TESTING HEPA FILTERED SYSTEMS & PHARMACEUTICAL CLEANROOMS

Course Description:

This three-day class will use lecture, hands-on workshops and group activities to provide the knowledge needed to test HEPA filters and the support systems in regulated cleanrooms and controlled environments per the FDA's Aseptic Guidelines, and relevant ISO and US standards.

Participants Will Learn:

- How to identify different types and classes of filters
- How to perform in-situ integrity testing of HEPA filters
- How to handle and store HEPA filters
- How to repair HEPA filter media and gasket leaks
- Airflow definitions and equations used in testing cleanrooms and controlled environments
- How to measure airflow in clean benches, cleanrooms, and HVAC systems
- How to perform airflow visualization
- How to calculate room air exchange rates
- The theory and operation of photometers and particle counters
- How to verify a room 's cleanliness classification
- How to apply relevant standards and regulations when writing SOPs
- How to perform HEPA testing in accordance with ISO 14644-1, ISO 14644-2, IEST RP34, IEST RP006, IEST RP001, IEST RP002 and the FDA CGMP Guide

This Course is For:

Validation, quality assurance and contamination control personnel, facility engineers, maintenance personnel, cleanroom certifiers, and architects and engineers involved in cleanroom design.

Instructor Team:

The instructor team includes **Lewis Exner,** Director of Field Operations, Controlled Environment Consulting, LLC; **Shane Morris,** Owner, Champion Air Testing; **Aaron Johnson**, Senior Product Specialist, Baker; **Dan Takata**, Owner, Cleanroom Services.

Registration:

Tuition of $2095 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.

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