Workshop on Advanced Methods in Bioprocess Development

June 10th/11th 2015, TU WIEN, Festsaal, Vienna, Austria

Problem statement and goals

The development of bioprocesses is still an empirical, tedious, time consuming cost intensive process. However, already a broad spectrum of mechanistic methods to enable fast and science-based process development are available. This aims to reduce failed batches and faster process approval as outlined by Professor Christoph Herwig, Vienna University of Technology.
An industrial perspective to the development of a CHO process

Christoph Clemens, Boehringer Ingelheim, Biberach presented an industrial perspective on bioprocess development and scale-up. For safe and robust scale-up of CHO processes, Boehringer Ingelheim applies FMEA and MVDA tools as well as fluid dynamic simulations.

Converting data to scalable information

The calculation of volumetric- and specific reaction rates forms the basis for advanced bioprocess analysis- and optimization approaches. The science-based formulation of material balances to calculate these important descriptors were outlined by Paul Kroll, Vienna University of Technology, and Thomas Zahel, Exputec Vienna.
Data handling and achieving reliability

Extracting knowledge from process data is challenging due to the non-linearity of data and the presence of outliers. Aydin Golabgir, Vienna University of Technology, outlined cutting edge strategies for outlier removal and achieving data reliability based on multivariate data analysis and advanced signal processing approaches.

Combing data to enhanced information & Case studies

Data quality has a high impact on process control quality. Christoph Herwig outlined the importance of data quality and presented methods how to convert low-quality process data to reliable, tested information that can be trusted.
Quality by Design, PAT & Case Studies

Quality by design has recently gathered strong momentum due to the successful Genentech/Roche full QbD submission. Professor Anurag Rathore, Department of Chemical Engineering, IIT Delhi outlined benefits and challenges of process development along QbD principles. The presentation initiated a high-class discussion of industrial experts on the topics design space validation and practical issues for putting QbD to practice.

Social Event

This year’s social event took place in a brewery close to castle Belvedere and brought together representatives from industry and academia to discuss advanced methods in bioprocess development and the industrial implementation of advanced methods.
**Physiological process control**

Physiological process parameters such as the specific substrate uptake rate stir process productivity and product quality. Wieland Reichelt, Vienna University of Technology, outlined novel strategies to control physiological parameters in microbial biopharmaceutical processes. Reichelt showed, show process productivity can be increased by using a feeding strategy that holds the specific uptake rate constant.

**Constraint-based rational experimental design**

Patrick Sagmeister, Exputec, Vienna outlined how dynamic methods, Design of Experiments and mechanistic modelling can be purposefully combined to develop platform knowledge and thereby an efficient manufacturing platform.
Downstream: Refolding, Filtration & Chromatography

Prof. Rathore outlined in three intensive sessions advanced design & scale up concepts for the unit operations refolding, filtration and chromatography. Plenty of industrial case studies provided the audience with a clear understanding of DSP design, scale-up and regulatory aspects. Once more the talk of Prof. Rathore was intensively discussed with contributions from industrial delegates.

Mechanistic modelling

Mechanistic models are key tools for process optimization, simulation and real-time process control. Sophia Ulonska and Paul Kroll described workflows that enable to build and verify mechanistic models. The discussion involving industrial experts centered on the topic how mechanistic models can be used within the regulatory submission of biopharmaceutical processes.
Technology Transfer

Denes Zalai, Gedeon Richter, Hungary, outlined an industrial perspective on technology transfer from academia to industry, small- to large scale as well as facility transfer. Furthermore, he presented an industrial success story on advanced process development approaches: He developed approaches to control the specific productivity in mAb processes. Based on this control approach, he showed that the quality attribute of a mAb product can be changed by controlling the specific productivity.