



RIGHT the First Time

Implementation of a cost-effective GMP-compliant quality system

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San Diego, CA
To be announced

Complying with GMP demands is expected by all regulatory authorities. However, depending on the approach, implementation of these requirements can mean an additional cost burden or a positive contribution to the company's bottom line. A cost-effective GMP-compliant quality system concentrates on and controls the elements that have the greatest impact on product quality with the goal of having no rejected product while complying with all regulatory expectations. Such a well thought-out system, will result in no regulatory problems, no customer complaints and an excellent reputation of the company in the market-place.

Course participants will learn the attributes of a cost-effective quality system, how to identify weaknesses in their current organization, how to implement strategies aimed at cost-effective augmentation of their quality system for marketed products and products under development and how to simultaneously improve their company's regulatory compliance.

Course Content:

Planning for Quality

Company Organization
Development of Specifications for
Product - Materials and Components -
Unit processes - Utilities - Equipment -
Cleanliness - Facility

Design Qualification of

Product (Design Control) - Unit processes -
Utilities - Equipment - Facility

Manufacturing Controls

Batch Record and Supporting SOP's - Calibration Program - Materials Testing - In-process Testing - Utility Testing - Environmental Testing - Final Product Testing - Trending of Test Results

Materials Management

Purchasing Control - Materials Storage -

Materials Release - Materials Transport -
Product Storage and Shipping

Documentation System

Documentation Requirements
Document Hierarchy
Commitment Documents - Directive Documents -
Data Collection Documents - Summary Reports
Document Control
Electronic Documentation

Validation and Qualification

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

Change Management

Change Prevention
Calibration - Preventive Maintenance - Re-validation - Auditing and Training
Controlled Change
Criticality of Change - Off-line Validation - Acceptance Decision and Implementation
Learning from Problems
Out-of-Specification Result Handling - Customer Complaints - Deviations and Non-conformances - Root-cause Investigation - Decision Power - Implementation of Corrective and Preventive Actions

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 profit from this course, if you are involved in

- how a quality system can positively impact the company's bottom line
- how to identify the critical quality controlling elements
- national and international regulatory GMP requirements and expectations
- setting up a comprehensive documentation system
- validation requirements
- change control
- investigations aimed at identifying the root-cause of a detected problem

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,
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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 CEUs.

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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