Compounded Sterile Preparations Pharmacy Review Course for Recertification

**** Materials for this course will release 10/20/2021 ****

Compounded Sterile Preparations Pharmacy Review Course for Recertification + RECERT EXAMS Package (Cert # L219326)

Teaser: This online course will help you earn BCSCP recertification credit. With this course, get comprehensive, practical guidance, with a variety of complex cases, including references for further study.

Tag: Certifications; Compounded Sterile Preparations

ACPE Numbers: Various – see listing below
Pre-Sale Date: 09/22/2021
Content Release Date: 10/20/2021
Expiration Date: 04/05/2022
Activity Type: Application-based
CE Credits: 38 (BPS and ACPE)
Activity Fee: $495 (ASHP member); $595 (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

These recertification activities are intended for board certified pharmacists seeking to update their knowledge and skills in compounded sterile preparations pharmacy.

Activity Overview

This course is intended for BCSCP pharmacists in need of recertification credit and is designed based on the content outline developed by the Board of Pharmacy Specialties (BPS) to provide an overview of recent standards and guidelines that specialists should be familiar with in practice. The course uses a case-based approach to discuss patient care issues. In this series, faculty will:

- Review pertinent clinical topics and practice skills
- List valuable resources for further self-study

This online course consists of 16 activities (see table below) and provides up to 38 hours of continuing pharmacy education credit and/or recertification credit.

Recertification Credit*

Board certified pharmacists are eligible to receive up to 38 hours of recertification credit for completing this course. To earn recertification credit, learners must review the course content and successfully complete the online assessments by the deadline. Only completed assessments will be eligible for credit; no partial or incomplete assessments will be processed. You are allowed only one attempt to successfully complete the assessments.

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This course is not intended for those preparing to take the BPS Compounded Sterile Preparations Pharmacy Specialty Examination for Certification. To prepare for the examination, please see courses here: https://store.ashp.org/Default.aspx?TabID=251&productId=674936100

These activities are part of the ASHP professional development program for BCSCP recertification approved by the BPS.

** Please note: Review Course for Recertification may only be completed for recertification credit up to two times, in nonconsecutive years, during the 7-year recertification cycle.*

Learning Activity	ACPE Number	Credit Hours	*Assessment Pass Point
Introduction to Sterile Product Preparation	0204-0000-19-739-H07-P	2.5	80%
Pharmacy Calculations	0204-0000-19-740-H07-P	1.75	
Overview of Compounding Facilities and Engineering Controls	0204-0000-19-741-H07-P	2.25	
Cleanroom Personnel Basics	0204-0000-19-742-H07-P	1.5	
	Group 1 Assessment	**8.0**	
Compounding Materials, Equipment, and Resources for Sterile Product Preparation	0204-0000-19-743-H07-P	3.25	77%
Getting Started in Sterile Product Preparation	0204-0000-19-744-H07-P	1.5	
Stability and Sterility: Assigning Beyond Use Dates	0204-0000-19-745-H07-P	2.5	
	Group 2 Assessment	**7.25**	
Aseptic Techniques for Compounding Non-Hazardous Preparations	0204-0000-19-746-H07-P	2.75	80%
Small Volume Parenterals and Other Non-Hazardous Preparations	0204-0000-19-747-H07-P	2.5	
Nonsterile to Sterile Compounding	0204-0000-19-748-H07-P	1	
Maintaining the Cleanroom Environment	0204-0000-19-749-H07-P	2.25	
	Group 3 Assessment	**8.5**	
Handling Hazardous Drugs: Part 1	0204-0000-19-750-H07-P	2	80%
Handling Hazardous Drugs: Part 2	0204-0000-19-751-H07-P	2.5	
Managing the Product until Final Check or Disposal	0204-0000-19-752-H07-P	3.5	
	Group 4 Assessment	**8.0**	
Patient Care	0204-0000-19-753-H07-P	3.25	82%
Quality Management	0204-0000-19-754-H07-P	3	
	Group 5 Assessment	**6.25**	

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Learning Objectives
After participating in this CPE activity, learners should be able to:

Introduction to Sterile Product Preparation
ACPE #: 0204-0000-19-739-H07-P
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.

Pharmacy Calculations
ACPE #: 0204-0000-19-740-H07-P
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.

Overview of Compounding Facilities and Engineering Controls
ACPE #: 0204-0000-19-741-H07-P
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.

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Cleanroom Personnel Basics
ACPE #: 0204-0000-19-742-H07-P
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.

Compounding Materials, Equipment, and Resources for Sterile Product Preparation
ACPE #: 0204-0000-19-743-H07-P
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.

Getting Started in Sterile Product Preparation
ACPE #: 0204-0000-19-744-H07-P
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.

Stability and Sterility: Assigning Beyond Use Dates
ACPE #: 0204-0000-19-745-H07-P
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.

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Aseptic Techniques for Compounding Non-Hazardous Preparations
ACPE #: 0204-0000-19-746-H07-P
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.

Small Volume Parenterals and Other Non-Hazardous Preparations
ACPE #: 0204-0000-19-747-H07-P
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.

Nonsterile to Sterile Compounding
ACPE #: 0204-0000-19-748-H07-P
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.

Maintaining the Cleanroom Environment
ACPE #: 0204-0000-19-749-H07-P
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.

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Handling Hazardous Drugs: Part 1
ACPE #: 0204-0000-19-750-H07-P
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.

Handling Hazardous Drugs: Part 2
ACPE #: 0204-0000-19-751-H07-P
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.

Managing the Product until Final Check or Disposal
ACPE #: 0204-0000-19-752-H07-P
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.

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Patient Care
ACPE #: 0204-0000-19-753-H07-P
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.

Quality Management
ACPE #: 0204-0000-19-754-H07-P
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.

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All other planners, presenters, reviewers, ASHP staff and others with an opportunity to control content report no financial relationships relevant to this activity.

Methods and CE Requirements
Activities can be completed in any order. Each activity consists of audio, video, and/or PDFs and evaluations. Learners must review all content and complete the evaluations to receive continuing pharmacy education credit for each activity.

Follow the prompts to claim, view, or print the statement of credit within 60 days after completing the activity.

System Technical Requirements
Learning activities are delivered via your Web browser and Acrobat PDF. For all activities you should have a basic comfort level using a computer and navigating web sites.

View the minimum technical and system requirements for learning activities.

Development
These activities were developed by ASHP.