CE Activity Announcement
Compliance for ASHP CE Activity

Sterile Product Preparation Training and Certificate Program

ACPE Activity Number(s): 0204-0000-16-717-H04-P & T thru 0204-0000-16-724-H04-P & T
Release Date: May 16, 2016
Expiration Date: May 16, 2019
Activity Type: Knowledge-based
CE Credit Hour(s) *(no partial credit)*: 17.25 hours

Accreditation for Pharmacists and Pharmacy Technicians

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, pharmacy technicians, or other pharmacy personnel who have responsibility for compounding sterile preparations.

Activity Overview

These modules are designed for participants to recognize the importance of aseptic processing and develop the knowledge and skills necessary to prepare sterile products safely and effectively. Participants will learn the history and evolution of aseptic processing as it relates to today's practice standards and will be taught the behaviors and skills required of all personnel engaged in compounding sterile products. After completing all of the modules, participants should be proficient in the basic fundamental concepts required for safe and compliant sterile product preparation in a cleanroom environment.

Learning Objectives and Schedule of Activities

Activity CE Information	Title, Descriptions, and Learning Objectives
ACPE: 0204-0000-16-717-H04-P 0204-0000-16-717-H04-T **CE Hours:** 2.5 **Activity Type:** Knowledge-based	**Title: Evolution and Overview of Aseptic Processing** This activity discusses the key events influencing the evolution of aseptic processing and the general principles and guidelines that affect sterile product preparation today. **Learning Objectives** • List key advancements in aseptic processing since pioneered in the 1860's. • Discuss key considerations for compounding outlined in the Drug Quality and Security Act (DQSA). • Explain the purpose, objectives, and main components of USP Chapter 797. • Describe how USP Chapter 800 expands on aseptic processes established in USP Chapter 797. • Recognize unique considerations associated with compounding parenteral nutrition. • Describe the effect drug shortages can have on sterile compounding practices.

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ACPE: 0204-0000-16-718-H04-P 0204-0000-16-718-H04-T **CE Hours:** 2 **Activity Type:** Knowledge-based	**Title: Core Competencies and Facilities Basics** This activity describes the basic personnel qualifications, training, facilities, and equipment for aseptic processing. **Learning Objectives** • Describe a training and assessment program to ensure mastery of core competencies by aseptic processing personnel. • Identify sterile compounding facility requirements. • Describe primary and secondary engineering controls used in compounding facilities. • Recognize air quality differences as defined by International Organization for Standardization (ISO) air classifications. • Explain key concepts associated with aseptic processing.
ACPE: 0204-0000-16-719-H04-P 0204-0000-16-719-H04-T **CE Hours:** 2.25 **Activity Type:** Knowledge-based	**Title: Sterile Product Categorization** This activity explains the compounding processes and considerations associated with categorizing sterile products and radiopharmaceuticals. **Learning Objectives** • Explain differences between Category 1 and Category 2 compounded sterile products. • Recognize appropriate Beyond Use Dating principles. • Describe key variances between risk level classifications. • Discuss unique factors to consider when compounding radiopharmaceuticals. • Define terminology used in sterile product categorization.
ACPE: 0204-0000-16-720-H04-P 0204-0000-16-720-H04-T **CE Hours:** 1.75 **Activity Type:** Knowledge-based	**Title: The Basics All Cleanroom Personnel Need To Know** This activity covers the standard behavior and procedures all personnel working in the cleanroom should understand along with generally accepted best practices for the safe preparation of sterile compounds. **Learning Objectives** • Explain necessary behaviors for cleanroom staff. • Describe techniques for proper hand hygiene. • Describe the appropriate garbing sequence. • Identify the components and performance characteristics of garb and gloves for non-hazardous drug and hazardous drug compounding. • Discuss key concepts related to practice guidelines for safe sterile product preparation.
ACPE: 0204-0000-16-721-H04-P 0204-0000-16-721-H04-T **CE Hours:** 2.5 **Activity Type:** Knowledge-based	**Title: Primary Engineering Controls** This activity discusses primary engineering controls and the general principles of creating airflow appropriate for sterile product preparation. **Learning Objectives** • Identify primary engineering controls. • Explain the principles of generating a laminar flow environment in the primary engineering control. • Discuss general considerations for choosing primary engineering control. • Describe the differences between primary engineering controls. • Discuss the contributions barrier isolator technologies have made in aseptic processing.

