

CriticalPoint Pearls of Knowledge — September 2025

The Blueprint to Certification: Certifier Vendor Qualification

Introduction

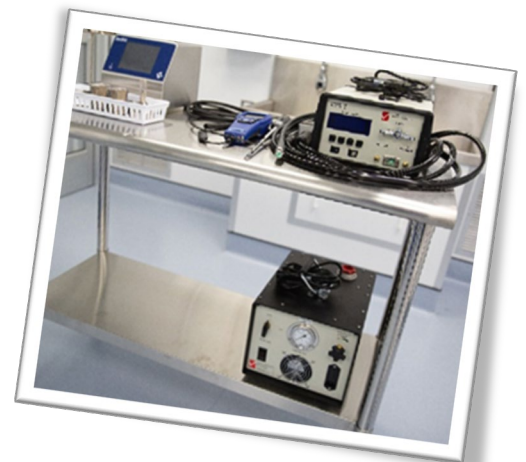
CriticalPoint concludes its certification series with a focus on certification vendors—highlighting key considerations for vendor evaluation, expectations for service and quality, and the importance of training and competency. Controlled environment certification is a cornerstone of patient safety for sterile compounding facilities. By verifying the engineering design and functionality of primary and secondary engineering controls (PECs and SECs), certification ensures these systems perform as intended and remain compliant with design requirements. When cleanroom environments meet current industry standards, patients can trust the compounded sterile preparations (CSPs) they receive.

This confidence is made possible through the work of certification professionals, whose independent testing and evaluations confirm that devices and engineering controls provide the conditions required for sterile compounding. But how can you be certain the certification services you rely on are accurate, meaningful, and performed with integrity?

In this month's Pearl, we explore what to look for when evaluating a certification vendor—and how to ensure the services you receive truly support compliance.

What pharmacies need to know about certification

USP <797> requires that the designated person(s) (DP) ensures each compounding area meets the appropriate classified air quality standard (ISO classification) for the activities conducted there.¹ DPs are also responsible for verifying that these environments are certified to meet chapter requirements by reviewing certification documentation.



While pharmacy DPs rely on certification vendors to conduct facility certification, they retain ultimate responsibility for selecting the vendor and managing the results. Before sterile compounding can begin, both primary and secondary engineering controls (PECs and SECs) must be independently certified to meet USP <797> requirements and, when applicable, manufacturer specifications. The certification confirms that the compounding area is operating according to its design and air quality standards.

All classified areas, including the PEC, must be certified initially and recertified at least every six months. However, it remains the responsibility of the sterile compounding organization to ensure the accuracy and appropriateness of certification. Therefore, it is critical to understand what standards and methods your certification vendor uses when testing and certifying your facility.

Understanding certification and vendor expectations

There's much more to certification than a certifier arriving onsite and performing tests. You're not only selecting services, you're also selecting the quality that comes with those services. The evolution of engineering control design, USP regulations, and compliance expectations has raised the bar for certification vendors.



The field certification industry is highly competitive, and cost is often a major factor, especially since PECs and SECs must be certified every six months. The challenge is finding a competitive price without sacrificing training, education, or integrity. Developing a well-qualified field certifier can take years, which makes vendor training programs and competency critical.

We often equate quality with value, the you-get-what-you-pay-for mindset. A strong certification vendor delivers services grounded in training, documentation, and a commitment to quality. One of the best ways to evaluate a potential vendor is through a vendor qualification audit—conducted in person, by phone, or with a paper questionnaire. This process helps you understand how a vendor operates and whether their services align with compliance needs.

Questions to ask during a vendor qualification audit

- How quickly can a certifier be onsite for an emergency call?
- What is the turnaround time for reporting?
- Will we receive both the raw data and a final report?
- Do you have a quality management system in place for services, operations, and reporting?
- Do you perform services according to CETA's Application Guides (CAGs)? If not, what standards do you follow?
- Does your organization hold any accreditations?
- How many field certifiers are on staff?
- What type of training do your field certifiers receive?
- How many years of experience do your field certifiers have?
- Do your field certifiers hold certifications?
- Can you provide customer references?

