



Essentials of Sterile Compounding

An Accredited CE Activity (21 contact hours / 2.10 CEUs) designed for Pharmacists and Pharmacy Technicians

Summary

In 2015, a proposed revision to USP Chapter <797>, outlining standards for preparing compounded sterile preparations, was published and is currently under appeal. In addition to covering the key standards of the current chapter, this 3-day (21-hour) course will review the proposed changes and demonstrate key skills in the hands-on lab. Prior to the live program, attendees will evaluate the proposed revisions and submit answers to an online quiz to assess baseline knowledge.

Highlighted topics include:

- Aseptic technique
- Formulation methodology
- Component selection
- Contamination risks
- Sterilization and depyrogenation
- Release testing
- Documentation
- cGMPs

In Spectrum's state-of-the-art sterile compounding laboratory, attendees will:

- Practice cleaning and disinfecting
- Complete hand hygiene and garbing
- Prepare three CSPs utilizing three sterilization methods
- Perform fingertip-glove sampling
- Execute aseptic technique and a media fill

Upon completion of this activity, participants should be better able to:

- List preparations required to be sterile per <797>
- Identify common causes of contamination
- Recognize associated risk factors in sterile compounding
- Outline facility requirements, with specific consideration to primary and secondary engineering controls
- Select appropriate equipment and components
- List the considerations in assigning a beyond-use-date
- Develop acceptance of CSP with approved release testing based on scientific data
- Assess key considerations in formulation development and methodology
- Recognize the documentation required for:
 - the compounding facility
 - formulation development
 - complaints and adverse events
 - compounding within Chapter <797>Standards
 - Quality Assurance
 - CAPA
- Implement formal policy and procedures utilizing documentation
- Cite compliance standards for 503B facilities paired with common Form 483s

Training Location:

Spectrum Pharmacy Institute
777 Jersey Avenue
New Brunswick, NJ 08901

Training Dates:

February 12-14, 2020
May 13-15, 2020
August 12-14, 2020
November 4-6, 2020

Instructed by:

Richard Dilzer, RPh, FACA, FIACP,
Director of Pharmacy Technical Services
Spectrum Pharmacy Institute

Registration:

Visit SpectrumPharmacyInstitute.com or call 800.370.6231



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Essentials of Sterile Compounding

Cost

\$2,495

Food & Beverages

Lunch will be provided daily during the program.

Travel and Hotel Accommodations

Course participants will be responsible for their own reservations and travel.

Information will be included in the course confirmation email, or contact Spectrum Pharmacy Institute 800.370.6231 ext. 5479.

Cancellation Policy

30+ days before event - Full Refund; 29-14 days before event - 50% Refund; 13-0 days before event - No Refund. Transfer to an alternate class date may be permitted one time with notice or request made at least 14 days prior to the start of the program. Spectrum Pharmacy Institute reserves the right to modify the activity content, faculty and activities; and reserves the right to cancel this activity prior to the start of the program if necessary. We recommend purchasing travel insurance or booking with an airline that will allow you to reschedule your flight if the need arises.

CE Credit Late Fee Policy

In order to receive CE, a correct NABP number, birthdate (MM/DD), and a completed post-event evaluation are required. Participants must supply this information within 14 days of the activity to allow for processing. Due to new ACPE guidelines, if this information is received after 60 days, a \$250 late fee will be assessed before CE will be processed.

Planning Committee

Evelyn Hermes DeSantis, PharmD, BCPS, Clinical Professor and Co-Chair, Continuing Education; Mary Bridgeman, PharmD, BCPS, BCGP, Clinical Associate Professor and Co-Chair Continuing Education; Richard Dilzer, RPh, FACA, FIACP, Director of Pharmacy Technical Services; Margaret Cannon, CPhT, Pharmacy Technical Services Representative; Jaclyn Diem, CPhT, Pharmacy Technical Services Representative.

Questions?

For additional program information, questions, or concerns; or if you require special arrangements to attend this activity, please contact RBHS Ernest Mario School of Pharmacy Office of Continuing Education, Debra Diller at 848.445.6823 or ce@pharmacy.rutgers.edu; or, Spectrum Pharmacy Institute at 800.370.6231 ext. 5479 or info@spectrumrx.com.

Jointly Accredited Provider

This activity has been planned and implemented by Rutgers Biomedical and Health Sciences and Spectrum Pharmacy Institute. Rutgers Biomedical and Health Sciences is accredited by the American Nurses Credentialing Center (ANCC), the Accreditation Council for Pharmacy Education (ACPE), and the Accreditation Council for Continuing Medical Education (ACCME), to provide continuing education for the healthcare team.



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Jointly provided by: Ernest Mario School of Pharmacy, Rutgers Biomedical and Health Sciences (RBHS) and Spectrum Pharmacy Institute

This practice-based activity (UAN JA0000855-9999-19-006-L07-P-T) qualifies for 21 contact hours (2.1 CEUs) of continuing pharmacy education credit. The attendee must pass an aseptic glove test, media fill, and minimum score of 70% on in-class quizzes to successfully complete the program. Attendees will be required to complete an evaluation form at the end of the program. Your NABP e-Profile ID and date of birth will be collected at the beginning of the program. CPE credit will be processed after the program evaluation has closed to participants, which will be approximately four weeks following the completion of the activity.



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AGENDA

Day One

8:00 AM - 9:30 AM

Sterile Compounding Introduction

USP Chapter <797> Sections 1 through 3 / Quiz

Break 9:45 AM - 10:00 AM

10:00 AM - 11:30 AM

USP Chapter <797> Sections 4 through 8 / Quiz

Break 11:30 AM - 11:45 AM

11:45 AM - 12:30 PM

USP Chapter <797> Sections 9 through 21 / Quiz

Lunch 12:30 PM - 1:30 PM

1:30 PM - 5:30 PM

Lab - Hand hygiene & garbing, finger-tip glove sampling, cleaning and disinfection media fill 1

Salicylic Acid Ointment

Day Two

8:00 AM - 9:30 AM

Aseptic Technique

Nonviable and Viable Contamination / Quiz

Syringes and Needles / Quiz

Break 9:45 AM - 10:00 AM

10:00 AM - 11:30 AM

Sterilization & Depyrogenation / Quiz

Break 11:30 AM - 11:45 AM

11:45 AM - 12:30 PM

Formulation Methodology

Lunch 12:30 PM - 1:30 PM

1:30 PM - 5:00 PM

Lab - Media fill 2, Prednisolone Acetate Injection, Tobramycin

Ophthalmic

Day Three

8:00 AM - 9:30 AM

Components in CSPs / Quiz

Break 9:45 AM - 10:00 AM

10:00 AM - 11:30 AM

CSP Release Testing / Quiz

Documentation in Sterile Compounding / Quiz

Break 11:30 AM - 11:45 AM

11:45 AM - 12:30 PM

cGMP and 483 Findings

Lunch 12:30 PM - 1:30 PM

1:30 PM - 2:30 PM

Lab - Acyclovir Ophthalmic Ointment, (repeater pump filtration demonstration)