Best Practices for Field Certification of Sterile Compounding Facilities
2019 Learning and Performance Objectives

Day 1

Why Does Certification Matter? The Certifier's Role in Sterile Compounding (0.5 hours)
- Correlate the history of compounding mishaps with the evolution of compounding standards of practice and sterile compounding regulations.
- Understand the role certification plays in the production of a CSP and patient safety.
- Recognize certification shortcomings and how they can affect pharmacy compliance.
- Discuss the FDA's perspective and plan for oversight of 503A pharmacy sterile compounding practice.

Concepts of Sterile Compounding (1 hour)
- Explain the current compounding risk levels and the proposed compounding categories.
- Identify the current and proposed USP <797> Beyond-Use Dates (BUDs).
- Differentiate between non-hazardous and hazardous sterile compounding in order to identify safety risks.
- Understand the practices that ensure good aseptic technique.
- Apply the first air concept as it relates to critical sites and the compounding of sterile preparations.
- Assist compounders in identifying proper hand and material placement when performing airflow visualization tests.

Contamination Control: Hand Hygiene and Garbing, Material Transfer, and Cleanroom Behavior (1.25 hours)
- Discuss contamination control as a critical principle to maintaining a state of control.
- Properly sequence the activities of hand hygiene and garbing for sterile nonhazardous compounding.
- Differentiate between requirements of the current chapter <797> (2008 version), the 2018 proposed revision to <797> and best practice recommendations.
- Analyze and discuss the rationale for best practice conduct within controlled environments and how poor or inconsistent practice can negatively impact the state of microbial control.
- Integrate best practice contamination control practices when bringing your equipment into a controlled environment.

Primary Engineering Controls: Applications and Limitations (1.5 hours)
- Discuss the appropriate applications and limitations of the PECs used for sterile compounding.
- Understand how pharmacy uses Biological Safety Cabinets (BSC) and select the appropriate BSC to meet their needs.
- Integrate a PEC into a facility design to ensure proper work flow and equipment functionality.
- Identify and perform the necessary certification testing according to CETA Application Guide (CAG)-003.

CAG-003 Airflow Visualization Test (1 hour)
- Select the necessary materials for performing the airflow visualization test in the DCA of a PEC.
- Explain the test objectives and understand the test acceptance criteria.
- Perform the test methods and document the results in a manner that meets regulatory expectations.
- Discuss how poor aseptic technique and hand positioning affects airflow and the results of this test.

Lab Exercise: Hand Hygiene and Garbing Practice (1 hour)
- Successfully perform hand hygiene and garbing for nonhazardous sterile to sterile compounding.
- Successfully don sterile gloves.
- Perform one instance of initial GFS (both hands) according to USP <797> requirements.

Lab Exercise: Airflow Visualization Test (1 hour)
- Visualize how first air can be affected by placement of materials in the direct compounding area (DCA).
- Identify the conditions needed to properly establish a DCA.
- Practice performing and video recording an airflow visualization test.

Day 2

Lab Exercise: Review Air Flow Visualization Tests (0.5 hours)
- Evaluate the quality of an airflow visualization test video and determine if the test needs to be repeated.
- Identify the necessary components of an airflow visualization test video.

Principles of Air Flow, Facilities and HVAC Systems (1 hour)
- Understand the principles of airflow and how they apply to the certification for sterile compounding facilities.
- Calculate airflow and velocity using the appropriate formulas.
- Describe the mechanisms that create airflow.
- Recognize required facility design parameters related to the HVAC system.
- Apply facility engineering requirements to the certification of sterile compounding facilities.

ISO 14644 Non-Viable Particle Counting for USP <797> (1.5 hours)
- Recognize and interpret the current ISO standards for non-viable particle counting.
- Determine room classification based on the requirements of ISO 14644.
- Identify the differences between as built, at rest and operational occupancy states and understand how this applies to sterile compounding facilities.
- Establish sample locations based on the table in ISO 14644 and industry best practices.

CAG-003 HEPA Filter Leak Test (1 hour)
- Define what a HEPA filter is and explain its purpose in both PECs and SECs.
- Categorize the HEPA filter styles and classifications.
- Perform ISO 14644-3 Testing Methods on HEPA filters in a variety of different locations.
- Apply IEST-RP-CC034 HEPA and ULPA Filter Leak Tests to classified sterile compounding environments.

Lab Exercise: Non-Viable Particle Counting (0.75 hours)
- Perform non-viable sampling methods using a discrete particle counter.
- Determine the best non-viable particle count sample locations for the CCTR.

Lab Exercise: HEPA Filter Leak Testing (0.75 hours)
- List the necessary equipment to perform HEPA Filter Leak Testing.
- Test PECs and SECs using an aerosol photometer.

Lab Exercise: Induction Leak/Backstreaming Test (0.75 hours)
- Practice performing the testing specified in IEST-RP-CC002.3.
- Recognize when the positioning of the LAWF can affect the performance of the unit.

Lab Exercise: Determining HEPA Airflow Volumes Using a K-factor (0.75 hours)
- Use a flow hood and calculate the HEPA airflow volume for a HEPA filter that cannot be directly tested.
- Determine when the K-factor must be used.

Day 3

Lab Exercise: RABS Testing (2.5 hours)
- Perform certification on a RABS using the methods described in the CAG-002.
- Identify the issues associated with certifying a RABS.

Day 3 continued

USP <797> and <800> Design Requirements (3 hours)

- Describe how proper facility design is necessary to ensure a cleanroom can maintain a state of control.
- Differentiate between current and proposed USP <797> requirements.
- Summarize how occupancy state and equipment can affect the particulate and microbial state of control.
- Explain the difference between the minimum requirements of USP <797> and <800> and best practice.
- Recognize facility design required by USP <797> and <800>.

Cleanroom Certification Procedures (2 hours)

- Determine the proper field certification equipment for the testing to be performed.
- Test a sterile compounding cleanroom suite and support areas such as HD storage rooms.
- Calculate room square footage, cubic footage and air changes per hour (ACPH) for controlled environments.
- Explain certification testing methods as described in CAG-003 and industry best practices.

Day 4

Lab Exercise: Airflow Troubleshooting (4.25 hours)

- Identify issues with airflow in a sterile compounding facility.
- Determine the repairs necessary to correct airflow problems.

Viable Environmental Monitoring (2 hours)

- List the Why, When, Where, Who and What (how) of environmental monitoring (EM).
- Summarize the importance of having a robust environmental monitoring program.
- Select the appropriate sampling media and equipment based on pharmacy needs.
- Utilize air samplers and surface sampling devices to perform monitoring.
- List appropriate times and temperatures for sample incubation.
- Recognize the essential components of a testing report.

Lab Exercise: Environmental Sampling Lab (1.5 hours)

- Plan and produce a written environmental sampling plan (ESP) for a defined area of the controlled pharmacy space at the CCTR.
- Practice performing air and surface sampling.
- Discuss required elements of environmental and personnel sampling documentation.

Day 5

Certification Documentation and Training Records (1 hour)

- Summarize documentation requirements per the applicable standards and guidelines.
- Apply best practice reporting principles to your certification documentation.
- Explain the value of a Quality Assurance system and how it will ensure better customer service.

Lab Exercise: Environmental Monitoring Competency (3.5 hours)

- Prepare all equipment, materials and documentation needed for the session.
- Execute an environmental monitoring session.
- Describe the steps to prepare samples for incubation and/or laboratory submission.
