Learning Objectives Module 1 – Sterile Compounding Non-HD In-Person Training

14.5 CE hours

Lecture or Practical Knowledge Check (PKC)	Learning Objectives
Overview of Compounding (Lecture 1)	1. Describe the history and events that are important to the evolution of sterile compounding in Canada. 2. Review organizations responsible for implementing and enforcing standards and raising the bar for sterile compounding in Canada. 3. Describe the difference between compounding and manufacturing. 4. Learn how to identify drugs as hazardous or non-hazardous. 5. Describe the importance of high-quality standards and how they apply to sterile compounding.

Quality Assurance (Lecture 2)	1. Differentiate between quality assurance and quality control. 2. List the requirements from the NAPRA Model Standards related to QA, documentation and policies and procedures (PnPs). 3. Describe the roles of the compounding supervisor and compounding staff as they relate to QA, documentation, and PnPs. 4. Explain how to develop a robust document control system for PnPs. 5. Identify the important elements during a recall and incident management
Training and Competency Assessments (Lecture 3)	1. Review the training and assessment requirements from the NAPRA Model Standards. 2. Review best practice recommendations for training and performing assessments. 3. Identify documentation requirements of results of training and assessment programs and how best to share them with compounding personnel. 4. Explain the importance of supervision for non-regulated compounding personnel. 5. Describe the different methods for training and assessments.

Inventory, Storage, Verification, and Packaging	1. Explain important considerations for sourcing appropriate ingredients to be used to prepare CSPs. 2. Describe the NAPRA Model Standard requirements for storage of ingredients and CSPs. 3. Identify the verification steps required during compounding and the final verification for CSPs. 4. Identify the NAPRA Model Standard requirements for packaging and transport
Assigning Beyond-Use Dates (Lecture 5)	1. Define requirements for the use of commercially available SDCs, MDCs, and pharmacy bulk packages. 2. Identify the compounding categories and associated beyond-use date limits from NAPRA Model Standards. 3. Identify situations that are “not compounding”. 4. Contrast potency testing with stability indicating methods for drug stability.
Engineering Controls (SEC and PEC) (Lecture 6)	1. Identify primary engineering controls (PECs) and the controlled area in which they are placed. 2. Determine the NAPRA Model Standards requirements for non-HD PECs and controlled areas. 3. Discuss best practice recommendations for designing controlled compounding areas. 4. Describe maintenance requirements for engineering controls

Practical Knowledge Check: Certification (Lab 1)	1. Identify common issues found with environmental monitoring sampling plans and results in non-HD anteroom and clean room suites. 2. Explain key components for investigation and remediation of environmental excursions. 3. Provide suggestions for investigation and remediation strategies.
Practical Knowledge Check: Quality Assurance and Beyond-use Dates (Lab 2)	1. Identify appropriate evidence-based sources of information for developing a CStPP. 2. Assess the assignment of BUDs to CSPs following NAPRA Model Standards and evidence-based information. 3. Describe and identify the key differences between a compounding log and CStPP. 4. Evaluate compliance with a NAPRA Model Standard quality assurance program
Environmental Monitoring (EM) (Lecture 7)	1. Develop an environmental monitoring program, including the identification of action levels of microbial growth. 2. Determine the locations and steps to conducting viable air and surface sampling. 3. Explain the appropriate use of equipment and supplies for air and surface sampling. 4. Identify the steps for investigating an exceeded action level.

Practical Knowledge Check: EM Investigation and Remediation (Lab 3)	1.Identify common issues found with environmental monitoring sampling plans and results in non-HD anteroom and clean room suites. 2. Explain key components for investigation and remediation of environmental excursions. 3. Provide suggestions for investigation and remediation strategies.
Gloved Fingertip Sampling and Media Fill Testing (Lecture 8)	1. Differentiate between the NAPRA Model Standard requirements and best practice recommendations for personnel gloved fingertip sampling and media fill testing. 2. Describe the best practice integration of media-fill testing, surface sampling, and subsequent gloved fingertip sampling. 3. Determine the importance of using media-fill testing to verify the aseptic technique skills of compounding staff 4. Explain required corrective actions and additional training in the event of failures.
Cleaning and Disinfecting (Lecture 9)	1. Develop contamination control principles. 2. Explain NAPRA Model Standard for cleaning and disinfection in a sterile compounding environment. 3. Describe CCR's best practice recommendations for cleaning and disinfection in a sterile compounding environment. 4. Identify the type of agents and supplies to use during cleaning and disinfection. 5. Describe PnP, training, competency, and documentation requirements

Contamination Control Principle: Hand Hygiene and Garbing (Lecture 10)	1. Determine hand hygiene and garbing procedures that meet NAPRA's Model Standards. 2. Discuss best practice recommendations when performing hand hygiene and garbing procedures. 3. Identify the requirements and best practice recommendations for the type of PPE and clean room garb donned during hand hygiene and garbing procedures. 4. Compare the sequence of hand hygiene and garbing in a clean room suite versus a segregated compounding area (SCA).
Contamination Control Principle: Material Handling & Operator Conduct (Lecture 11)	1. Review contamination control principles. 2. Discuss material handling procedures per NAPRA Model Standards. 3. Identify the type of agents to use during material handling procedures. 4. Explain NAPRA Model Standard and best practice recommendations for compounder conduct in a sterile compounding environment.

Contamination Control Principle: Aseptic Technique (Lecture 12)	1. Identify the best practice recommendations when it comes to aseptic technique and promoting patient safety. 2. Define the importance of the proper setup of equipment and supplies and good aseptic technique reduce the risk of contamination. 3. Discuss the aseptic requirements in the NAPRA Model Standards. 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 4)	Assess the ability of the attendee to perform all necessary contamination control principles to prepare a CSP. 2. Evaluate knowledge necessary to prevent contamination to enter the environment and the CSP.
Technology in the Cleanroom (Lecture 13)	1. Identify the types of technology and devices used in the sterile compounding areas. 2. Describe the NAPRA Model Standard requirements for introducing technology, devices, and equipment into the anteroom and clean room. 3. Discuss the best practice recommendations for cleaning, installing, and using technology devices and equipment in the cleanroom