

## COURSE PROGRAM

### Sunday, 16 October 2016

19:00 Check-In and Dinner in Restaurant "Pixhaier Mühle"  
20:00 Oberharzer Wasserregal and Mining History

### Monday, 17 October 2016

08:30-09:00 Welcome and Introduction  
09:00-09:45 Downstream Processing (DSP) Basics  
10:00-11:15 Fundamentals Bio-Chromatography  
11:15-12:00 Lunch  
12:00-13:00 Institute, Guided Tour  
13:00-13:45 Equipment and Plant Technology Chromatography  
13:45-14:30 LL-Extraction  
14:30-15:15 Precipitation  
15:30-17:30 Experiments in the Laboratory  
Part I (1-4 a 30 min.)  
Chromatography Screening, Method  
Optimization/Model Parameter Determination,  
Column Packing, Preparative/Scale-up  
18:30-22:00 Guided Tour Mining Museum and Dinner

### Tuesday, 18 October 2016

08:30-09:15 Introduction in Fundamentals of Modeling and  
Simulation Software  
09:15-10:00 Experimental Model Parameter Determination  
10:15-11:15 Membrane Technology  
11:15-12:00 Lunch  
12:00-14:30 Experiments in the Laboratory  
Part II (5-9 a 30 min.)  
LL-Extraction, Membranes, Cryst./Precip,  
Distillation, Lyophilization  
16:30-19:00 Guided Tour and Dinner in Goslar  
20:00-24:00 Midnight Session Pixhaier Mühle  
Simulation Tutorials Chromatography,  
Membrane, Crystallization/Precipitation,  
Extraction, Distillation

### Wednesday, 19 October 2016

08:30-09:15 Fundamentals Continuous Bio-Chromatography  
09:15-10:00 Design of ContiBioChrom  
10:15-11:15 GMP Regulatory CBP  
11:15-12:00 Lunch  
12:00-12:45 QbD-Technology in DSP  
12:45-13:30 Lyophilization  
13:30-14:15 CBP – Industrialization  
14:15-15:00 PAT and Bioanalytics, Regulatory  
15:00-15:30 Discussion and Course End

(subject to modifications)

## GENERAL INFORMATION

### ACCOMMODATION

Waldhotel "Die Pixhaier Mühle" (phone: +49 5323 2215) and Hotel  
„Goldene Krone" (phone: +49 5323 9300)

A transfer is offered from/to Göttingen ICE Main Station (16.10.2016 at  
18:00 and 19.10.2016 after course end with transfer time about 45-60  
min.) and in Clausthal between the hotels listed and course locations.

In the cafeteria of the university opportunity for lunch is given (self-  
pay basis).

### REGISTRATION

You can register online, using the registration form or by e-mail:

DECHEMA-Forschungsinstitut  
Training department  
Postfach 170352  
D-60077 Frankfurt am Main

Phone: +49 69 7564-253/202  
Fax: +49 69 7564-414  
E-Mail: [gruss@dechema.de](mailto:gruss@dechema.de)  
E-Mail: [weber-heun@dechema.de](mailto:weber-heun@dechema.de)  
Internet: <http://dechema-dfi.de/en/kurse>

### REGISTRATION FEE

2,495.- €

2,480.- € (personal DECHEMA members)

(incl. accommodation with breakfast and dinner, course material,  
certificate of attendance and coffee breaks)

The number of participants is limited.

Please consider the successive "CBP - Continuous Bioprocessing"  
training course on 19 and 20 October 2016 as well.



## TRAINING COURSE

16 - 19 October 2016  
Clausthal-Zellerfeld / Germany

# DSP - Purification of Biomolecules

Design and Scale-up by Laboratory  
Experiments and Process Simulation



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## DOWNSTREAM PROCESSING

In manufacturing of amino acids, peptides, proteins and monoclonal antibodies 50-90 % of the Cost of Goods (COG) are caused by Downstream Processing. In process development separation processes must be proposed in an efficient sequence based on physico-chemical properties of target molecules, contaminants, side components and impurities to increase yield/recovery, and meet the needed product purity and quality while simultaneously reducing the number of unit operations involved.

The methods of Downstream Processing for complex molecules have become more efficient and thereby more economic. New developments in stationary phases and media, in innovative manufacturing equipment as well as new process design methods by process simulation combined with experimental model parameter determination in laboratory scale made this progress possible.

In this course the design of unit operations like UF/DF-, ion exchange- and affinity-membranes as well as affinity, ion exchange, immobilized metal affinity, size exclusion, hydrophobic interaction and reversed phase chromatography is presented and explained. These are established key-technologies which are highly efficient and broadly used in manufacturing. Additionally, protein refolding, extraction and precipitation/crystallization are discussed. Moreover, methods for virus inactivation and clearance are explained.

