TU Clausthal

25 February – 1 March 2018
Clausthal-Zellerfeld | Germany

25 – 28 February 2018

DSP - Purification of Biomolecules

27 February – 1 March 2018

CBP-Continuous Bioprocessing of Biomolecules

Design and Scale-up by Laboratory Experiments and Process Simulation

Supported by

PDA
Parenteral Drug Association

SCHEDULE AT A GLANCE

25 – 28 February	**Downstream Processing (DSP)- Purification of Biomolecules**	**Training Course**
27 February – 1 March	**CBP-Continuous Bioprocessing of Biomolecules**	**Training Course**

For latest information, please visit: **pda.org/EU/**

TRAINING COURSE FACULTY

1 **Dr. R. Ditz,** *formerly Merck KGaA*
2 **Dr. K. Hudel,** *Christ*
3 **Dr. D. Melzner,** *Sartorius - invited*
4 **Dr. M. Munk,** *NNE Pharmaplan - invited*
5 **Dr. F. Oehme,** *Bayer Health Care GmbH*
6 **Dr. S. Schmitt ,***Parexel, representing PDA Europe*
7 **Dr. M. Schulte,** *Merck KGaA - invited*
8 **Prof. J .Strube and co-workers,** *TU Clausthal*

(subject to modifications)

Training & Education Program

europe.pda.org

PDA Education offers courses that are developed and taught by experts. They are uniquely targeted to professionals involved in the development and manufacturing of quality pharmaceutical and biopharmaceutical products.

Facts that Make a Difference

- Up-to date training courses and workshops taught by internationally renowned instructors
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Downstream Processing (DSP) - Purification of Biomolecules

Overview

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, hydro-phobic 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.

Who Should Attend:

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 provided 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.

Learning Objectives:

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

21 Aug 2017

Sunday, 25 February 2018

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

Monday, 26 February 2018 — 8:30 – 22:30

8:30	**Welcome and Introduction**
9:00	**Downstream Processing (DSP) Basics**
10:00	**Fundamentals Bio-Chromatography**
11:15	**Lunch**
12:00	**Institute, Guided Tour**
13:00	**Equipment and Plant Technology Chromatography**
13:45	**Liquid-Liquid-Extraction (LL-Extraction)**
14:30	**Precipitation**
15:30	**Experiments in the Laboratory** Part I (1-4 à 30 min.) Chromatography Screening, Method Optimization / Model Parameter Determination, Column Packing, Preparative / Scale-up
18:30	**Guided Tour: Mining Museum and Dinner**
22:30	**Return to Hotel "Pixhaier Mühle"**

Tuesday, 27 February 2018 — 8:30 – 24:00

8:30	**Introduction in Fundamentals of Modeling and Simulation Software**
9:15	**Experimental Model Parameter Determination**
10:15	**Membrane Technology**
11:15	**Lunch**
12:00	**Experiments in the Laboratory** Part II (5-9 à 30 min.) LL-Extraction, Membranes, Cryst. / Precip, Distillation, Lyophilization
16:30	**Guided Tour and Dinner in Goslar**
20:00 - 24:00	**Midnight Session at Hotel "Pixhauer Mühle": Simulation Tutorials Chromatography, Membrane, Crystallization/Precipitation, Extraction, Distillation**

Wednesday, 28 February 2018		8:30 – 15:00
8:30	Fundamentals Continuous Bio-Chromatography	
9:15	Design of ContiBioChrom	
10:15	GMP Regulatory Continuous Bioprocessing (CBP)	
11:15	Lunch	
12:00	Quality by Design (QbD) - Technology in Downstream Processing (DSP)	
12:45	Lyophilization	
13:30	CBP – Industrialization	
14:15	Process Analytical Technology (PAT) and Bioanalytics, Regulatory	
15:00	Discussion and Course End	

Attention:
These Agenda Topics overlap with CBP-Continuous Bioprocessing of Biomolecules Training Course

Modifications of the Program are possible.

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the leading global provider of science, technology and regulatory information and education for the bio/pharmaceutical industry.

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CBP-Continuous Bioprocessing of Biomolecules

Overview

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 downtimes 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 processrelated 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.

Who Should Attend:

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 provided 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.

