



The Technical Regulatory Expectations in Development & Manufacture of Biotherapeutics

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San Diego, CA
To be announced

The path from the discovery of a new biopharmaceutical drug to its commercial production is mostly narrow, steep, thorny and filled with many obstacles. Some of these obstacles are created by the regulatory requirements which rightfully demand proof of safety, potency, efficacy and stability of the new drug and proof for a reliable manufacturing process and a stable, controlled production environment that minimizes the risk of product contamination. The fulfillment of these regulatory requirements can easily become overwhelming, unless everybody involved in development and manufacture of the new therapeutic knows from the onset what will be required when, how and why.

This course will teach the reason why the requirements are what they are and how and when in the development process they should be addressed to satisfy regulatory authorities.

Course Content:

The Development Plan

Product Characterization

Physicochemical • Biological

Specification and Qualification of

Product • Host Cell • Raw Materials • Components

Development of Reference Standard

Development and Validation of Analytical Methods

Stability Testing Program

Establishment of MCB and MWC

Development of the Manufacturing Process

Development of Process Specifications

Scaleup to Pilot Plant Size

Standard Operating Procedures

Analytical Testing • Materials Handling
• Production • QC • Maintenance • QA Procedures

The Master Batch Production Record

Documentation of the Development Progress

Assignment of Responsibilities

Materials Handling • Production • Maintenance • Quality Control • Quality Assurance
• Regulatory Affairs • Executive Management

Production Facility

Design Requirements • Flow of Personnel, Materials, Equipment, Product and Waste • HVAC and Architectural Finishes • Utilities • Dedicated Facilities vs. Multi-Product Facilities

Facility Validation

Design Qualification • Construction Qualification • Operational Qualification • Performance Qualification

Process Validation

Design Qualification • Installation Qualification • Operation Qualification • Computer Qualification • Cleaning Validation • Performance Qualification

Personnel

Training • Qualification

Manufacture for Clinical Trials

Scaleup to Commercial Production Size

Contract Production

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. Until 1990, he was Technical Director for BioTechnetics, San Diego, CA where his responsibilities included cellular and molecular biology, process development and 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 the

Regulatory, Quality Assurance, Quality Control, Process Development, R&D, Engineering, or Manufacturing Department of an FDA-regulated company.

Vendors to the FDA-regulated industry and anybody who needs a more thorough understanding of the technical aspects of regulations will also greatly benefit from this course.

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**.



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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