



Biopharmaceutical Production Technology

• A Cross-training Course •

Frieder K. Hofmann, Ph.D.

San Diego, CA

May 15 to 18, 2006

For a newly discovered product, it is important that it reaches the market early to secure market share and that it can be manufactured at affordable cost to ensure profitability. Unfortunately, development of a new biopharmaceutical drug is far from trivial, because it requires cooperation of disciplines with different talents and mindsets and the path to success is filled with regulatory hurdles. Thus, to ensure smooth transition from product discovery to economical GMP-conforming production, company executives and all specialists from product development, QA/QC, manufacture, facility engineering and regulatory affairs need to understand the basics of the production technology and the important process development and regulatory issues.

Course Content:

Basics of Molecular and Cell Biology

- Properties and Characterization of Proteins
- Protein Synthesis in Prokaryotes and Eukaryotes
- Expression of Foreign Proteins in E. coli, Yeast, Animal Cells and Transgenic Animals
- Physiological Requirements of Bacteria, Yeast and Animal Cells

Selection of Appropriate Expression System

- Advantages and Disadvantages of the Major Host Systems
- Optimization Strategies for Cell Specific Productivity
- Nutrient Development Strategies
- Regulatory Concerns
- Cell Bank Establishment, Characterization and Qualification

Scaleup to Production Size

- Estimation of Required Production Scale
- Fermenter/Bioreactor Design
- Batch vs. Continuous Production
- Inoculum and Nutrient Preparation
- Optimization of Reactor Operation
- Reactor Scaleup

Sanitization, Sterilization and Depyrogenation

- GMP-Conforming Equipment Design
- Clean-in-Place (CIP)
- Steam-in-Place (SIP)
- Autoclaving
- Dry-Heat and Chemical Treatments
- Sterile Filtration
- Integrity Testing of Equipment and Filters

Product Recovery and Purification

- Product Harvest
- Tangential-Flow Micro- and Ultrafiltration
- Protein Purification Methods
- Removal of DNA, Viruses and Pyrogens
- Scaleup and Validation of Purification Methods

Process Design

- Logical Sequencing of Unit-processes
- Development of Process Flow and Piping and Instrumentation Diagrams

Facility Design

- Requirements of GMP-Conforming Production Facilities
- Pilot Plant vs. Production Facility
- Multiproduct vs. Dedicated Manufacturing Facility
- Utility Requirements

Regulatory Requirements

- Integration of Regulatory Requirements with Process Development

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 Affairs, Quality Assurance, Quality Control, Process Development, R&D, Engineering, or Manufacturing Department of a CBER-regulated company.

Vendors to the CBER-regulated industry and anybody who needs a more thorough understanding of biopharmaceutical process development will also greatly benefit from this course.

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

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:

\$1,895 for payment received by **April 7, 2006**
\$1,995 for payment received by April 21, 2006
\$2,095 for payment received after April 21, 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 2.4 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 21, 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 20, 2006. 50% of the paid fee is refundable for cancellation received by April 28, 2006. **No refund** can be made for cancellation **after April 28, 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 Participant:

"...by far the best course I have ever attended! Thank you!" © CCE.