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ACPE: 0204-0000-16-722-H04-P 0204-0000-16-722-H04-T **CE Hours:** 2 **Activity Type:** Knowledge-based	**Title: Compounding Basics in Laminar Airflow Systems** This activity discusses the key considerations required to maintain laminar airflow systems and effectively compound sterile preparations. **Learning Objectives** • Explain the principles of laminar airflow in primary engineering controls. • Describe the personnel behaviors necessary to maintain the effectiveness of laminar airflow. • Describe the process to clean and disinfect a classified area other than a Primary Engineering Control (PEC). • Explain the required supplies and cleaning / disinfecting agents used in Laminar Air Flow Systems (LAFS). • Describe the process to clean and disinfect a PEC. • Identify the drug containers, fluids, final containers, supplies, and transfer devices used in sterile compounding. • Explain the aseptic handling and processing skills necessary to compound sterile products.
ACPE: 0204-0000-16-723-H04-P 0204-0000-16-723-H04-T **CE Hours:** 2 **Activity Type:** Knowledge-based	**Title: Secondary Engineering Controls** This activity covers secondary engineering controls with associated work behaviors and cleaning procedures. **Learning Objectives** • Discuss components and appropriate work behaviors in the SEC to reduce contamination. • Describe cleaning and disinfecting procedures and frequency in the SEC. • Recognize different characteristics of SEC areas. • Explain SEC requirements based on compounded sterile preparation classifications. • Discuss key considerations when creating and maintaining SEC.
ACPE: 0204-0000-16-724-H04-P 0204-0000-16-724-H04-T **CE Hours:** 2.25 **Activity Type:** Knowledge-based	**Title: Navigating Equipment and Workflow Until the Final Check** This activity describes the equipment, procedures, and strategies used to ensure the safe preparation of compounded sterile products. **Learning Objectives** • Describe the use and best practices of key compounding equipment. • Describe the integration of error prevention strategies into sterile compounding and checking workflows. • Explain best practices associated with batch compounding. • Discuss documentation required for quality control in batch compounding. • Describe the key components required to validate the final check and release for use for sterile compounded preparations.

Methods and CE Requirements

This online activity consists of a combined total of 8 learning modules. Pharmacists and pharmacy technicians are eligible to receive a total of 17.25 hours of continuing education credit by completing all 8 modules within this certificate program.

Participants must participate in the entire activity and complete the evaluation to earn continuing pharmacy education credit. Follow the prompts online at the ASHP eLearning portal (http://elearning.ashp.org) to claim credit and view statements of credit within 60 days of completing the activity. Credits will be reported directly to CPE Monitor.

Faculty Information

Matthew W. Eberts, Pharm.D., M.B.A, FASHP
Director of Pharmacy Services
Lancaster General Health
Lancaster, PA

Lisa Ginsberg-Evans, B.S. Pharm
Manager, Clean Room and Sterile Products
University of Michigan Hospitals and Health System
Clinical Instructor
University of Michigan College of Pharmacy
Ann Arbor, MI

Marc Stranz, Pharm.D.
Vice President of Compliance
Elwyn Pharmacy Group
Garnet Valley, PA

Angela W. Yaniv, B.S.Pharm, Pharm.D.
Assistant Director of Pharmacy
Cleveland Clinic
Cleveland, OH

Disclosures

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In keeping with this requirement, ASHP asks that all faculty, advisory board members, planning committee members, content development consultants, and staff complete a disclosure form for each program in which they are involved. Anyone who refuses to disclose relevant financial relationships must be disqualified from any involvement with a continuing pharmacy education activity.

Faculty, planners, ASHP Staff and consultants report no relevant financial relationships pertinent to this activity.

Matthew W. Eberts, Pharm.D., M.B.A., FASHP
Lisa Ginsberg-Evans, B.S. Pharm
Marc Stranz, Pharm.D.
Angela W. Yaniv, B.S.Pharm, Pharm.D.
Jill L. Haug, Pharm.D., M.B.A.
Alicia M. Ross, B.S.

ASHP staff has no relevant financial relationships to disclose.

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