



Bulletproof VALIDATION

of
Methods,
Equipment,
Process,
Utilities &
Facility

Frieder K. Hofmann, Ph.D.

San Diego, CA

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As part of GMP compliance, regulatory authorities expect healthcare manufacturers to validate their production and control equipment, production process, facility, and production utilities.

Inadequate validation still tops the list of objectionable observations of regulatory inspectors during pre-licensing and GMP inspections.

This course teaches how to plan for validation and how to write and execute validation protocols that meet regulatory expectations. In addition, selection and appropriate supervision of outside validation contractors will be discussed.

Course Content:

Introduction to Validation

Validation Approach

The Master Validation Plan
Content and Format

Phases of Validation

Design Qualification
Installation Qualification
Operational Qualification
Software Qualification
Analytical Methods Validation
Cleaning Validation
Performance Qualification
Computer Validation
Process Validation
Revalidation

Documentation

Validation Records

Facility Validation

Location
Layout
Cleanroom Classes and Pressurization
Utilities
- HVAC Systems
- Water Systems
- Steam Systems
- Compressed Gases
- Electricity

Multi-product Facilities

Concurrent Facility Validation

Process Equipment Validation

Reactors
Ultrafilters
Sterile Filters

Autoclaves
Purification Equipment
Aseptic Filling Line
Lyophilizer
Validation Contractors
Selection Criteria
Supervision

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

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

Engineering contractors and anybody who needs a more thorough understanding of state-of-the-art validation will also benefit from this course.

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

Please contact us for
details.

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 4:00 p.m.

Fee Schedule:

\$1,695 for payment received by **May 2, 2006**
\$1,795 for payment received by May 16, 2006
\$1,895 for payment received after May 16, 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 register through our website, www.cce-us.com, or you can **fax** or **e-mail** us this information.



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, May 16, 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 May 15, 2006. 50% of the paid fee is refundable for cancellation received by May 23, 2006. **No refund can be made for cancellation after May 23, 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.

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