choose appropriate methods of source ingredient verification prior to compounding sterile products. • Identify appropriate components of physical inspection for source ingredients and final products. • Interpret a Master Formulation Record and Compounding Record as part of the compounded sterile preparation verification process.

	• Describe when sterility testing and bacterial endotoxin testing is a required quality control in the sterile compounding process. • Apply FDA repackaging guidance to ensure compliance with routine cleanroom practices. • Choose appropriate supplies for packaging and repackaging compounded sterile preparations. • Differentiate between storage, transport, and disposal requirements for hazardous and non-hazardous compounded sterile products. • Analyze storage and transport conditions to ensure compounded sterile product integrity is maintained prior to administration. • Choose appropriate waste disposal stream for pharmaceutical products and supplies used in sterile compounding.
ACPE # 0204-0000-19-753-H07-P **CE Hours:** 3.25 **Activity Type:** Application	**Title: Patient Care** This activity covers patient- and preparation-specific parameters associated with sterile product preparation that affect patient outcomes, communication strategies to influence adherence or provider practices, and managing adverse events. **Faculty:** Erich Brechtelsbauer, Pharm.D., M.S., BCPS **Learning Objectives:** • Discuss how sterile compounding has evolved with a greater focus on patient care. • Assess patient-specific and preparation-specific parameters that affect patient outcomes. • Differentiate methods of medication administration and delivery systems. • Recommend communication strategies to influence patient adherence and healthcare provider practices. • Contrast pharmaceutical storage, handling, and disposal requirements for healthcare workers and patients. • Evaluate how duration of therapy impacts preparation and administration techniques. • Restate core principles of patient safety and infection control. • List relevant drug information resources. • Describe effective communication systems for problems, concerns, and complaints. • Compare patient-specific risk factors with associated adverse events. • Recommend approaches to treat or prevent adverse events. • Analyze adverse events utilizing appropriate investigative inquiry and reporting systems.
ACPE # 0204-0000-19-754-H07-P **CE Hours:** 3 **Activity Type:** Application	**Title: Quality Management** This activity describes managing all the components associated with ensuring high quality sterile product preparation operations including personnel training, environmntal monitoring, and standard operating procedures.

	Faculty: Elaine Strauss, Pharm.D., M.S. **Learning Objectives:** • Summarize components of a sterile product preparation training program. • Contrast personnel education and testing methods to ensure safe and compliant sterile product preparation. • Propose a plan for remediating sterile product preparation competency. • Identify mechanisms for ensuring employee safety during the compounding process. • Differentiate methods for analyzing and reporting cleanroom safety events. • Design an employee Medical Surveillance Program. • Develop an environmental and personnel sampling program. • Restate equipment and cleanroom certification and maintenance requirements. • Distinguish key components for developing and revising master formulation records, compounding records, and standard operating procedures. • Evaluate outsourced compounded sterile preparations and services using key variables, decision points, and regulatory standards. • Recommend a plan for conducting routine inspections of internal compounding operations and outsourced compounding services. • Identify challenges and opportunities for working with internal facilities and environmental departments.

Faculty Information

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Disclosures

In accordance with the ACPE's and ACCME's Standards for Commercial Support, anyone in a position to control the content of an educational activity is required to disclose to the accredited provider their relevant financial relationships. In accordance with these Standards, all potential conflicts of interests have been resolved. *An individual has a **relevant financial relationship** if he or she (or spouse/domestic partner) has a financial relationship in any amount occurring in the last 12 months with a commercial interest whose products or services are discussed in the activity content over which the individual has control.*

As defined by ACCME, a **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The Standards for Commercial Support do not consider providers of clinical service directly to patients to be commercial interests.

- Ryan A. Forrey, Pharm.D., M.S., FASHP, Becton, Dickinson and Company (BD): employee
- Kevin N. Hansen, Pharm.D., M.S., BCPS, Baxter International, Inc.: speaker and PharMEDium Services, LLC: speaker
- Patricia C. Kienle, B.S.Pharm., M.P.A., FASHP, Cardinal Health: employee and CriticalPoint, LLC: consultant
- Elaine Strauss, Pharm.D., M.S., WorkingBuildings Group: consultant
- All other planners, presenters, reviewers, and ASHP staff report no financial relationships relevant to this activity.

Methods and CE Requirements

This online activity consists of a combined total of 16 learning modules. Pharmacists are eligible to receive a total of 38.00 hours of continuing education credit by completing all 16 modules within this certificate program.

Participants must participate in the entire activity, complete the evaluation and all required components to claim continuing pharmacy education credit online at ASHP eLearning Portal. Follow the prompts to claim credit and view your statement of credit within 60 days after completing the activity.

Important Note – ACPE 60 Day Deadline:
Per ACPE requirements, CPE credit must be claimed within 60 days of being earned – no exceptions!
To verify that you have completed the required steps and to ensure your credits have been reported to CPE Monitor, we encourage you to check your NABP eProfile account to validate your credits were transferred successfully before the ACPE 60-day deadline. After the 60 day deadline, ASHP will no longer be able to award credit for this activity.

System Technical Requirements

System Requirements Courses and learning activities are delivered via your Web browser and Acrobat PDF. Users should have a basic comfort level using a computer and navigating web sites.

View the minimum technical and system requirements for learning activities.