CE Activity Announcement

Compounded Sterile Preparations Certificate for Pharmacists

ACPE Activity Number:

- 0204-0000-21-819-H07-P
- 0204-0000-21-820-H07-P
- 0204-0000-21-821-H07-P
- 0204-0000-21-822-H07-P
- 0204-0000-21-823-H07-P
- 0204-0000-21-824-H07-P
- 0204-0000-21-825-H07-P
- 0204-0000-21-826-H07-P
- 0204-0000-21-827-H07-P
- 0204-0000-21-828-H07-P
- 0204-0000-21-829-H07-P
- 0204-0000-21-830-H07-P
- 0204-0000-21-831-H07-P
- 0204-0000-21-832-H07-P
- 0204-0000-21-833-H07-P
- 0204-0000-21-834-H07-P
- 0204-0000-21-835-H07-P

Release Date: December 1, 2021
Expiration Date: December 1, 2024
Activity Type: Application-based
CE Credit Hours (No partial credit): 32 contact hours/17 activities (see below for details)
Activity Fee: $445.00/$545.00 member/non-member

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 activity is intended for pharmacists preparing and managing the operations associated with compounding sterile preparations and serves as a preparatory course for the Board of Pharmacy Specialties Board Certified Compounding Pharmacist (BCSCP) certification exam.

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Activity Overview

The online learning activities provide 32 hours of ACPE continuing education for pharmacists, incorporating recorded presentations, readings, video demonstrations, and exercises in curricular modules. The learning activities cover compounding sterile preparation practice standards and regulations, pharmacy calculations, facilities and engineering controls, environmental monitoring, cleanroom personnel behaviors, sterile compounding components and procedures, basics of parenteral nutrition, stability and sterility, beyond-use date assignment, nonsterile to sterile compounding, hazardous drugs, managing the compounding process from sourcing 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 cleanroom operations.

Learning Objectives and Schedule of Activities

Activity CE Information	Title, Description, and Learning Objectives
ACPE #: **0204-0000-21-819-H07-P** CE Hours: **1.75 contact hours (0.175 CEUs)** Activity Type: **Application**	**Title: Overview of Standards, Guidelines, Regulations, and Best Practices** This activity discusses the guidelines, best practices, standards, and regulations that impact the practice of compounding sterile preparations. **Faculty:** Michael Ganio, Pharm.D., M.S., BCSCP, FASHP **Learning Objectives:** 1. List the standards of practice that apply to sterile compounding in the United States. 2. Identify best practices to ensure sterile compounding safety. 3. Differentiate between sterile compounding standards, guidelines, and best practices. 4. Describe the role of the United States Pharmacopeia in sterile compounding. 5. Discuss provisions of the Pharmaceutical Quality, Security and Accountability Act. 6. Contrast federal mechanisms that influence sterile compounding practice. 7. Differentiate the roles of the Food and Drug Administration and states in sterile compounding regulation. 8. Identify other regulations related to workplace safety. 9. Compare USP <797> standards to the noncompliance findings from FDA Form 483 inspection reports.

Activity CE Information	Title, Description, and Learning Objectives
	10. Analyze corrective and preventive action plans. 11. Explain the role of the compounder in assuring the safety of compounded sterile preparations.
ACPE #: **0204-0000-21-820-H07-P** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Pharmacy Calculations for Pharmacists** This activity covers calculations routinely used by pharmacists when compounding sterile preparations. **Faculty:** DeeAnn Wedemeyer-Oleson, Pharm.D., M.H.A., CPHQ, CPPS **Learning Objectives:** 1. Calculate doses in both weight and volume using proportions with concentrations expressed as fractions, percents, and ratios. 2. Use common conversions to perform sterile compounding calculations. 3. Calculate doses based on patient weight and body surface area. 4. Select quantity of dosage units required to supply an order for a specified time period. 5. Calculate infusion rates. 6. Calculate concentrations and doses involving milliequivalents and millimoles. 7. Apply the alligation method to calculate parts of two solutions with different concentrations to compound a solution with a different desired concentration.
ACPE #: **0204-0000-21-821-H07-P** CE Hours: **1.75 contact hours (0.175 CEUs)** Activity Type: **Application**	**Title: Compounding Facilities and Engineering Controls** This activity discusses the design, construction, purpose, and maintenance of compounding facilities including the primary and secondary engineering controls and ancillary compounding equipment used in compounding sterile preparations. **Faculty:** Angela Yaniv, Pharm.D., BCSCP **Learning Objectives:** 1. Describe the primary engineering controls used in sterile compounding.

