Presentation Titles and Learning Objectives – Sterile Compounding In-Person Training

Module 1 Non-HD Sterile Compounding: 16.5 CE hours

Lecture or Practical Knowledge Check (PKC)	Learning Objectives
Introduction of Compounding (Lecture 1) Melanie Dorey and Mary Nazzal 60 mins	1. Describe the historical events and key developments in the evolution of sterile compounding in the United States. 2. Review the roles of organizations responsible for implementing and enforcing sterile compounding standards in the US. 3. Differentiate between compounding pharmacy, 503B outsourcing pharmacy, and manufacturing. 4. Explain the importance of high-quality standards in sterile compounding and how they apply to practice.

Quality Assurance (Lecture 2) Mary Nazzal 60 mins	1. Differentiate between quality assurance and quality control in the context of sterile compounding. 2. List the USP 797 (2023) requirements related to quality assurance, documentation, and standard operating procedures (SOPs). 3. Describe the roles of the designated person and compounding staff in relation to quality assurance, documentation, and SOPs. 4. Explain how to develop a robust document control system for SOPs. 5. Identify the critical elements during a recall and incident management process.
Training and Competency Assessments (Lecture 3) Mary Nazzal 60 mins	1. Review the training and competency assessment requirements outlined in USP 797 (2023). 2. Discuss best practice recommendations for training and conducting competency assessments. 3. Identify the documentation requirements for training and assessment results, and how to effectively communicate these with compounding personnel. 4. Explain the importance of supervision in ensuring compounding staff competency. 5. Describe various methods for training and competency assessments.

Inventory, Storage, Verification, and Packaging (Lecture 4) Melanie Dorey 45 mins	1. Explain key considerations for sourcing appropriate components for preparing compounded sterile preparations (CSPs). 2. Describe the USP 797 (2023) requirements for the storage of components and CSPs. 3. Identify the verification steps required during compounding and the final verification for CSPs. 4. Outline the requirements for packaging and transporting CSPs according to USP 797 (2023).
Assigning Beyond-Use Dates (Lecture 5) Mary Nazzal 60 mins	1. Define the requirements for the use of commercially available single-dose containers (SDCs), multiple-dose containers (MDCs), and pharmacy bulk packages. 2. Identify the compounding categories and associated beyond-use date (BUD) limits per USP 797 (2023). 3. Recognize situations that are classified as "not compounding." 4. Define immediate-use compounding and its applicable scenarios. 5. Contrast potency testing with stability-indicating methods for assessing drug stability.

Practical Knowledge Check: Quality Assurance and Beyond-use Dates (Lab 1) Mary Nazzal and Melanie Dorey 30 mins	1. Identify appropriate evidence-based sources of information for developing a master formulation record. 2. Assess the assignment of BUDs to CSPs following USP 797 (2023) and evidence-based information. 3. Describe the key differences between a compounding record and a master formulation record (MFR). 4. Evaluate compliance with a quality assurance program per USP 797 (2023).
Engineering Controls (SEC and PEC) (Lecture 6) Jake Warden 90 mins	1. Identify primary engineering controls (PECs) and the secondary engineering controls (SECs) in which they are placed. 2. Define the USP 797 (2023) standards for non-hazardous drug (non-HD) PECs and SECs. 3. Discuss best practice recommendations for designing secondary engineering controls. 4. Explain the maintenance requirements for engineering controls.
Practical Knowledge Check: Certification (Lab 2) Jake Warden, Melanie Dorey, and Mary Nazzal 60 mins	1. Describe the certification tests performed in SECs and PECs within a non-HD sterile compounding environment. 2. Define the certification requirements for SECs and PECs per USP 797 (2023). 3. Identify key reporting elements found in certification reports and discuss how to address deviations.

