



Isolators, Cleanrooms and Controlled Environments

Design, Validation,
Operation

Anne Marie Dixon

San Diego, CA
To be announced

Contamination is one of the greatest challenges that face healthcare manufacturers.

This course presents an integrated systems approach to the design, construction, certification, validation, monitoring, maintenance and operation of a cleanroom. This comprehensive course provides a wealth of in-depth technical knowledge to allow companies to cost-effectively meet the challenges required.

New systems and technologies including mini-environments, isolation systems, material and work flows and new design concepts are reviewed. The major changes in cleanroom standards - ISO TC 198, ISO TC 209, EU Annex 1, USP <1116> - will be discussed. New garment fabric materials, new gloves, wipes and new methods of performing equipment maintenance are also highlighted. Personnel issues and training methods will be discussed.

At the end of this course you will have a clear understanding of the newest developments and practical concerns involved in all aspects of cleanroom and controlled environment technology.

Course Content:

Designs

- Cleanroom Standards
- Cleanroom Designs
- Integration of Isolation Technology
- Facility Layouts
- Materials of Construction
- Certification
- Regulatory Concerns

Validation

- Cleanrooms - DQ, IQ, OQ, PQ
- Isolators - DQ, IQ, OQ, PQ

Cleanroom Operations

- Controlling Contaminants from Personnel
- Gowning and Garments
- Personnel Monitoring
- Training

Isolator Operations

- Decontamination Agents
- Glove/Suit Integrity
- Transfer of Supplies and Equipment

Support and Maintenance

- Housekeeping Sanitization
- Surface Testing
- Startup Cleaning Validation
- Equipment and Facility Repairs

Monitoring and New Standards

- Environmental Monitoring
- New ISO Standards
- Standard Operating Procedures
- Audit Checklist

Course Faculty:

Anne Marie Dixon is the Principal of Cleanroom Management Associates, a consulting firm that specializes in competitive benchmarking, training, and auditing of clean and aseptic operations and management.

Anne Marie has been actively engaged in the field of contamination control for over two decades with extensive experience in the areas of training, technical writing, strategic consulting, facility start-up, construction protocols and process optimization.

A University of Illinois graduate, Anne Marie is the author of the Cleanroom Management Manual. She has authored over 70 technical articles and publications including the definitive text book for cleanroom technician training. Anne Marie is also the first recipient of the PDA-James P. Agalloco Award for Excellence in Education.

A frequent lecturer and chairperson at technical sessions here and abroad as well as a guest lecturer at the University of California - Irvine, the Parenteral Drug Association, and the Institute for Applied Technology, she is the first woman to ever be elected to the post of President of The Institute of Environmental Sciences (1991-1992) and chairs several Recommended Practices work groups of the Institute of Environmental Sciences. She is an active member of The Institute of Environmental Sciences, Parenteral Drug Association, the American Society of Quality Control, National Environmental Training Association, American Management Association, Semiconductor Safety Association, and the American Society of Heating, Refrigeration and Air Conditioning Engineers. Anne Marie is also a certified ISO 9000 Internal Auditor.

She is the head of the U.S. Technical Advisory Group - TC 209 and represents the American National Standards Institute (ANSI) for the ISO Technical Committee 209 on Cleanrooms and Other Associated Controlled Environments.

You will profit from this course, if you belong to the

facility engineering, validation, QA, facility maintenance, manufacturing, or regulatory affairs department of a FDA-regulated company.

You will also profit from this course, if you simply need to know more about cleanroom and isolator technology.

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on
all CCE-courses.

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Venue:

To be announced

When making your hotel reservation, please mention the **Center for Continuous Education** to receive the **special group rate!**

Course Schedule:

Each Course Day:
8:00 a.m. to 4:00 p.m.

Fee Schedule:

\$1,595 for early payment
\$1,695 for payment received by closing date
\$1,795 for payment received after closing date

**To assure your participation,
REGISTER EARLY!**

For Registration...

we only need your **name, affiliation, postal address, and phone and fax numbers** together with the **course title**. You can **call, fax or e-mail** us the information or you can register through our **web site**.



The Unavoidable Small Print!

The course fee includes a **comprehensive course book** containing the complete presentation material. It also covers **continental breakfast** and **refreshments** served in the course room and **lunch** on course days. Course participants will receive a **certificate** confirming 1.8 CEU's.

Course acceptance is based on a **first come, first served basis**. To hold your place as a confirmed participant, CCE must receive your **payment made with check or major credit card by the course closing date**. CCE must have received your payment at the latest 5 business days prior to course start.

90% of the paid fee is refundable, if participant cancels before the course closing date. 50% of the paid fee is refundable for cancellation received no later than two weeks prior to course start. **No refund** can be made for cancellation after that date. However, **confirmed participants may send a substitute participant at any time**.

CCE reserves the right to cancel the course or to replace faculty at any time. In case CCE needs to cancel the course, participants will receive a full refund of fees paid to CCE. CCE will not be responsible for any other costs incurred due to course cancellation.

Course participants and their companies agree to these terms by making their payment to CCE.

This course is also available as an
in-house course
at your facilities!