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	2. Explain the principles of generating a laminar airflow environment in the primary engineering control. 3. Identify the secondary engineering control elements in a clean room environment. 4. Differentiate between a segregated compounding area and a clean room. 5. Discuss essential design elements for a sterile compounding facility. 6. Analyze the advantages and disadvantages of available finish materials. 7. Contrast the ancillary equipment and automated compounding devices used in compounding sterile preparations. 8. Assess selection, placement, calibration, and maintenance of ancillary equipment and automated compounding devices. 9. Describe equipment and cleanroom certification and maintenance requirements. 10. Develop a downtime plan for secondary and primary engineering control maintenance or failure.
ACPE #: **0204-0000-21-822-H07-P** CE Hours: **1.75 contact hours (0.175 CEUs)** Activity Type: **Application**	**Title: Cleanroom Personnel Behaviors and Competencies** This activity describes the necessary behaviors and competencies cleanroom staff must master to minimize contamination in cleanroom facilities. **Faculty:** Angela Yaniv, Pharm.D., BCSCP **Learning Objectives:** 1. Identify sources of contamination within the cleanroom. 2. List work behaviors required to prevent the introduction of contaminants into the cleanroom environment. 3. Evaluate appropriate hand hygiene technique. 4. Describe donning and doffing procedures for personal protective equipment used in cleanrooms. 5. Contrast garb and glove requirements and procedures for non-hazardous and hazardous compounding. 6. List core competencies required for sterile compounding personnel. 7. Describe the testing requirements to assess appropriate garbing and aseptic technique.

Activity CE Information	Title, Description, and Learning Objectives
	8. Design a training program to ensure mastery of core competencies by sterile compounding personnel.
ACPE #: **0204-0000-21-823-H07-P** CE Hours: **2.25 contact hours (0.225 CEUs)** Activity Type: **Application**	**Title: Compounding Materials, Equipment, and Resources** This activity covers supplies, critical sites, equipment, labels, and references essential for compounding sterile preparations. **Faculty:** Ashley M. Duty, Pharm.D., M.S., BCSCP **Learning Objectives:** 1. List basic compounding supplies. 2. Differentiate between the critical sites and non-critical sites on syringes, needles, vials, and bags. 3. Assess a vial's medication label to determine number of doses and ingredients. 4. Select appropriate compounding materials based on review of medication order. 5. Differentiate between the types of automated compounder pumps used in compounding sterile preparations. 6. Choose the appropriate compounding equipment needed for various situations. 7. Interpret several types of patient medication labels. 8. Create a master formulation record and a compounding record. 9. Use tertiary resources to find necessary drug information.
ACPE #: **0204-0000-21-824-H07-P** CE Hours: **1.75 contact hours (0.125 CEUs)** Activity Type: **Application**	**Title: Getting Started in Compounding Sterile Preparations for Pharmacists** This activity describes dosage forms, small and large volume parenterals, routes of administration, an introduction to parenteral nutrition, high alert medications, and general considerations for automated compounding devices. **Faculty:** Ashley M. Duty, Pharm.D., M.S., BCSCP **Learning Objectives:** 1. Describe the dosage forms, preparation requirements, and routes of administration.

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	2. Differentiate between small and large volume parenterals. 3. Discuss appropriate routes of administration for compounded sterile preparations. 4. Evaluate medications used in sterile compounding that require special safeguards to reduce the risk of errors. 5. Explain the components and role of parenteral nutrition. 6. Evaluate parenteral nutrition orders and processes. 7. Assess automated compounding devices for safety, interoperability, and overall functionality.
ACPE #: **0204-0000-21-825-H07-P** CE Hours: **2.5 contact hours (0.25 CEUs)** Activity Type: **Application**	**Title: Basics of Parenteral Nutrition** This activity covers products, patient and product-related factors, and vascular access considerations when recommending and compounding parenteral nutrition for patients. **Faculty:** • Todd W. Canada, Pharm.D., BCNSP, BCCCP, FASHP, FTSHP, FASPEN • David C. Evans, M.D. • Anne M. Tucker, Pharm.D., BCNSP **Learning Objectives:** 1. Differentiate among available parenteral nutrition products. 2. Compare advantages and disadvantages of standardized commercially-available parenteral nutrition products versus customized parenteral nutrition formulations. 3. Select parenteral nutrition products based on relevant patient characteristics, availability, stability and compatibility. 4. Recommend strategies for handling parenteral nutrition product shortages. 5. Assess the parenteral nutrition compatibility issues for a given formulation. 6. Differentiate between stability concerns for 2-in-1 parenteral nutrition versus total nutrient admixture formulations. 7. Describe educational instruction techniques for home preparation of parenteral nutrition.

