



# Recovery and Purification of Biopharmaceuticals

From Lab Scale to Production Scale

Process Design, Operation  
and Validation

Frieder K. Hofmann, Ph.D.

San Diego, CA

June 26 to 28, 2006

Development of successful industrial purification procedures requires integration from the start of regulatory issues, molecular limitations of the product, application requirements, and economic constraints. All of these considerations must be addressed without compromise and usually within compressed timelines. Consistently fulfilling this challenge requires a thorough understanding of the mechanisms, strengths and weaknesses of the various purification tools; an appreciation for the physicochemical characteristics of major contaminant classes; and a systematic approach to process development and scaleup.

This course will provide a unified comprehensive framework for development and application of industrial protein recovery and purification processes. Emphasis will be placed on field-proven methods and strategies.

## Course Content:

### Product characteristics

Physicochemical  
Biological

### Product recovery

from host cells  
from spent nutrient

### Characteristics of key contaminants and strategies for their removal

Nutrient-derived contaminants • Host Cell Protein • DNA • Endotoxin • Viruses

### Operating principles and limitations of key recovery and purification methods

Depth Filtration • Cross-Flow Filtration • Diafiltration • Centrifugation • Precipitation • Size exclusion • Ion exchange • Hydrophobic interaction • Affinity • Sterile filtration • Nanofiltration • Other methods

### Process development

Method selection  
Matrix selection  
Development of separation conditions  
Capacity vs. separation performance  
Process optimization  
Small-scale vs. large-scale processing

## Assuring proper performance of purification processes

Purification setup  
Protection of column life  
Cleaning and sanitization methods  
Control of bioburden  
Predictors of column performance and on-stream life

## Scale-up and scale-down

Lab scale vs. production scale  
Defining and meeting production-scale goals  
Guiding parameters for scaleup  
Technology transfer from lab to production floor

## Process validation

Qualification of materials and components  
DQ, IQ, OQ and PQ of equipment  
Cleaning and sanitization validation  
Removal/Inactivation validation of key contaminants  
Software validation

## 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 benefit from this course, if you belong to the

process development, R&D, validation, QA, QC, regulatory affairs, or manufacturing department of a biopharmaceutical company.

## 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](http://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 19, 2006**  
\$1,795 for payment received by June 2, 2006  
\$1,895 for payment received after June 2, 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](http://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, June 2, 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 June 1, 2006. 50% of the paid fee is refundable for cancellation received by June 9, 2006. **No refund** can be made for cancellation **after June 9, 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.

© CCE.