



Preapproval and GMP Inspections

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Companies are required by law to audit their own operations and the operations of their vendors, suppliers and contract laboratories. In addition, Regulatory Authorities are conducting inspections of companies prior to licensing a product and periodically later when product is manufactured for the market.

This course teaches how to effectively audit for GMP compliance and how to behave if being audited. The course therefore is equally useful for both, auditors and auditees.

The course further instructs how to properly document the inspection and how to appropriately follow up on commitments made during and after the audit.

To get the most out of this course participants should have at least a basic knowledge of GMP requirements and expectations of regulatory authorities.

Course Content:

The Why, Who, How, Where and When of Inspections

Audit Preparation for Auditors

- Definition of Audit Goals
- Agenda Development
- Collection of Information on Auditee
- Contacting Auditee

How to Conduct an Audit

- Entry Meeting
- Company Organization
- Review of Documents
 - MBR and supporting SOP's
 - Policies and Plans
 - SOP's supporting
 - Operations
 - Materials Handling
 - QA
 - QC
 - Manufacturing
 - Facility and Equipment Maintenance
- Validation Records for
 - Analytical Methods
 - Facility
 - Utilities
 - Process Equipment
 - Manufacturing Process
 - Product Shipping
- Vendor Qualification and History Records
- Change Control
- Document Control
- Handling of Planned and Unplanned Deviations
- Handling of Failed Batches
- OOS Result Handling

- Job Descriptions
- Training Records
- Facility Tour
 - Materials Receiving and Storage
 - Manufacturing Suites
 - Product Storage and Shipping
 - Utility Equipment and Routing
 - QC Laboratories
 - Operator Interviews
 - Review of Log Books and Equipment Readiness
- Exit Interview / Form-483 Observations

Audit Preparation for Auditees

- Solid GMP Implementation
- Assignment of Responsibilities
- Internal Audits
- Mock Audits
- Auditing Etiquette for Auditees
- Training of Personnel

How to Receive an Audit

- Reception of Inspectors
- Presentation of Company
- Cooperation with Inspectors
- Clarification of Misunderstandings
- Proper Note Taking

Audit Follow-up

- Submission of Draft Audit Report
- Auditee's Response to Draft Audit Report
- Responding to Form-483 Observations
- Establishment Inspection Report
- The Re-audit
- Avoiding Regulatory Warning Letters

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. In this function, he has performed numerous mock pre-approval and compliance inspections, has served as expert witness in court battles and has trained over 5,000 employees of healthcare manufacturers in GMP and quality system design.

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

Quality Assurance, Quality Control, Regulatory Compliance, Manufacturing, Operations Management, Engineering, Maintenance or Company Management.

Venue:

Horton Grand Hotel
311 Island Avenue
San Diego, CA 92101
Tel 619.544.1886 or 800.542.1886
Fax 619.239.3823
www.hortongrand.com

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 5:00 p.m.

Fee Schedule:

\$1,695 for payment received by **March 31, 2006**
\$1,795 for payment received by April 14, 2006
\$1,895 for payment received after April 14, 2006

**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 us or 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 by the course closing date, April 14, 2006**. No payment can be accepted after 5 business days prior to course start.

90% of the paid fee is refundable, if participant cancels by April 13, 2006. 50% of the paid fee is refundable for cancellation received by May 21, 2006. **No refund** can be made for cancellation **after April 21, 2006**. 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.

Former course participants:

"Great course! Now I understand why and how FDA inspects and how they are thinking."

"This course has certainly improved my auditing skills. I will be able to conduct our vendor audits with more confidence and exactly know what to look for. Thanks and keep up the good work."

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