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	8. Identify factors that influence the selection of an appropriate vascular access device for parenteral nutrition. 9. Compare and contrast the vascular access options available for administering parenteral nutrition. 10. Describe strategies for preventing potential complications of vascular access devices.
ACPE #: **0204-0000-21-826-H07-P** CE Hours: **2.5 contact hours (0.25 CEUs)** Activity Type: **Application**	**Title: Stability and Sterility: Assigning Beyond-Use Dates** This activity discusses the factors that influence the stability and sterility of compounded sterile preparations, considerations when assigning or extending beyond-use dates, and quality control testing. **Faculty:** Kevin N. Hansen, Pharm.D., M.S., BCPS, BCSCP **Learning Objectives:** 1. List factors that influence beyond-use date assignments for compounded sterile preparations. 2. Describe physical and chemical compatibility criteria for components. 3. Apply USP <797> risk categories to assigning a proper beyond-use date for compounded sterile preparations. 4. Recommend a beyond-use date for a final compounded sterile preparation using evidence-based information. 5. Differentiate conditions under which sterility, potency, and endotoxin testing are required. 6. Identify requirements for quality control testing. 7. Interpret results of quality control testing. 8. Apply USP standards to properly extend a beyond-use date.
ACPE #: **0204-0000-21-827-H07-P** CE Hours: **1.5 contact hours (0.15 CEUs)** Activity Type: **Application**	**Title: Aseptic Techniques for Compounding Sterile Preparations** 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, Pharm.D., BCSCP **Learning Objectives:** 1. Define the concept of “first air”.

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	2. Contrast the location of the direct compounding area in horizontal and vertical airflow. 3. Describe proper methods for disinfecting critical sites on commonly used sterile components. 4. Differentiate workflow steps and best practices associated with compounding in a horizontal laminar airflow workbench and a compounding aseptic isolator. 5. Describe techniques for reconstituting sterile powders. 6. Evaluate placement of hands to prevent disruption of airflow to critical sites when reconstituting powders and withdrawing diluent or medication from vials. 7. Summarize various strategies used to prevent the potential for coring vial stoppers. 8. Recommend compounding techniques and behaviors that should be used to prevent and address a sharps injury.
ACPE #: **0204-0000-21-828-H07-P** CE Hours: **1.25 contact hours (0.125 CEUs)** Activity Type: **Application**	**Title: Compounding Medication Cassettes and Other Special Sterile Preparations** This activity covers techniques and procedures associated with compounding medication cassettes and other "specials" including epidural, intrathecal, and ophthalmic preparations. **Faculty:** Lynda Kiliany, Pharm.D., BCSCP **Learning Objectives:** 1. Describe techniques for compounding medication cassettes. 2. Calculate doses and infusion rates used with medication cassettes. 3. Explain how to accurately measure components using principles of volumetric accuracy. 4. Describe techniques for compounding 'specials' including epidural, intrathecal, and ophthalmic preparations. 5. Differentiate situations when sterile filtration and/or preservative-free ingredients must be utilized when compounding special administration medications.
ACPE #: **0204-0000-21-829-H07-P** CE Hours: **2 contact hours (0.2 CEUs)**	**Title: Compounding Non-sterile to Sterile Preparations**

