

CERTIFICATION OF STERILE COMPOUNDING FACILITIES & ASEPTIC ISOLATORS



"All workshops are extremely useful and instructors were very willing to share real life working experiences and tips." - Former Course Participant

Course Description:

This three day class uses lecture, hands-on workshops and group activities to provide a review of the facility design, and environmental control requirements of USP Chapter <797><800> and the NIOSH Alert. The "Engineering Control Performance Verification" section of USP <797> is covered in detail. The specific certification procedures outlined in the Controlled Environment Testing Association's (CETA) CAG-003 are also discussed and utilized for the course's hands-on workshops. In addition, other relevant CETA Applications Guides, IEST Recommended Practices and ISO standards will be examined and utilized for the certification of compounding aseptic isolators.

Participants Will Learn:

- Sterile compounding facility design and environmental controls requirements
- How to establish cleanroom "state of control" points and "performance objective" parameters
- How facility design impacts test choices
- The difference between flow control / dilution control
- How to perform airflow smoke pattern testing
- How to perform viable and non-viable environmental sampling
- How to apply airflow measurement techniques for cleanrooms and calculate room air exchange rates
- How to develop strategies for room segregation testing
- Appropriate applications for mixed flow cleanrooms

This Course is For:

Certifiers, cleanroom designers, cleanroom contractors, pharmacists, and anyone involved with cleanrooms for sterile compounding.

Instructor Team:

The lead instructor for this program is **Jim Wagner**, President, Controlled Environment Consulting. Other instructors include: **Jeff Smith**, Controlled Environment Consultant; **Mark St. Marie**, National Technical Lead - Healthcare, The Vertex Companies LLC; **Erin Thane**, Vice President, Azzur Labs.

Registration:

Tuition of \$2495 must be paid in full to guarantee a space in the class. Tuition includes: course manual, lunch each day, an Eagleson Institute certificate and a special class reception and dinner with plenty of time to network with peers and instructors. The CETA Exam is offered immediately following the class. Tuition does not include CETA Exam Fees.

Register online at www.eagleson.org/USP or call (207) 490-1076 to register or request a registration form.

Register for the CETA Exam at <https://coeta.memberclicks.net/sterile-compounding-facilities-scf-exam>.