

CriticalPoint's Field Certification eLearning Curriculum

The information presented in CriticalPoint's eLessons is consistent with current and proposed 2019 USP standards as well as procedures outlined in CETA Application Guides (CAGs). It also reflects CriticalPoint's additional recommendations for best practice. Each organization must determine its own specific standard operating procedures (SOPs) for certification. The eLessons do not reflect state-specific requirements. It is the responsibility of each organization to know and comply with its state's Pharmacy, Department of Health, or other applicable regulations.

The eCurriculum includes high-resolution images, video, and interactivity, which help to create an engaging learning experience we believe will result in improved learning.

In CriticalPoint eLearning,

- procedures are broken down into steps that require user intervention.
- high-definition videos demonstrate procedures in real work environments.
- learners' attention and abilities to use the information are checked during eLessons.

eCourse: Field Certification (9 eLessons)

Overview of Certification Testing

- Describe the role certification plays in ensuring patient safety.
- Identify the differences between the 2008 version of USP 797 and the revisions to USP 797 published on June 1, 2019 and how these differences could affect certification.
- Summarize the applicable testing documents used to perform certification.
- List the engineering and environmental controls that require certification or performance verification.

PEC and SEC High-Efficiency Particulate Air (HEPA)–Filter Integrity Testing

- Define the purpose of performing a HEPA-filter integrity test on primary engineering controls (PECs) and secondary engineering controls (SECs).
- List the equipment used for HEPA-filter integrity testing.
- Identify the different aerosol induction methods for engineering controls.
- Explain the testing process, procedures, and acceptable results of HEPA-filter integrity testing.

PEC Airflow Velocity Testing

- Recognize and contrast the airflow direction in different types of PECs.
- Describe the purpose of airflow velocity testing.
- Recall the manufacturers' airflow criteria for certification testing, and understand how they are applied.
- Summarize the basic principles of airflow testing.
- Identify the equipment used for airflow velocity testing.

Airflow Smoke-Pattern Test for Primary Engineering Controls (PECs) in Sterile Compounding Facilities

- Select the appropriate materials for performing airflow smoke-pattern testing in the direct compounding area (DCA) of a PEC used for sterile compounding.
- Document and perform airflow smoke-pattern testing following CAG-003 Certification Guide for Sterile Compounding Facilities.



- Summarize testing requirements, methods, and certification equipment used in static and dynamic airflow smoke-pattern testing.
- Evaluate a dynamic airflow smoke-pattern testing video for proper identification of the DCA.

Total Particle Count Testing for ISO-Classified Environments

- Explain the importance of total particle count testing.
- Determine primary engineering control (PEC) and secondary engineering control (SEC) classification based on the requirements of ISO 14644 and USP 797.
- Recall and interpret the current ISO standards for total particle counting.
- Identify the differences between as-built, at-rest, and operational operating occupancy states.
- Derive and establish the appropriate number of sample locations employing the table in ISO 14644.

Airflow and Room-Segregation Testing for Sterile Nonhazardous Cleanroom Suites and C-SECs

- Describe the purpose and methods of airflow testing as it relates to cleanroom suites and containment segregated compounding areas (C-SCAs).
- Use testing formulas to calculate room-air-change rates and understand how to determine air changes per hour.
- Identify the equipment used for airflow testing and room-segregation testing.
- Recall the air change rate and room-to-room pressure requirements for each ISO-classified room and nonclassified C-SCAs.
- Discuss the differences between USP airflow-pressurization requirements for hazardous and nonhazardous compounding.

Specific Testing for Restricted Access Barrier Systems (RABS)

- List the four specific tests outlined in CAG-002: Compounding Isolator Testing Guide.
- Identify the specific tests for RABS that ensure pressure isolation.
- Describe the purpose and criteria for each of the required tests for compounding aseptic isolators (CAIs) and compounding aseptic containment isolator (CACIs).
- Discuss the importance of proper material transfer into a RABS.
- Explain the purpose of ingress/egress testing and how it relates to the functionality of the RABS.
- Name the two primary tests that ensure containment for CACIs.

Facility Site Installation Tests for Laminar Airflow Systems (LAFS) and Containment Testing for Biological Safety Cabinets (BSCs)

- Describe the purpose of and verification process for properly integrating LAFS into the facility.
- Summarize the importance of site installation tests performed on externally ventilated BSCs.
- Name the two primary tests that ensure proper containment, and list acceptable results for containment primary engineering controls (C-PECs).
- Identify the equipment used to complete site installation and containment testing.
- Determine the appropriate placement of LAFS in a cleanroom suite and segregated compounding areas (SCAs).

Certification Report Best Practices

- Describe the elements certification reports must provide according to CAG-003: Certification Guide for Sterile Compounding Facilities.
- Identify the best practice components of a certification report and describe why those components are essential for reporting.
- List certifier and pharmacy roles and responsibilities as related to certification reporting.