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Activity CE Information	Title, Description, and Learning Objectives
Activity Type: **Application**	This activity describes the regulatory requirements and other unique considerations associated with nonsterile to sterile compounding. **Faculty:** Matthew M. Brown, Pharm.D., DPLA, MLS(ASCP) **Learning Objectives:** 1. Summarize the requirements in section 503A of the Food, Drug, and Cosmetic Act regarding compounding with bulk active pharmaceutical ingredients. 2. Apply USP <797> standards and guidelines to non-sterile to sterile compounding. 3. Differentiate between best practices and regulatory guidance. 4. Discuss key requirements for installation, calibration, and maintenance of equipment used in non-sterile to sterile compounding. 5. Describe validation processes for sterilization equipment. 6. Compare terminal and aseptic sterilization. 7. Calculate endotoxin limits for final products. 8. Summarize sterility testing requirements outlined in USP <71>. 9. Explain best practice quality assurance standards for non-sterile to sterile compounding.
ACPE #: **0204-0000-21-830-H07-P** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Managing and Maintaining the Cleanroom Environment** This activity discusses the important elements of cleaning and environmental monitoring required to maintain the cleanroom environment. **Faculty:** Majid Tanas, Pharm.D., M.H.A., M.S. **Learning Objectives:** 1. Contrast the roles engineering and administrative controls have in maintaining a cleanroom environment. 2. Discuss principles to consider when implementing design and cleaning processes to ensure and maintain high quality aseptic compounding practices. 3. Differentiate key roles, purpose, and scope of staff working in the cleanroom.

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	4. Assess the different reagents and processes used to clean primary engineering controls. 5. Describe how to clean primary and secondary engineering controls used for compounding hazardous and non-hazardous preparations to ensure regulatory compliance. 6. Summarize how cleaning regimens impact environmental monitoring results. 7. Design an environmental monitoring performance qualification plan including regularly scheduled monitoring. 8. Recommend appropriate action plans based on personnel and environmental monitoring data.
ACPE #: **0204-0000-21-831-H07-P** CE Hours: **1.75 contact hours (0.175 CEUs)** Activity Type: **Application**	**Title: Hazardous Drugs: Safety and Compliance** 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, R.Ph., M.P.A, BCSCP, FASHP **Learning Objectives:** 1. Describe the key requirements of USP <800> Hazardous Drugs – Handling in Healthcare Settings, including limiting risk to personnel, facility design, and safe work practices. 2. Define the scope of USP <800>. 3. Categorize the handling of hazardous drugs in your organization to determine their eligibility for inclusion in your Assessment of Risk. 4. Create an acknowledgement of risk document. 5. List questions relevant to your organization after reviewing USP <800>. 6. Assess your organization's current compliance with USP <800>. 7. Evaluate the organization's storage and compounding areas. 8. List the three types of containment primary engineering controls used for compounding hazardous drugs. 9. List the two types of containment secondary engineering controls used for storage and compounding hazardous drugs.

Activity CE Information	Title, Description, and Learning Objectives
	10. Analyze your organization's most recent certification report. 11. Interpret pressure gradients, air flow direction, and air changes per hour.
ACPE #: **0204-0000-21-832-H07-P** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Hazardous Drugs: Training and Work Practices** 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, R.Ph., M.P.A, BCSCP, FASHP **Learning Objectives:** 1. List the key responsibilities of the Designated Person. 2. Differentiate personal protective equipment used in hazardous drug compounding from that used in non-hazardous compounding. 3. Describe work practice from receiving through compounding. 4. Design a policy and procedure for handling spills. 5. Apply appropriate strategies to achieve compliance identified in gap analyses. 6. Create a checklist that can be used for daily, monthly, and annual monitors for facilities and personnel.
ACPE #: **0204-0000-21-833-H07-P** CE Hours: **2 contact hours (0.2 CEUs)** Activity Type: **Application**	**Title: Managing Compounded Sterile Preparations until Final Check or Disposal for Pharmacists** This activity discusses the appropriate movement of drugs and supplies used in compounding sterile preparations from receipt through final check or disposal. **Faculty:** Angela Yaniv, Pharm.D., BCSCP **Learning Objectives:** 1. Choose appropriate methods to verify the appropriateness of source ingredients. 2. List cold-chain requirements for refrigerated and frozen products. 3. Identify USP <797> requirements and best practices to introduce materials into a controlled environment. 4. Differentiate storage requirements for hazardous and non-hazardous drugs.

