



Quality Healthcare Products

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San Diego, CA

To be announced

Although Good Manufacturing Practices (GMP) have been in effect since 1963, they are an evolving set of regulations that must be customized to your product, your product technology and delivery system, your manufacturing facility and your corporate culture.

Implementing and maintaining GMP is not a trivial task. It requires that you know the fundamental regulatory concerns and expectations, that you apply this knowledge to your product and that you make decisions about how to comply with GMP regulations.

Processes change, corporations change, management changes, regulations change, but the need to ensure that products are safe, effective and stable remains the same. Quality systems, as a result, must be designed and implemented to endure the inevitability of change.

Learn the fundamentals and you will be able to apply them in your current position as well as throughout your career. This course is designed to teach you how to "think GMP", how to implement GMP systems of compliance, and how to maintain these systems over time and through change. The information will be presented in a manner that will help you make the day-to-day decisions that are so difficult.

Course Content:

Why are Healthcare Products Regulated?

Development of the GMP Regulations in the U.S
European and Japanese GMP Guidelines
The Meaning of "current" in cGMP

Regulation of Healthcare Products

Product Life Cycle
Design Control
Manufacture of clinical supplies
Manufacture of approved products

Designing a cGMP-Supporting Quality System

Defining Goals
Development of Requirements for
- Product,
- Materials,
- Processes,
- Personnel and
- Facility
Development of Specifications
Development Test Methods

Implementation of the Documentation System

What needs to be documented?
Ensuring Comprehensive Documentation
The Document Hierarchy
- Commitment Documents
- Policies, Plans
- Directive Documents
- MS, SOP's, MBR, MDR, Validation Protocols
-Data Collection Documents
- BR, DHR, Logbooks, Validation Records, Inventory Cards
- Summary Reports
-Validation Summary Reports, Trend Reports
Ensuring Accountability and Traceability
Document Control
Electronic Documentation

Validation and Qualification

Test Method Validation
Materials Qualification
Facility Validation
Utility Validation
Equipment, Software and Cleaning Validation
Operator Qualification
Process Validation
Documentation of Validation

Change Management

Change Prevention
- Calibration, Maintenance and Revalidation
- Auditing and Training
Controlled Change
- Criticality of Change
- Off-line Validation
- Acceptance Decision and Implementation
When things go wrong
- Out-of-Specification Results
- Customer Complaints
- Deviations
- Conducting Investigations
- Decision Power
- Implementation of Corrective Action

Regulatory Inspections

What to Expect, how to Prepare and how to Respond

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. For the past ten years Frieder has worked as a technical, regulatory, process engineering and quality systems consultant for both small start-up pharmaceutical and biopharmaceutical companies and multinational 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 benefit from this course, if you belong to the

quality assurance, quality control, manufacturing, process development, engineering and maintenance or regulatory compliance department of an FDA-regulated company.

Vendors to the health care industry and anybody who needs a more thorough understanding of cGMP's and quality standards will also 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.