Learning Objectives:

After the course each participant should be

- able to apply modern up- and Downstream 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

21 Aug 2017

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19:00	Check-In and Dinner in Restaurant "Pixhaier Mühle"
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13:30	CBP – Industrialization
14:15	Process Analytical Technology (PAT) and Bioanalytics, Regulatory
15:00	Discussion and Course End
19:00	Dinner Restaurant „Glück-auf"
21:00 - 24:00	Midnight Session at "Pixhaier-Mühle": Simulation Tutorials Batch and Conti-Biochromatography

Attention:
These Agenda Topics overlap with DSP - Purification of Biomolecules Training Course

Thursday, 1 March 2018 8:30 – 14:30

8:30	Continuous Bioprocessing (CBP) Fundamentals
9:15	CBP batch to conti – cost studies
10:15	Tutorial: CBP Total Process Studies
11:15	Lunch
12:00	Guided Tour Institute
13:00	Case study CBP for MABs
13:45	QbD studies
14:30	Course End and Discussion

Modifications of the Program are possible.

VENUE

Clausthal University of Technology
Institute for Separation and Process Technology
Leibnizstr. 15
38678 Clausthal-Zellerfeld
Germany
http://www.tu-clausthal.de/

DIRECTIONS

© Google For directions click on the picture, scan the QR-code or go to **https://goo.gl/maps/L98uW8CEuRy**

ACCOMMODATION

Waldhotel "Die Pixhaier Mühle"
An der Pixhaier Mühle 1
38678 Clausthal-Zellerfeld
Germany
http://www.pixhaier-muehle.de/
Tel.: +49 53 23 22 15

Transfers are offered

- from / to Göttingen ICE Main Station (on first Course Day on 18:00 and after Course End - transfer time about 60 min)
- in Clausthal between Hotel "Pixhaier Mühle" and course locations

In the Mensa of the University opportunity for lunch is given (self-pay basis).

SPONSOR

PDA Europe gGmbH
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13507 Berlin, Germany
Tel: +49 30 436 55 08-0
Fax: +49 30 436 55 08-66

CONTACT INFORMATION

Registration Customer Care
Tel: +49 30 436 55 08-10
registration-europe@pda.org

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DSP - Purification of Biomolecules
CBP-Continuous Bioprocessing of Biomolecules

25 February – 1 March 2018 | Clausthal-Zellerfeld | Germany

Supported by PDA Parenteral Drug Association

3 WAYS TO REGISTER

1 **ONLINE: pda.org**
2 **FAX: +49 30 436 55 08-66**
3 **EMAIL: registration-europe@pda.org**

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

☐ Mr. ☐ Ms. ☐ Dr. ☐ Nonmember ☐ **I want to become a PDA Member.** Please send me a subsription form

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Mailing Address

City Postal Code

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Business Phone Fax

☐ Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

2 Registration

No PDA membership included

All fees given in Euro and excluding VAT (7 %)

Training Course (25 – 28 February)
DSP - Purification of Biomolecules
All Participants ☐ **2495***

Training Course (27 February – 1 March)
CBP-Continuous Bioprocessing of Biomolecules
All Participants ☐ **1895***

* A 20% fee reduction is offered when both courses are booked.

Registration fees include accommodation with breakfast, dinner, course material and coffee-breaks with drinks and snacks.

3 Payment Options

☐ **By Credit Card** (one week prior to event)

☐ American Express ☐ MasterCard ☐ VISA

For your credit card information safety:
Please send your details by fax only (+49 30 436 55 08-66) or register online.

☐ **By Bank Transfer**

Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEDBBER
Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

☐ **By Purchase Order** Purchase Order Number

PDA Europe VAT I.D.: DE254459362

Billing Address: ☐ Same as contact information address above.
If not, please send your billing address to: **registration-europe@pda.org**

Your Company VAT I.D.:

This number starts by your country code with two characters
(example: PDA Europe's country code starts with: DE | followed by the number)

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **25 January 2018** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **registration-europe@pda.org or fax to +49 30 4365508-66. DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

2017 PDA EUROPE CONFERENCES

19 – 20 September	Pharmaceutical Freeze Drying Technology	* Cologne, Germany
26 – 27 September	Particles in Injectables	* Berlin, Germany
26 – 27 September	10th Workshop on Monoclonal Antibodies	* Berlin, Germany
10 – 11 October	Pharmaceutical Cold & Supply Chain Logistics	* Prague, Czech Republic
7– 8 November	The Universe of Pre-filled Syringes and Injection Devices	* Vienna, Austria
21 – 22 November	Outsourcing & Contract Manufacturing	* Munich, Germany

Subject to change | For latest info: **pda.org/pda-europe** | Shortlist 21 Aug 2017

*** Events with additional Education Program. More information – pda.org/pda-europe**

General Information
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