



GMP-Supporting Manufacturing Facilities

- Planning
- Design
- Validation
- Maintenance

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San Diego, CA

To be announced

A well-designed facility must meet many requirements. First and foremost, it must protect the entire manufacturing process from the entry of contaminant and must aid in avoiding mix-ups of equipment and materials. Equally important is its function in protecting facility staff and the environment from process-derived contaminants. Finally, the manufacturing facility must be designed for the lowest possible cost to enable economically justifiable product manufacture. To fulfill all of these expectations the facility must be well planned.

Course participants will learn how to properly design a facility around a given manufacturing process and how to cost-effectively validate and maintain the facility while meeting current and future GMP expectations.

Course Content:

GMP Overview

- Function of Facilities
- General Design Concepts
 - Segregation
 - Unidirectional Flow
 - Multistory Facilities
- Site Selection

Materials Handling

- Storage Facility Design

Chemically Synthesized APIs

- Process Examples
- Explosion-proof Design
- Facility Design

Biopharmaceutical APIs

- Cell Culture / Fermentation
- Product Recovery
- Product Purification
- Bulk Fill

Biologics

- Blood Products
- Cell Products
- Gene Therapy Products
- Vaccines

Final Dosage

- Fill and Finish
- Orally administered Products
- Parenteral Products

Contaminant Control

- Process Segregation
- Cleaning, Sterilization and Sanitation
- Controlled Environments
 - Cleanroom Classes
 - Cleanroom Design
 - HVAC Design

Waste Handling

Utility Systems

- Electrical Power
- Water
 - City / Well
 - Purified
 - WFI
- Steam
 - Process
 - Clean
- Process Gases
- Vacuum
- Waste Handling

Design for Best Economy

- Architectural Finishes
- Minimization of Cleanroom Space
- Clean-Built Construction

Pilot Plants vs. Manufacturing Facilities

Dedicated vs. Multiproduct Facilities

Facility Validation

- Design Qualification
- Construction Qualification
- Operational Qualification
- Performance Qualification

Facility Maintenance

Course Faculty:

Frieder K. Hofmann, Ph.D. is Principal Consultant of ProCon International, an internationally operating consulting firm that provides comprehensive technical, regulatory and managerial advice in all areas associated with GMP-conforming pharmaceutical and biopharmaceutical manufacturing, product and process development, process engineering, validation, and facility design. Since 1990, Frieder has worked as a technical, regulatory, process engineering and quality systems consultant for both small start-up pharmaceutical and biopharmaceutical companies and multi-national pharmaceutical concerns in the U.S., Europe and Japan.

Until 1990, he was for seven years Technical Director for BioTechnetics, San Diego, CA where his responsibilities included molecular and cell biology, process development and GMP-conforming production scaleup of numerous cell-expressed proteins. Previous positions included European applications manager for a membrane manufacturer where he invented and developed a patented automated upstream integrity tester for filters and three years of work in applied physics for the German pharmaceutical concern Hoechst A.G.

Frieder earned his M.S. and Ph.D. degrees in microbiology and biochemistry at J.W. Goethe University in Frankfurt, Germany. Among others, he is a member of the American Institute of Chemical Engineers, the European Society for Animal Cell Technology, the American Society for Quality Control, the Regulatory Affairs Professional Society and the PDA. He was presented the Parenteral Science and Technology Journal Award 1985 by PDA and was awarded six process development related patents.

His previous employer received the prestigious Kirkpatrick Chemical Engineering Achievement Honor Award in 1989 for Frieder's bioproduction technology. Frieder published numerous articles and authored two book chapters on biopharmaceutical development. He is a frequent speaker and chairperson at national and international pharmaceutical and biotechnology conferences.

You will profit from this course, if you belong to

Facility Planning or Design, Project Management, Validation, Manufacture, Maintenance, Regulatory Compliance, Executive Management

Engineering contractors and anybody who needs a more thorough understanding of state-of-the-art GMP-supporting facilities will greatly benefit from this course.

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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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.

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