Scientists and technicians, involved in process development, should be familiar with the way, how Downstream Processing sequences are efficiently transferred from preparative into pilot- and production-scale

Profound theoretical and experimental knowledge as well as comprehension of newest design methods will help to meet the time pressure and enormous experimental efforts in daily project work.

### AFTER THE COURSE EACH PARTICIPANT SHOULD BE

- » able to apply modern downstream processing and process design methods in the daily project work
- » familiar with handling of membrane, extraction, crystallization/precipitation, distillation and chromatography equipment
- » able to evaluate platform-technologies and the consequences of the „Process Analytical Technology“ (PAT) initiative from „American Food and Drug Administration“ (FDA)
- » in a position to propose experiments for design of DSP unit operations
- » able to make a scale-up transfer of DSP processes
- » well informed about possibilities and limitations of process design of DSP processes by aid of simulations.

### PRESENTATION OF COURSE CONTENT

The content of the course will be presented in lectures with the opportunity for discussion.

At first the theoretical fundamentals are explained as back-ground knowledge. These basics will be deepened interactively with the aid of examples in interactive tutorials. Typical industrial applications will be chosen.

An experimental introduction in the laboratories into membrane, membrane adsorber and chromatography equipment as well as extraction, crystallization/precipitation, lyophilization and distillation will be provided.

Process design will be explained, at first theoretically and afterwards deepened by interactive simulation tutorials.

Course language is English. Nevertheless, of course, detailed additional explanations in German are possible.

### TARGET GROUP

Scientists and laboratory technicians involved in process development and/or manufacturing. Besides basic knowledge in computer handling no previous knowledge is required.

### COURSE MATERIAL AND INFRASTRUCTURE

Each participant will be provided with a manual with all lectures at the beginning of the course. The experimental part will be offered in the laboratories of the Institute. For the simulation tutorials laptops are provided. The experiments will be made in groups of about 2-3 participants.

### LECTURERS

Dr. R. Ditz (formerly Merck KGaA)  
 Dr. K. Hudel (Christ)  
 Dr. Falk Klar (PDA Europe)  
 Dr. D. Melzner (Sartorius)  
 Dr. F. Nygaard (NNE Pharmaplan)  
 Dr. F. Oehme (Bayer Health Care GmbH)  
 Dr. M. Schulte (Merck KGaA)  
 Prof. J. Strube and co-workers (TU Clausthal)

(subject to modifications)

### VENUE

Clausthal University of Technology  
 Institute for Separation and Process Technology  
 Leibnizstr. 15  
 38678 Clausthal-Zellerfeld, Germany

## Reply form

(Fax-No.: +49 69 7564-414)

DECHEMA-Forschungsinstitut  
Training department  
P.O. Box 17 03 52  
D-60077 Frankfurt am Main

### Registration (please check the respective course)

DSP/CBP

DECHEMA training course 3160 "DSP – Purification of Biomolecules"

16 – 19 October 2016, Clausthal-Zellerfeld

DECHEMA training course 3170 "CBP – Continuous Bioprocessing of Biomolecules"

18 – 20 October 2016, Clausthal-Zellerfeld

Deadline for registration: 23 September 2016

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#### Participant

Ms  Mr  Title \_\_\_\_\_

Name \_\_\_\_\_ Surname \_\_\_\_\_

Company \_\_\_\_\_

Department \_\_\_\_\_

Street/POB \_\_\_\_\_

Code/Place \_\_\_\_\_

Phone/Fax \_\_\_\_\_ E-mail \_\_\_\_\_

I am a personal DECHEMA member  yes  no

#### Invoice address

Company \_\_\_\_\_

Department \_\_\_\_\_

Street/POB \_\_\_\_\_

Code/Place \_\_\_\_\_

#### Method of payment

bank transfer after receipt of invoice

by credit card:

Mastercard  Visa

Card number \_\_\_\_\_ Expiration date \_\_\_\_\_ / \_\_\_\_\_

The course fee amounts to € 2,495.-/€ 2,480 (personal DECHEMA members) for the DSP training course and € 1,895.-/€ 1,880.- (personal DECHEMA members) for the CBP training course. If both training courses are booked, there will be a 20% reduction for the CBP training course. If we receive a notice of withdrawal at least two weeks prior to the beginning of the course, the participation fee less 10% for administration expenses will be reimbursed. Thereafter, a reimbursement will not be possible.

\_\_\_\_\_  
Place, date

\_\_\_\_\_  
signature + company stamp