Once you've selected a vendor, establish a vendor quality agreement. This agreement formalizes expectations, scope of work, and deliverables—ensuring the certification vendor meets the specific requirements of your organization.

Certification vendor responsibilities

Not every certification organization follows CETA's guideline documents or maintains CETA membership—and that may be acceptable, provided the vendor demonstrates experience and adequate training in controlled environment testing and certification. Both ongoing training for seasoned certifiers and foundational training for new hires are essential before they can enter your cleanrooms.

The depth of training a certifier receives reflects how the company values integrity and service quality, much like how pharmacies uphold their own standards of practice. Certifiers carry the responsibility of delivering accurate, reliable service by being highly knowledgeable in their roles.



Certification vendors can demonstrate this commitment by:

- establishing a structured technician training program for both experienced certifiers and new hires
- requiring field certifiers to obtain and maintain relevant industry accreditations
- implementing a quality management program that includes data review, final report verification, and equipment calibration
- providing a dedicated customer service liaison



Certifier training expectations

Certification vendors should maintain a detailed training program and records documenting both internal and external training for their certifiers. At minimum, fundamental certification training should cover:

- airflow testing and collection methods
- testing methods based on manufacturer specifications
- general cleanroom testing and performance principles
- HEPA filter leak (integrity) testing
- total particle count testing



Field certifier experience is often categorized into three tiers:

Tier 1: New hire or <1 year of experience; understands certification basics and assists the lead certifier

Tier 2: 2–3 years of experience; may hold some field certification credentials; capable of performing testing independently

Tier 3: 3+ years of experience; holds field certification accreditations; serves as lead technician and is considered highly qualified

CETA's certification guides are widely recognized as industry resources that help certifiers perform testing in compliance with USP <797> requirements for controlled environments. However, USP does not require certifiers to hold formal credentials in order to perform certification in sterile compounding facilities.

Certification vendor considerations

To ensure technicians are adequately trained, CriticalPoint strongly recommends engaging certifiers who are credentialed—or actively working toward credentials—in the field of certification.

The Registered Certified Professional for Sterile Compounding Facilities (RCP-SCF) credential, offered through the CETA National Board of Testing (CNBT), demonstrates that a certifier has fundamental knowledge and skills in testing PECs and SECs used in sterile compounding facilities. A certifier's RCP-SCF status can be verified online.



Pharmacy leadership should request training records that correlate to services performed at their facilities to confirm certifier competency in:

- PEC-specific certification testing
- cleanroom certification
- viable air and surface sampling (if performed at your facility)

A reputable certification vendor will provide these training records upon request.

Quality management procedures are critical to a vendor's operation. Certification report data should be verified through the vendor's quality management system to ensure accuracy and proper documentation. Additionally, vendors should maintain standard operating procedures (SOPs) for all services performed. Pharmacy leadership should request these SOPs to gain insight into the vendor's testing methods, standards, and adherence to industry guidelines.



Certification equipment calibration is also essential. If vendors do not provide calibration reports for each piece of testing equipment, pharmacy leadership should request them to confirm that equipment is properly calibrated. Ultimately, it is the responsibility of pharmacy leadership to review and understand the data and results presented in the certification report.

Summary

CETA, CNBT, and the CAGs help ensure quality and knowledge in certification services. Certifiers who are registered certified professionals and follow CAG testing procedures provide customers with confidence that a well-qualified and trained individual is performing certification in their facility.

However, a certifier who is not a registered certified professional is not necessarily unqualified. It remains the responsibility of pharmacy leadership to request training documentation or proof of credentials to determine whether a certifier is competent to perform services in their facility.

CETA credentials and adherence to CAGs simplify the vendor evaluation process by providing standardized benchmarks. They reduce the need to review every vendor document or cross-reference testing procedures, making it easier to confirm that a certifier is following recognized and equivalent standards.

References

¹United States Pharmacopeia USP <797> Pharmaceutical Compounding—Sterile Preparation. 2024