Environmental Monitoring (EM) (Lecture 7) Christine Hong 60 mins	1. Discuss the purpose of an environmental monitoring program, including the identification of action levels for microbial growth. 2. Determine the requirements of an environmental monitoring program per USP 797 (2023). 3. Explain the appropriate types of sampling media used for air and surface sampling. 4. Define the course of action when samples exceed the action level.
Practical Knowledge Check: Performing Air and Surface Viable Monitoring (Lab 3) Christine Hong and Melanie Dorey 45 mins	1. Develop an environmental monitoring program. 2. Determine the locations and steps for conducting viable air and surface sampling. 3. Explain the appropriate use of equipment and supplies for air and surface sampling.
Practical Knowledge Check: EM Investigation and Remediation (Lab 4) Christine Hong and Melanie Dorey 45 mins	1. Identify common issues found with environmental monitoring sampling plans and results in non-HD anteroom and clean room suites. 2. Explain the key components for investigating and remediating environmental excursions. 3. Provide suggestions for investigation and remediation strategies.

Gloved Fingertip Sampling and Media Fill Testing (Lecture 8) Melanie Dorey 45 mins	1. Differentiate between the USP 797 (2023) requirements and best practice recommendations for personnel gloved fingertip sampling and media fill testing. 2. Describe the integration of media-fill testing, surface sampling, and subsequent gloved fingertip sampling as best practices. 3. Determine the importance of using media-fill testing to verify the aseptic technique skills of compounding staff. 4. Explain the required corrective actions and additional training in the event of test failures.
Cleaning and Disinfecting (Lecture 9) Melanie Dorey 60 mins	1. Develop strategies address for contamination control issues. 2. Explain the USP 797 (2023) requirements for cleaning and disinfection in a sterile compounding environment. 3. Describe best practice recommendations for cleaning and disinfection in a sterile compounding environment. 4. Identify the types of agents and supplies to use during cleaning and disinfection. 5. Outline the SOPs, training, competency, and documentation requirements for cleaning and disinfection.

Contamination Control Principle: Hand Hygiene and Garbing (Lecture 10) Melanie Dorey 60 mins	1. Determine hand hygiene and garbing procedures that meet USP 797 (2023) standards. 2. Discuss best practice recommendations for performing hand hygiene and garbing procedures. 3. Identify the requirements and best practice recommendations for personal protective equipment (PPE) and cleanroom garb used during hand hygiene and garbing procedures. 4. Compare the sequence of hand hygiene and garbing in a cleanroom suite versus a segregated compounding area (SCA).
Contamination Control Principle: Material Handling & Operator Conduct (Lecture 11) Melanie Dorey 45 mins	1. Review contamination control principles that affect the state of microbial control. 2. Discuss material handling procedures per USP 797 (2023). 3. Identify the types of cleaning agents to use during material handling procedures. 4. Explain the USP 797 (2023) requirements and best practice recommendations for compounder conduct in a sterile compounding environment.

Contamination Control Principle: Aseptic Technique (Lecture 12) Melanie Dorey 45 mins	1. Identify best practice recommendations for aseptic technique and promoting patient safety. 2. Define the importance of proper setup of equipment and supplies and good aseptic technique in reducing the risk of contamination. 3. Discuss the requirements for aseptic technique per USP 797 (2023). 4. Describe the proper way to move items in and out of the PEC.
Practical Knowledge Check: Applying Contamination Control Principles in the Cleanroom (Lab 5) Melanie Dorey and Mary Nazzal 90 mins	1. Assess the attendee's ability to perform all necessary contamination control principles to prepare a CSP. 2. Evaluate the knowledge necessary to prevent contamination of the environment and CSPs.
Technology in the Cleanroom (Lecture 13) Melanie Dorey 30 mins	1. Identify the types of technology and devices used in sterile compounding areas. 2. Describe the USP 797 (2023) requirements for introducing technology, devices, and equipment into the anteroom and cleanroom. 3. Determine best practice recommendations for cleaning, installing, and using technology devices and equipment in the cleanroom. 4. Discuss the challenges associated with planned and unplanned downtime, cyberattacks, etc., and their impact on the cleanroom.

Module 2 HD Sterile Compounding: 11 CE hours

Lecture or Practical Knowledge Check (PKC)	Learning Objectives
Handling Hazardous Drugs and Standards to Prevent Harm (Lecture 1) Fred Massoumi 60 mins	1. Describe the history and development of USP 800 standards for compounding hazardous drugs. 2. Provide examples of the effects of HD exposure on healthcare workers. 3. Discuss key strategies to prevent healthcare worker exposure to HDs. 4. Describe the requirements for hazardous drug compounding facilities.