Activity CE Information	Title, Description, and Learning Objectives
	5. Compare cleanroom storage options for high-risk medications, controlled drugs, investigational drugs, non-sterile bulk ingredients, and bulk chemicals. 6. Define preparation labeling guidance and best practices. 7. Apply FDA repackaging guidance to sterile preparations. 8. Differentiate the elements of a master formulation record and a compounding record. 9. Compare the advantages and disadvantages of available final preparation verification methods. 10. Describe the requirements and best practices for controlled substance documentation. 11. Compare storage options for finished compounded sterile preparations prior to administration. 12. Describe requirements and best practices for transport of finished sterile preparations within and outside of the facility. 13. Identify appropriate waste streams for unused compounded sterile preparations, controlled drugs, and used supplies.
ACPE #: **0204-0000-21-834-H07-P** CE Hours: **2 contact hours (0.175 CEUs)** Activity Type: **Application**	**Title: Patient Care** This activity covers strategies to identify and manage patient- and preparation-specific parameters, caregiver and provider communications, adverse events, and investigative analysis to positively impact patient outcomes. **Faculty:** Joanna Robinson, Pharm.D., M.S., BCSCP **Learning Objectives:** 1. Assess patient-specific and preparation-specific parameters that affect patient outcomes. 2. Differentiate methods of medication administration and delivery systems. 3. Categorize elements of a patient and caregiver training program. 4. Recommend communication strategies to influence patient adherence, healthcare provider practices, and address problems or concerns. 5. Create a script for a pharmacist teaching a patient or caregiver how to monitor for therapeutic complications.

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	6. Compare patient-specific risk factors with associated adverse events. 7. Recommend approaches to treat or prevent adverse events. 8. Analyze adverse events utilizing appropriate investigative inquiry and reporting systems. 9. Explain major steps and components of a root cause analysis process.
ACPE #: **0204-0000-21-835-H07-P** CE Hours: **1.25 contact hours (0.125 CEUs)** Activity Type: **Application**	**Title: Quality Management** This activity discusses using a quality management system approach to ensure safe and compliant operations resulting in high quality compounded sterile preparations. **Faculty:** Majid Tanas, Pharm.D., M.H.A., M.S. **Learning Objectives:** 1. Identify key components of quality management associated with compounding hazardous and nonhazardous sterile preparations. 2. Explain how quality management processes serve as a safety tool for nonhazardous and hazardous sterile compounding activities. 3. Apply the four pillars of quality management to cleanroom operations. 4. Recommend corrective action and preventive action plans based on discoveries from continuous quality improvement processes. 5. Discuss the challenges and pitfalls associated with implementing a quality management program. 6. Differentiate between 503A and 503B. 7. Create standards for documentation including master formulation records, compounding records, and standard operating procedures. 8. Assess outsourced products and services to ensure compliance with established processes and facility requirements.

Faculty Information

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Relevant Financial Relationship Disclosure

In accordance with our accreditor's Standards of Integrity and Independence in Accredited Continuing Education, ASHP requires that all individuals in control of content disclose all financial relationships with ineligible companies. An individual has a relevant financial relationship if they have had a financial relationship with ineligible company in any dollar amount in the past 24 months and the educational content that the individual controls is related to the business lines or products of the ineligible company.

An ineligible company is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The presence or absence of relevant financial relationships will be disclosed to the activity audience.

The following persons in control of this activity's content have relevant financial relationships:

- Todd Canada
  - Fresenius Kabi: speakers bureau
- David C. Evans
  - Abbott Laboratories: consultant, speakers bureau
  - Alcresta: consultant, speakers bureau
  - Fresenius Kabi: consultant, speakers bureau
  - CVS/Option Care: consultant
- Kevin N. Hansen
  - Baxter: speakers bureau, advisory board
  - Omnicell: speakers bureau, advisory board

All other persons in control of content do not have any relevant financial relationships with an ineligible company.

As required by the Standards of Integrity and Independence in Accredited Continuing Education definition of ineligible company, all relevant financial relationships have been mitigated prior to the CPE activity.

Methods and CE Requirements

This online activity consists of a combined total of 17 learning modules. Pharmacists are eligible to receive a total of 32 hours of continuing education credit by completing all 17 modules within this certificate.

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

Important Note – ACPE 60 Day Deadline:
Per ACPE requirements, CPE credit must be claimed within 60 days of being earned. To verify that you have completed the required steps and to ensure your credits have been reported to CPE Monitor, check

your NABP eProfile account to validate that 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.