



DOCUMENTATION

Meeting the Regulatory Expectations

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San Diego, CA

To be announced

A rugged documentation system is of pivotal importance to a company because it supports various important functions. It provides un-equivocal legal proof that work was adequately planned and performed at the claimed time, it helps in the troubleshooting of technical and managerial problems, it facilitates company growth and technology transfer, it provides a written history of company and products, and it proves to regulators that the company follows its commitments.

To fulfill these functions documents must be clear, comprehensive, not overlapping in their content, authentic, falsification resistant and must cover all important aspects in sufficient detail.

In spite of its obvious importance to companies as regulators, inadequate or inappropriate documentation still ranks high on the list of objectionable findings of inspectors during preapproval and regular GMP inspections.

This course teaches how to set up or augment an existing documentation system and how to appropriately document commitments, procedures and work to comply with current GLP and GMP regulations.

Course Content:

- **Why Documentation?**
 - Proof of Invention
 - Company Operations
 - Technology Transfer
 - Regulatory Requirements
 - Liability Protection
- **The Documentation System**
 - What needs to get documented?
 - What should get documented?
 - Ensuring comprehensive documentation
 - Avoiding contradiction in documents
 - Document Control
- **The Regulatory Expectations**
 - R&D Documentation
 - GLP-Documentation
 - GMP-Documentation
- **Implementation of a new Documentation System**
- **Augmentation of an Existing Documentation System**

• The Documentation Hierarchy

- Commitment Documents
 - Policies
 - Contracts
 - Plans
- Directive Documents
 - Specifications
 - Standard Operating Procedures (SOP's)
 - Production Batch Record
 - Master Device Record
 - Validation Protocols
 - Notebooks
- Data Collection Documents
 - Production Batch Record
 - Device History Record
 - Quality Control Records
 - Validation Records
 - Equipment and Facility Logbooks
 - Calibration and Maintenance Records
 - Vendor History File
 - Inventory Cards
- Reports
 - Study Reports
 - Process Flow Diagrams
 - Process Development Report
 - Validation Reports
 - Facility Qualification Report
- **Content and Format of the Different Types of Documents**
- **Document Design**
- **Electronic Documentation and Compliance with 21 CFR Part 11**

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 and regulatory consultant for both small start-up pharmaceutical and biopharmaceutical companies and multinational 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, Frieder was Technical Director for BioTechnetics, San Diego, CA where his responsibilities included the R&D of anticancer monoclonal antibodies and the GMP-conforming production scaleup of numerous cell expressed proteins. Previous positions included applications manager for a membrane manufacturer and work in applied physics at 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 Drug Information Association, 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 biopharmaceutical processing 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 biotechnology conferences.

You will profit from this course, if you belong to

Quality Assurance, Quality Control, R&D, Process Development, Manufacturing, Validation, Operations Management or Regulatory Compliance.

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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