Assessment of Risk (Lecture 2) Mary Nazzal 45 mins	1. Define the components required in an assessment of risk per USP 800. 2. Evaluate different approaches for creating and maintaining an assessment of risk. 3. Discuss specific examples of alternative handling strategies from actual practice.
Containment Engineering Controls (Lecture 3) Jake Warden 75 mins	1. Identify containment primary engineering controls (C-PECs) and the controlled areas in which they are placed. 2. Outline the USP 800 requirements for C-PECs and controlled areas. 3. Discuss best practice recommendations for designing containment-controlled compounding areas. 4. Describe different types of C-PECs and the differences between them.
Interactive: Problem Solving Downtime Issues with Engineering Controls (Lecture 4) Jake Warden, Melanie Dorey, and Mary Nazzal 45 mins	1. Discuss potential issues that may arise with engineering controls and containment engineering controls. 2. Determine downtime procedures for different types of issues and downtimes. 3. Evaluate the operational procedures needed to resume preparing CSPs.

HD PPE Donning and Doffing (Lecture 5) Melanie Dorey 60 mins	1. Identify the necessary PPE when handling hazardous drugs and explain why it is required. 2. Explain the USP 800 requirements and best practice recommendations for PPE donning and doffing. 3. Outline the sequence of donning and doffing PPE in both a cleanroom and containment segregated compounding area. 4. Evaluate industry requirements and best practice recommendations for PPE worn during HD compounding.
Receiving, Material Handling and Transport (Lecture 6) Melanie Dorey 45 mins	1. Summarize work practices essential for reducing hazardous drug contamination and exposure risk during receipt, storage, and transportation. 2. Explain the USP 800 requirements and best practice recommendations for receiving, storing, and transporting hazardous drugs. 3. Describe safe transport procedures for hazardous materials and compounded sterile preparations.
HD Spills and Kits (Lecture 7) Melanie Dorey 45 mins	1. Identify the USP 800 requirements for handling an HD spill. 2. Describe best practice recommendations for cleaning up a spill. 3. Discuss the purpose and advantages of using an ancillary HD spill kit.

HD Wipe Sampling (Lecture 8) Mark St. Marie 45 mins	1. Define hazardous drug surface wipe sampling and explain its importance. 2. Outline the differences between quantitative and qualitative wipe sampling. 3. Develop a hazardous drug wipe sampling program
Medical Surveillance (Lecture 9) Mark St. Marie 45 mins	1. Describe the purpose and elements of a medical surveillance program for employees exposed to hazardous drugs. 2. Discuss the stance of different organizations on developing a medical surveillance program.
Practical Knowledge Check: HD Donning and Doffing (Lab 1) Melanie Dorey and Mary Nazzal 45 mins	1. Perform PPE donning and doffing procedures when handling hazardous drugs. 2. Assess the efficacy of using two pairs of linen shoe covers versus an inner pair of linen shoe covers and an outer pair of seamless water-resistant shoe covers. 3. Compare the efficacy of using coated versus non-coated HD gowns.
Decontamination, Cleaning and Disinfecting (Lecture 10) Melanie Dorey 45 mins	1. Define the terms deactivation, decontamination, cleaning, disinfection, and sanitization as they apply to HD compounding environments. 2. List the types of agents that may be used for decontamination of hazardous drugs. 3. Properly sequence the cleaning-related activities performed in HD environments.

Compounding HDs (Lecture 11) Melanie Dorey and Fred Massoomi 60 mins	1. Identify the USP 797 (2023) and USP 800 requirements related to compounding hazardous drugs. 2. Explain the importance of protecting workers from HD residues during compounding. 3. Review the key differences between negative pressure technique and the use of a Closed System Transfer Device (CSTD). 4. Discuss the process for decontaminating and removing the completed CSP from the C-PEC.
Practical Knowledge Check: CSTDs vs. Traditional Compounding (Lab 2) Melanie Dorey and Mary Nazzal 45 mins	1. Identify both types of compounding methods when preparing hazardous drugs. 2. Perform simulated compounding using both CSTDs and traditional compounding methods. 3. Assess the efficiency and safety components of using CSTDs versus traditional compounding methods.