

2019 PDA EUROPE TRAINING

Accelerating Biomanufacturing by Modelling



15-18 SEPTEMBER 2019
CLAUSTHAL-ZELLERFELD, GERMANY
CLAUSTHAL UNIVERSITY
OF TECHNOLOGY

Innovative biologics, including cell therapeutics, VLPs, exosomes, recombinant proteins, peptides etc. seem to substitute monoclonal antibodies as the main therapeutic entities in manufacturing over the next decades. This molecular variety causes a growing need for a general change of methods as well as mindset in the process development stage as there are no platform processes available like for mabs.

Moreover, market competitiveness demands hyper-intensified processes, including accelerated decisions toward batch- or continuous operation of dedicated modular plant concepts. This indicates gaps in process comprehension, when operation windows need to be run at the edges of optimization.

In this training course potential methods are demonstrated for possible solutions throughout the workflow from process development over piloting towards manufacturing operation from process engineering point of view and experience. Especially, the state-of-art for modelling in biologics manufacturing is assessed, clarifying differences and application of statistical, rigorous physical-chemical based models as well as cost modelling. "Digital-twins" are described and efforts vs. benefits for new applications exemplified including the regulatory demanded QbD-(quality by design) and PAT-(process analytical technology)-approaches towards digitalization or industry 4.0 based on advanced process control strategies. Finally, an analysis of obstacles and possible solutions for any successful and efficient industrialization of innovative methods from process development over piloting towards manufacturing, operation, robustness, and analysis results in some recommendations. A central question is exemplified: Under the mindset of QbD and PAT demanded by authorities since 2004, could any biologics manufacturing process be regulatory approved without being modelled by a digital-twin as part of the filing documentation?

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.

Learning Objectives

Upon completion of the course participants will be

- able to apply modern Upstream and Downstream Processing and process design methods in the daily project work
- familiar with handling of fermentation, membrane, extraction, crystallization / precipitation, chromatography and lyophilization equipment
- able, to evaluate platform-technologies and the consequences of the 'Quality-by-Design'(QbD) approach incl. 'Process Analytical Technology' (PAT) initiative from 'American Food and Drug Administration' (FDA)
- in the position to propose experiments for design of USP and DSP unit operations
- able to make a scale-up transfer of total processes
- well informed about possibilities and limitations of process design of USP and DSP processes by aid of simulations

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.

Faculty

Jochen Strube, TU Clausthal

WELCOME TO CLAUSTHAL- ZELLERFELD



Sunday, 15 September 2019

19:00 Check-In and Dinner in Restaurant 'Pixhaier Mühle'

20:00 Networking Event: Oberharzer Wasserregal and Mining History

Monday, 16 September 2019

8:30 – 22:30

8:30 Welcome and Introduction

9:00 Introduction Biomanufacturing Modelling

10:00 Fermentation Modelling

11:15 Lunch Break

12:00 Institute - Guided Tour

13:00 Chromatography Modelling

13:45 Liquid-Liquid-Extraction (LL-Extraction) Modelling

14:30 Membranes Modeling

15:30 Experiments in the Laboratory
Part I: Fermentation, Membranes, Chromatography, LL-Extraction

18:30 Networking Event: Guided Tour Mining Museum and Dinner

22:30 Return to Hotel 'Pixhaier Mühle'

Tuesday, 17 September 2019

8:30 – 24:00

8:30 Introduction into Fundamentals of Modeling and Simulation Software

9:15 Experimental Model Parameter Determination

10:15 Crystallization/Precipitation Modelling

11:15 Lunch Break

12:00 Experiments in the Laboratory
Part II: Cryst./Precip, LL-Extraction, Lyophilization, PAT with PLS/PCA

16:30 Networking Event: Guided Tour and Dinner in Goslar

20:00 - 24:00 Midnight Session at Hotel 'Pixhauer Mühle':
Simulation Tutorials Fermentation, Chromatography, Membranes, Extraction, Lyophilization,
'Clausthaler-Mitternachtsschrei'

Wednesday, 18 September 2019

8:30 – 15:30

8:30 Fundamentals QbD and PAT

9:15 Cost Modelling

10:15 GMP Regulatory Continuous Bioprocessing (CBP)

11:15 Lunch Break

12:00 Quality by Design (QbD) - Technology in Total Process Design

12:45 Lyophilization

13:30 CBP-Industrialization

14:15 Process Analytical Technology (PAT) and Bioanalytics, Regulatory

15:00 Discussion, Q&A

15:30 End of Course

ACCOMMODATION – included in registration fee

Waldhotel 'Die Pixhaier Mühle'

An der Pixhaier Mühle 1

38678 Clausthal-Zellerfeld

Germany

<http://www.pixhaier-muehle.de/>

Tel.: +49 53 23 22 15

DIRECTIONS

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

VENUE

Clausthal University of Technology

Institute for Separation and Process Technology

Leibnizstr. 15

38678 Clausthal-Zellerfeld

Germany

<http://www.tu-clausthal.de/>

TRANSFERS

are offered (and organized by TU Clausthal)

- 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).

CONTACT INFORMATION

Registration Customer Care

Tel: + 49 30 436 55 08-10

registration-europe@pda.org



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3 WAYS TO REGISTER

- 1 online: pda.org/EU/eventname2019
- 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.

PDA Member ID Number

Name (Last, First, MI) _____

Job Title _____

Company _____ Department _____

Mailing Address _____

City _____ Postal Code _____

Country _____ Email _____

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.)

3 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).

3 Registration

All fees given in Euro, tax exempt in Germany

Training Course (15-18 September 2019)

All Participants 2750
 ACCOMMODATION – included in registration fee

Your consent is important. We manage your personal data responsibly.

For more information, please visit pda.org/privacy-policy

RESPONSE REQUIRED – By checking the box(es) below, I consent to:

- My contact information (name, company, job title, city, state, country) being printed on the attendee list distributed at the event.
- PDA recording and/or photographing me and using those recordings and/or photographs in future PDA promotional and marketing materials.
- PDA sending me promotional information via email.
- PDA sending me promotional information via post

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given.

4 Payment Options

By Credit Card

- 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): DEUTDE33HAN

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 **18 August 2019** 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 30 436 55 08-66.

PDA EUROPE EVENTS



2019

24 June 24 June 25-26 June	Workshop: The Digital Robot Pharma Fab Interest Group Meeting Quality Systems 4th PDA Europe Annual Meeting	Amsterdam, The Netherlands
2 September 2 September 3-4 September 5 September	Interest Group Meeting Freeze Drying Interest Group Meeting Technology Transfer BioManufacturing Interest Group Meeting Vaccines	★ Munich, Germany
2 September 5 September	Interest Group Meeting Technology Transfer Project Management in the Pharmaceutical Industry	★ Munich, Germany
24-25 September	Pharmaceutical Freeze Drying Technology	★ Berlin, Germany
24-25 September	Particles in Injectables	★ Berlin, Germany
21 October 21 October 21 October 22-23 October	Workshops: Innovating the Journey from Manufacturing to the Patient Innovative Drug Delivery Systems/Combination Products Impact of Pre-filled Syringe Components on Biopharmaceuticals The Universe of Pre-filled Syringes and Injection Devices	★ Gothenburg, Sweden
12-13 November 14 November	Pharma Logistics & Outsourced Operations Interest Group Meeting Supply Chain Management	★ Lisbon, Portugal

2020

25-26 February	Parenteral Packaging	★ Basel, Switzerland
21-22 April	Visual Inspection Forum	★ Berlin, Germany

Subject to change

For latest info: europa.pda.org

Shortlist 13 Jun 2019