



# GMP Compliance

Meeting the U.S. and International Regulatory Expectations

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San Diego, CA

To be announced

**Regulatory authorities** expect healthcare manufacturers to comply with **GMP regulations**. The function of GMP is to **guarantee reproducible production of unadulterated product of consistent quality**.

**Governments enforce compliance** with GMP through **comprehensive and exhaustive inspections** of company sites. **Non-compliance** with GMP regulations is considered a serious offense and can lead to **product recall, product seizure, facility closure and criminal prosecution** of company management and employees.

This course is designed to provide employees of regulated companies and vendors and suppliers to health care manufacturers with the **necessary knowledge of Current Good Manufacturing Practices** to effectively function in this highly regulated industry.

## Course Content:

### Introduction to GMP Regulations

- The Origin of GMP Regulations
- U.S. GMP Regulations for
  - Drugs
  - Biologics
  - Devices
- International GMP Regulations
  - Commonalities and Differences
  - WHO - USA - Canada - Europe - Japan
- ICH Guidelines
- GMP vs. ISO 9000

### GMP Implementation

- Design Controls
- Setting Specifications for
  - Product - Materials and Components - Processes - Equipment - Utilities - Facility
- Facility and Utility Requirements
- Facility Validation
- Monitoring of Process and Environment
- QC Lab and Test Methods
- Stability Testing Program
- Process Documentation
- Process Validation
- Calibration and Maintenance
- Materials Handling
- Vendor Qualification
- Staff Competence

## Documentation

- Structure of Documentation System
- Writing of GMP-conforming Documents
- Reviewing and Approval of Documents

## GMP Maintenance

- Company Organization
- Document Control
- Failure Investigation
- Corrective Actions
- Change Control
- Self-Inspection
- Inspection by Regulatory Authorities

## GMP Audits

- Preparation for Audits
- How to Audit
- How to Behave During Audits

## Regulatory GMP-Expectations during the Product Development Process

## 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

Manufacture, Quality Assurance, Validation, Quality Control, GMP Compliance, Project Management, Operations Management, Process Development, Engineering or Regulatory Affairs.

Vendors and contractors and anybody who needs a more thorough understanding of current Good Manufacturing Practices will also benefit from this course.

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

## 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 not 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.