

EAGLESON INSTITUTE

Promoting Laboratory Safety Globally Since 1989

PO Box 954, Sanford, ME 04073 | 207-490-1076 | www.eagleson.org

Certification of Sterile Compounding Facilities and Aseptic Isolators

Learn how to develop certification strategies for sterile compounding facilities and equipment based on an in-depth understanding of the USP and NIOSH guidelines

When & Where

May 6-10, 2013 | Star Center, Englewood, CO

October 7-11, 2013 | Star Center, Englewood, CO

Course Description

This four and a half-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> 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, CAG-001-2005 and CAG-002-2006 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 and 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.
- How to test compounding aseptic isolators to appropriate standards.

This Course is For

Certifiers, Cleanroom Designers, Cleanroom Contractors and anyone involved with cleanrooms for sterile compounding.

Instructors

The lead instructor for this course is **Jim Wagner**, Principal, Controlled Environment Testing. Other instructors include: **Kym Faylor**, President, Azzur Laboratories; **Aaron Johnson**, Engineering Test Supervisor, The Baker Company; **Jeff Smith**, President, Agape Instrument Services, Inc.



Highlights

"All workshops are extremely useful and instructors were very willing to share real life working experiences and tips" - 2011 Course Participant

Registration

Tuition of \$2295 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. Tuition does not include CETA Exam Fees.

NOTE: Following this class, participants are offered the opportunity to take the CETA Registered Cleanroom Certification Professional Written and Practical exams. CETA must receive your application 45 days in advance of the exams. To register for this exam, contact CETA at (919) 861-5576 or visit www.cetainternational.org

Register online at www.eagleson.org/USP797, or call (207) 490-1076 to register or request a registration form.

for more information
or to register, please visit

eagleson.org/USP797



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Agenda

DAY ONE

- Overview of USP <797> Sterile Compounding Standards
- Overview of NIOSH Alert for Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs
- USP <797> and NIOSH Specific Facility Requirements Engineering Controls
- Counting Total Particles and Non-Viable Particles in USP <797> Cleanrooms
- USP <797> Viable Particle Counting
- Gowning Requirements for USP <797> and the NIOSH Alert
- Workshops: Gowning, Fingertip Sampling
- Smoke Pattern Testing
- Documentation

DAY TWO

- Workshops: Viable Sampling, Non-Viable Sampling, Smoke Pattern Testing
- Cleanroom Concepts and Testing Procedures: Facility Objectives, Airflow Testing, Room Segregation, HEPA Filter Integrity Test, Problem Sets
- Site Visit To Local Hospital

DAY THREE

- Activity: Developing Test Plans for Real-World Locations
- Activity: Review of Test Plans
- Workshop: Execution of Test Plan for a Real-World Cleanroom
- Certification of Vertical and Horizontal Laminar Flow Benches, Including: Airflow Testing, Particle Counting, Environmental Monitoring and HEPA Filter Leak Testing
- Activity: Review of Test Documentation

DAY FOUR

- Isolator Descriptions and Background
- Isolator Testing
- Activity: Establishing a Test Plan

DAY FIVE

- Workshop: Certification of Isolators
- Activity: Certification Documentation Review



Local Information

AIRPORT



DEN | Denver International Airport
23 Miles North • www.flydenver.com

DIRECTIONS



We recommend renting a vehicle, as the class location is approximately 5 miles from the hotel. STAR Center physical address is 14445 Grasslands Drive, Englewood, CO 80112. Directions via Google: <http://g.co/maps/qepd9>

LODGING



May 6-10, 2013 | Holiday Inn - Parker | \$99*
(888) 465-4329 | www.holidayinn.com
Oct 7-11, 2013 | Holiday Inn - Parker | \$99*
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**Reservations must be made by the attendee.
Should there be a problem with the room block reservation line, please call Holiday Inn - Parker directly at (303) 248-2147*

Cancellation Policy

Individuals who cancel more than 15 business days prior to the class date will receive a full refund. For cancellations made 6 to 15 business days before the start of the program, a 50% refund will be given. For cancellations made 5 business days or less prior to the class date, no refunds will be given. Notification of cancellation must be received in writing. Substitutes for a registered attendee may be made at anytime.

for more information or to register, please visit

www.eagleson.org/USP797

