PRE-CONFERENCE SYMPOSIA SESSIONS

Topical symposium session - May 14, 10:00-11:30, Auditorium B

Data-driven approaches for cell culture process development

Alessandro Butté (ETH) and Christoph Freiberg (Genedata)

The development of production cell lines and optimal upstream processes has enormously been accelerated, amongst others, by introducing automation and parallelization such as the usage of scale-down bioreactor models and by applying more and more clone and product analytics methods. This symposium provides insights by experts from the biopharmaceutical industry about their ways of keeping track and analyzing the vast amounts of analytics data and process parameters and how their concepts look like to make data-driven decisions in the area of cell line and upstream process development. The presenters will illustrate their concepts with example case studies and will discuss about future outlooks and challenges on the use of data-driven approaches.

Topical symposium session - May 14, 10:00-11:30, Auditorium C

ESACT Frontiers session: Turning great ideas to commercial success: pathways, funding and …. luck?

Verena Lohr (Sanofi) and Emma Petiot (CPE Lyon)

This symposium will focus on approaches and strategies which can bring ideas to successful commercialisation, covering:

- The value of networks (as through the UK-based BioProNet) to define ideas, make connections and build confidence in concept.
- Translation of idea or initial product specification towards the basis for a commercial venture (licensed product, new company, product pipeline).
- Large company perspective and approaches in the processes of drug discovery, development and commercialization.

The session will build on case study experiences from experts, followed by a Q&A discussion session for active audience participation.

Topical symposium session - May 14, 12:00-13:30, Auditorium B

ACTIP/ESACT joint session: Advanced therapy medicinal products (ATMPs) – manufacturing, safety and regulatory aspects – examples from the industry

Luc Kupers (Sanofi) and Otto Merten (Genethon)

Viral vectors are extensively used as delivery systems for gene and cell therapies, oncotherapies and vectors for display or expression of antigens in different vaccination

strategies. Developments and optimisations in vectorology and cell culture technologies performed over many years have conducted to medium-large scale production of viral vectors allowing pre-clinical and clinical trials for therapeutic applications and finally to the arrival of the first gene therapy products on the market.

However, often animal cell culture technologists are not always informed on these advances and achievements because they are essentially presented and communicated at specialized scientific meetings or in specialized journals. The purpose of this symposium is to present an overview on mass production of viral vectors as well as on special achievements with respect to the use of AAV (adeno-associated viral) and retroviral vectors in clinical applications. Since the regulatory framework and safety aspects are of particular importance for the use of ATMPs, this issue will also be dealt with. The audience is invited to participate in the discussion on remaining challenges in the manufacturing, safety and regulatory aspects of ATMPs.

Merck Life Sciences sponsored symposium session - May 14, 12:00-13:30, Auditorium C

Cell culture media designed for intensified perfusion processes

Kevin Kollel (Merck Life Sciences)

Current market needs are driving the interest of the industry towards the application of intensified processes and continuous manufacturing. Most commonly intensified processes include the application of perfusion technology, which facilitates the accumulation of very high cell densities (>50 mio cells/mL) in the bioreactor. The accumulation of biomass can be applied as a scale up bioreactor or to increase volumetric productivity in the production bioreactor. The increased volumetric productivity allows using smaller bioreactors and consequently decreases the capital investment in a plant. However, in order to maintain high cell densities, cell culture media needs to be exchanged continuously and it is currently considered the highest expenditure in an upstream continuous process. Optimization of cell culture media that results in lower perfusion rates will drive the cost of the upstream process significantly down.

In this work, we applied an integrated design approach that includes nutritional fundamentals, design of experiments and multivariate analysis to formulate a new chemically defined perfusion medium. This perfusion medium was developed using multiple CHO cell lines and proteins to ensure broad spectrum applicability. In addition, this perfusion medium has been evaluated for several perfusion applications that include seed train bioreactor, steady state perfusion and other protein production modalities.

GE Healtcare sponsored symposium session - May 14, 14:00-15:30, Auditorium B

From research to clinic: intensify your cell culture process

Andreas Castan (GE Healtcare)

The journey from molecule discovery to manufacturing can be challenging and market success is heavily dependent on the swift creation of a high performing cell culture process. Cell culture scientists drive this success by striving for scalable, robust processes that reach target titres and deliver consistent protein profiles. They must also keep pace with accelerated development timelines, delivering a cost-effective solution to support a viable business case. During this session, seasoned experts will present case studies and share their insights into overcoming obstacles. We look forward to welcoming you to this interactive session and to share thoughts and experiences on your own journey from research to clinic.

Sartorius Stedim Biotech sponsored symposium session - May 14, 14:00-15:30, Auditorium C

Speed to clinic accelerating biopharmaceutical development

Miriam Monge and Joerg Weyand (Sartorius Stedim Biotech)

Bringing life-saving biopharmaceuticals to market as quickly as possible is the priority for many companies. The Sartorius Integrated Solutions team has assembled leading industry experts from the likes of Roche, Novartis and mAbXience to describe state-of-the-art methods for accelerating biopharmaceutical development and increasing speed to clinic. These presentations will be supplemented with customer case studies presented by Sartorius speakers.

During this symposium, you will learn how process characterization can be performed in micro-scale and benchtop bioreactors. We will describe practical tips for developing and implementing continuous and intensified bioprocesses platforms and we will illustrate this talk with a case study from Novartis describing how the firm implemented a perfusion process in 1000-L single-use bioreactors. Finally, you will see how working with a CRO can expedite the development of biosimilars ensuring they reach the clinic in the shortest time possible.

Topical workshop session - May 15, 19:00-20:30, Auditorium C

CHO genome workshop

Nicole Borth (BOKU University), Mike Betenbaugh (Johns Hopkins University) and Kelvin H Lee (University of Delaware)

Over the last few years, a surge of community efforts have generated significant amounts of publicly available genome scale information for scientists and industrialists working with Chinese Hamster Ovary cells. There are now two Chinese Hamster genomes available and more than 10 genome sequences for a variety of CHO cell lines. Both the CHO-K1 sequence and the Chinese Hamster genome are part of the RefSeq program and receive regular annotation updates. Tools available for systems biology research include www.CHOgenome.org as the single direct entry point to all CHO related information, a genome browser, a proteome database, a community generated consensus genome scale metabolic reconstruction and a CHOmine. In addition, with contributions from the scientific community and industry, a new reference genome of the Chinese Hamster was generated using PacBio sequencing, to overcome the drawbacks of the available, Illumina-based reference draft genomes (large number of contigs and scaffolds, high percentage of NNNs, some genes split across scaffolds/contigs, difficult to assemble repetitive sequences). The recently completed reference genome based on both the PacBio and the Illumina sequences is of much better quality than the previous version and boasts an N90 of 122 scaffolds and less than 0.2% NNNs. To celebrate its completion we plan to present in this workshop presentations on all systems biology applications and tools that will enhance our understanding and control of CHO cells as production vehicles for biopharmaceutics.