

[Curriculum]

für den Universitätslehrgang Protein Chromatography – Engineering Fundamentals and Measurements for Process Development and Scale up

(Kat. III mit 5 ECTS)

Datum (des Inkrafttretens): 01.07.2013

§ 1 Preamble

Chromatography is the most important unit operation in modern biopharmaceuticals manufacturing and also gains some significance in processing of renewable materials in the sector of high value products. Biopharmaceutical industry recruits its personnel mainly from the discipline of biology, molecular biology and biochemistry besides chemical and biochemical engineers. Basic chromatography and scale up is rarely instructed nowadays at universities, except in a few engineering institutions. There is a need for training of personnel in industry on the fundamentals and principles of chromatography including the engineering aspects.

The new initiative of Quality by Design in biopharmaceutical manufacturing requests a fundamental understanding of the process. Such process understanding is currently not available in a lot of companies manufacturing biopharmaceuticals. Thus deeper knowledge and intensified training in all the fields of bioprocess engineering will be required in future. BOKU has a strong mandate in bioengineering and one of its selling points is the engineering science and thus has an obligation for continued education in this area.

§ 2 Expectations and goals

We feel that the course provides the following benefits:

For the industrial participants:

- An introduction to the fundamental underpinnings of protein chromatography and to advanced laboratory equipment and techniques for process development and scale-up;
- The tools to understand and troubleshoot actual bio-manufacturing processes;
- Retraining of industrial separation scientists who have experience with small molecules but who are now challenged by large biomolecules;
- The background needed to implement Quality-by-Design (QbD), which is a critical component of FDA's efforts to improve the drug approval process, reduce costs and improve quality;
- Networking opportunities with other companies; and
- Motivation to pursue advanced studies by being immersed in thriving academic environments.

For the academic participants:

- An exposure to practical laboratory and manufacturing aspects of the biopharmaceutical industry;
- An understanding of the regulatory, economic, technological, and operational constraints affecting downstream process design and operation;
- The value of fundamentals in solving practical design problems;
- An exposure to teamwork in a highly multidisciplinary setting not commonly found in purely academic courses;
- An opportunity to learn how to present research results to a broad audience;
- Motivation to pursue careers in the biopharmaceutical industry; and
- Opportunities to network with industrial biotech.

Finally, for the graduate students involved as tutors:

- The opportunity to learn by teaching a multidisciplinary team;
- The development of team leadership skills;
- Motivation for their own research by gaining an understanding of its relevance to industrial practice;
- Motivation to pursue teaching careers; and
- A major professional service opportunity

§ 3 Course scheme

Protein Chromatography – Engineering Fundamentals and Measurements for Process Development and Scale up is designed a post graduate course in particular addressing industry and integrates theory, simple experiments, data processing guided evaluation and experiments and joint discussion of problems. The course consists of lectures, experiments, guided data evaluation and presentation of results. The course is planned for 5 ECTS. Course language is English.

§ 4 Cooperation partners

- University of Virginia, VA USA, Department of Chemical Engineering.
- GE Healthcare in Uppsala Sweden

(From University of Virginia, VA USA, Department of Chemical Engineering is the leading Person Prof. Giorgio Carta who is the second instructor is from the University course. He is a world leading expert in process chromatography and has also conducted the course for more than 10 years in Vienna, Austria and in Charlottesville VA, USA.

The GE Healthcare in Uppsala Sweden provides equipment for experiments)

§ 5 Course director

Course director is Prof. Alois Jungbauer from Department of Biotechnology. He is an expert in downstream processing of biopharmaceuticals and process chromatography.

§ 6 Duration and structure

Course duration is one week with a preparation time and a follow up. Lecture, practical experiments, evaluation of experiments and presentation of results are the core of the programme. The outline of the different modules is shown below.

The scope of the course is to provide insight in the application of chromatographic theory with special emphasis on mass transfer and dispersion.

The theory will cover the fundamentals, the sorption equilibria, modes of operation, types of chromatographic media, dynamics of chromatography, effects of dispersion and extra column effects. The experimental part will comprise pulse response experiments, dynamic binding capacity, shallow bed experiments, and linear gradient elutions. The experiments will be carried out with typical conventional porous media exhibiting different transport mechanisms.

Participants will be also trained in the pitfalls of peak fitting and evaluation of chromatographic data. Detailed course notes will be provided. At the end of the course a detailed protocol has to be worked out.

