



A Practical Approach to Cleanroom Operation and Management

Anne Marie Dixon

San Diego, CA
To be announced

To prevent product contamination manufacturers need to employ cleanroom environments. As the cost of cleanroom operations increases, management of this space becomes a critical task. The state of cleanliness can only be maintained through a deliberate program of training, personnel monitoring, proper gowning, cleaning and sanitization, process controls and environmental monitoring. Finding root causes for CAPAs and Investigations will be addressed and case study work will be included in this course.

Process simulation (media fills) is a difficult and often complex issue in today's fill/finish, bulk manufacturing and cell operations environments. The development of this requirement will be discussed in view of the new regulatory changes in the US and Europe. Environmental monitoring during validation and the selection of sites for routine monitoring will be discussed in great detail. An update of all the new standards will be included with comparisons to existing standards.

At the end of this course you will have a thorough understanding of cleanroom operations and management.

Course Content:

Personnel

- ✓ Rules regulations and disciplines
- ✓ Gowning
- ✓ Garment Selection
- ✓ Qualification of personnel
- ✓ Training

Cleaning and Sanitization

- ✓ Supplies
- ✓ Disinfectants
- ✓ Cleaning agents
- ✓ Techniques
- ✓ Frequency
- ✓ Testing

Environmental Monitoring

- ✓ Validation
- ✓ Routine monitoring - selection of sites
- ✓ Air, particle, surface monitoring
- ✓ Personnel monitoring
- ✓ New standards

Process Controls

- ✓ Media fills – initial validation
- ✓ Personnel qualification
- ✓ Re-qualification
- ✓ Sterility testing

Investigations and CAPAs

- ✓ Risk analysis
- ✓ Causes
- ✓ Investigation techniques
- ✓ Case studies

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 are involved in

specifying, designing, operations, auditing or monitoring of a cleanroom or controlled environment;

if you belong to

Manufacturing QA, QC, Engineering or Maintenance;

if you are

a cleaning contractor or cleanroom supplier;

if you

need an update in the new requirements of cleanroom operations or simply need to know more about contamination control and investigations.

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:

\$1,695 for early payment

\$1,795 for payment received by closing date

\$1,895 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**.



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1773 Kings Road
Vista, CA 92084-3640, USA
1-760-941-2040 or 1-800-698-2040
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www.cce-us.com registrar@cce-us.com

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 no6t 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.

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