

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

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 Midnight Session at Hotel “Pixhauer Mühle”: Simulation Tutorials Chromatography, Membrane, Crystallization/Precipitation, Extraction, Distillation

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24:00

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.