§ 7 Qualifications

The participants from biomanufacturing industry or supply industry must have at least bachelor's degree in biology, biochemistry, biochemical engineering or chemical engineering. Experience in process chromatography in industry is useful, but not mandatory. Participants

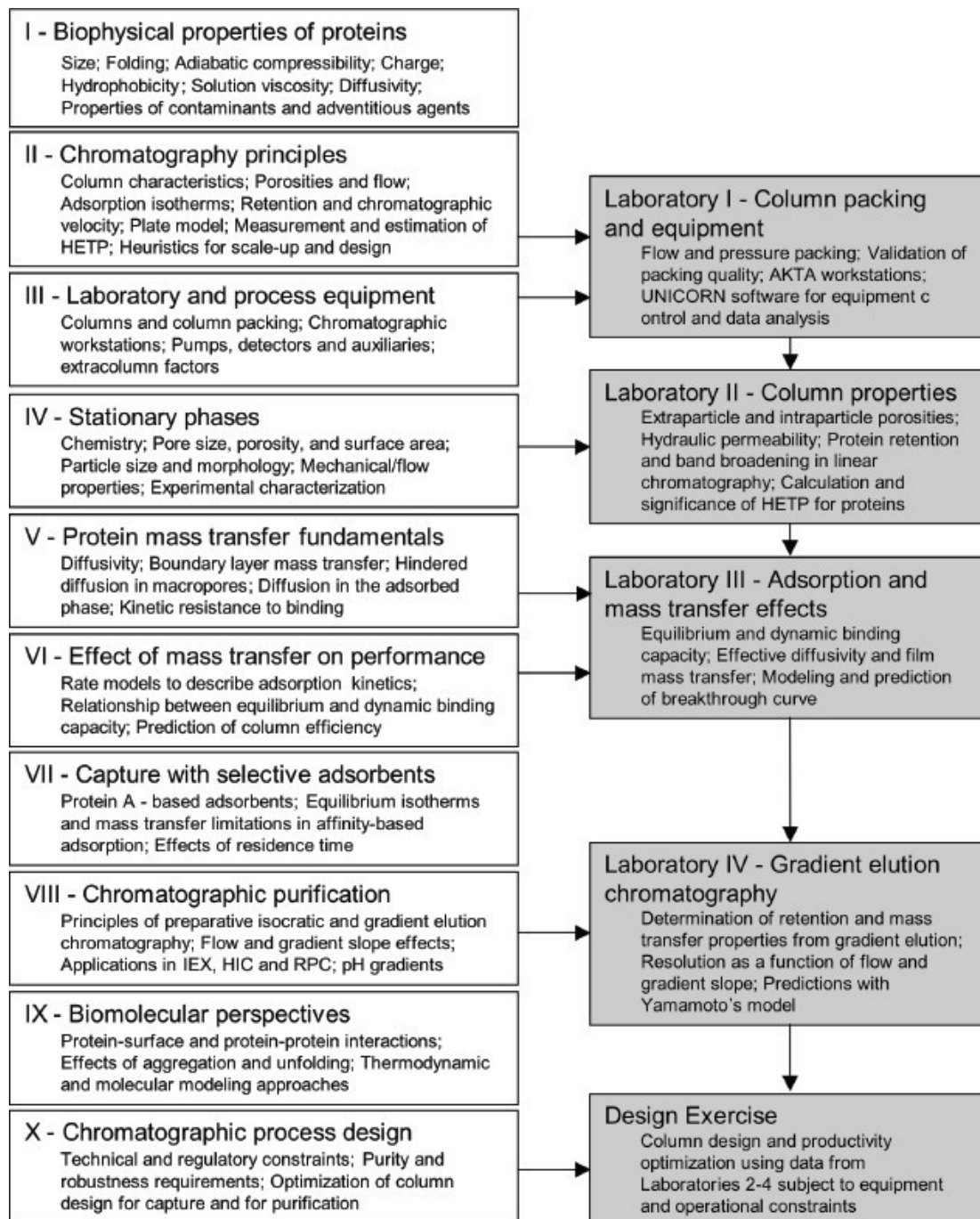
from academia must have at least a master's degree in in biology, biochemistry, biochemical engineering or chemical engineering.

§ 8 Number of participants

The number of participants is limited to 20.

§ 9 Curriculum

10 lectures, 4 laboratory practicals, 4 joint discussion of results from practicals and 1 design experiment are included in the course.



§ 10 Evaluation

A design exercise held in the last day of the course provides a further opportunity to strengthen conceptual and practical understanding of the factors that need to be considered to arrive at optimized designs that meet specified constraints. This is done again in a team setting with assistance from the tutors. The design exercise will be used to evaluate the participants.

§ 11 Evaluation of Course and Quality Assurance

A feedback form is distributed among the participants and evaluated. Actual feedback is also searched during the course and in particular during practicals. Participants are also encouraged to give feedback to the lecture notes, clarity of presentations and computer simulations.

§ 12 Completion of the course

After positive evaluation the participants will receive a certificate. It is expected that participants are present during the entire week.

§ 13 Course fee

A course fee has been calculated and agreed with the „Vizektor“ for finances.

§ 14 Venue

University of Natural Resources and Life Sciences Vienna, Department of Biotechnology,
Muthgasse 18, A-1190 Vienna, Austria

§ 15 Entry into force

This Regulation shall take effect on the first day of the month, following the announcement in the bulletin of the university.