

COURSE PROGRAM

TUESDAY, 18 OCTOBER 2016

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

WEDNESDAY, 19 OCTOBER 2016

08:00-08:30 Welcome and Introduction
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
15:00-17:30 Experiments Laboratory (1-3 à 45min)
Continuous Biochromatography and Design, Column

19:00 Packing and Testing, Method Development
Dinner Restaurant „Glück-auf“
21:00-24:00 Midnight Session Pixhaier-Mühle
Simulation Tutorials Batch and Conti-
Biochromatography

THURSDAY, 20 OCTOBER 2016

08:30-09:15 Continuous Bioprocessing (CBP) Fundamentals
09:15-10:00 CBP batch to conti – cost studies
10:15-11:15 Tutorial: CBP Total Process Studies
11:15-12:00 Lunch
12:00-13:00 Guided Tour Institute
13:00-13:45 Case study CBP for MABs
13:45-14:30 QbD studies
14:30-15:00 Course End and Discussion

(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 (18.10.2016 at 18:00 and 20.10.2016 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
E-Mail: weber-heun@dechema.de
Internet: <http://dechema-dfi.de/en/kurse>

REGISTRATION FEE

1,895.- €

1,880.- € (personal DECHEMA members)

A 20% fee reduction is offered when attending the preceding DSP course as well.

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

The number of participants is limited.

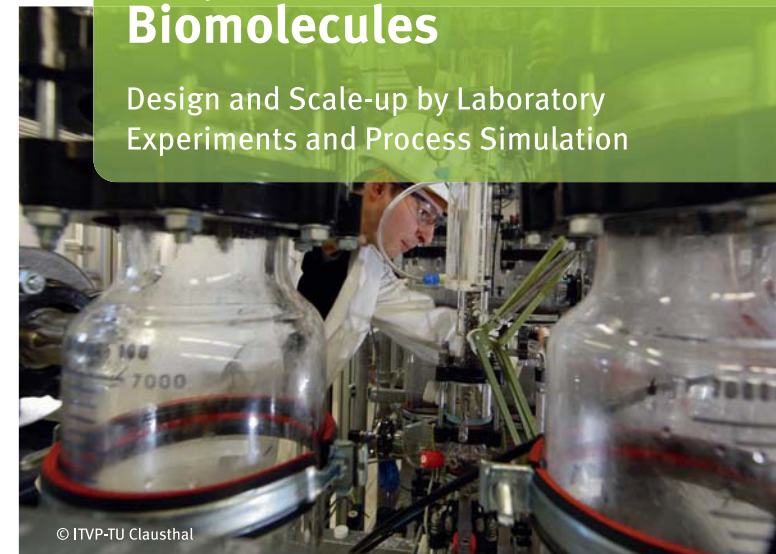
Please consider the "DSP - Downstream Processing" training course from 16 to 19 October 2016 as well.

TRAINING COURSE

18 - 20 October 2016
Clausthal-Zellerfeld / Germany

CBP - Continuous Bioprocessing of Biomolecules

Design and Scale-up by Laboratory Experiments and Process Simulation



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CONTINUOUS BIOPROCESSING

For synthetic APIs, increasing attempts to move from traditional batch to continuous manufacturing are ongoing. Advantages besides lower CAPEX und OPEX are in particular higher product safety by enhanced process robustness, smaller foot print of the plants, lower cleaning costs and down-times due to dedicated modular and flexible plants.

In manufacturing of biomolecules these concepts have so far only been applied for high-volume bulk or fine chemicals. However, with the upcoming cost issues in the manufacturing of biotherapeutics by low cost biogeneric manufacturers and stratified medicine scenarios, first approaches to industrialize continuous manufacturing for biologics like amino acids, peptides, proteins and monoclonal antibodies and fragments, are under investigation.

For the production of biopharmaceuticals, e.g. monoclonal antibodies, fermentation is already more often used in a continuous perfusion mode than is known to the public. Therefore, it is only consistent to apply continuous process concepts also for downstream processing operations. However, until recently the necessary unit operations and corresponding equipment has not been available. This is currently undergoing through a substantial change. Besides a broad variety of continuous chromatography applications with or without protein A, also older well known unit operations like liquid-liquid extraction processes based on ATP (Aqueous-Two-Phase) systems or precipitation by aid of suitable auxiliaries have become available and begin to find their place in a full continuous process scheme.

To accelerate slower unit operations better system performance, e.g. in chromatography, rod- or radial chromatography columns together with modern packings, as well as membrane adsorbers in IEX- or HIC-mode are available or under development.

The role of single-use (SUS)/disposable concepts, which are more and more applied also in industrial scale up to 2000 l volumes, in a fully continuous operation have yet to be defined. Their fields of use will depend on an individual process-related economic assessment.

New developments in manufacturing equipment, including analytics, as well as new process design concepts based on QbD-approaches can only be successfully integrated into efficient, reproducible, and robust continuous processes by the combination of modeling and simulations with laboratory-scale experiments.

The course will describe the design and scheduling of unit operations in continuous manufacturing processes in contrast to classical batch operations and aims at providing viable decision criteria.

Scientists and laboratory technicians, involved in process development and/or piloting/manufacturing will be trained how upstream and downstream processing sequences are efficiently scaled from preparative to pilot and production scale. Profound theoretical and experimental knowledge as well as comprehension of newest design methods will help to manage the time pressure and enormous experimental efforts in daily project work.

AFTER THE COURSE EACH PARTICIPANT SHOULD BE

- » able to apply modern up- and down-stream processing and process design methods in their daily project work
- » familiar with handling of continuous membrane, extraction, precipitation and chromatography equipment
- » capable to evaluate platform-technologies and the consequences of the „Process Analytical Technology“ (PAT) initiative from „American Food and Drug Administration“ (FDA)
- » able to lay out experiments for design of membrane, extraction, distillation, crystallization/precipitation and chromatography processes
- » capable to perform a scale-transfer for unit operations into pilot and manufacturing processes
- » well informed about possibilities and limitations of process design and CBP unit operations by aid of simulation

PRESENTATION OF COURSE CONTENT

The content of the course will be presented in lectures with ample 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 into batch and continuous chromatography equipment will be provided to the participants in the laboratories.

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

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

TARGET GROUP

Scientists and laboratory technicians, involved in process development and/or manufacturing. Besides some basic knowledge in computer handling no previous knowledge will be assumed.

COURSE MATERIAL AND INFRASTRUCTURE

Each participant will be given at the beginning of the course a manual with all lectures. 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)
 N.N. (Sanofi-Genzyme) requested
 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

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