ESACT 2019 Scientific Session Descriptions

1. Cell Engineering, novel technologies and the use of omics
Session chairs: Helene Faustrup Kildegaard, Kerstin Otte

Key words: New designed animal cell lines, genetic engineering, metabolic engineering for desired process performance, mode of action and product quality

Session description: Animal cells are essential for efficient and controllable production of life-saving therapeutics including biopharmaceuticals, viral vaccines, regenerative medicines and cell therapies. Synthetic biology and genomics have already advanced cell line engineering and development and presently, the power of emerging analytical technologies enables generation of enormous amounts of data from cell populations and single cells. Appropriate data handling and interpretation is still challenging but offers potential of innovative step-changes for optimized engineering of cells. This session will focus on emerging technologies used to study, modify or select cells for recombinant cell generation while improving our understanding of the basic biology of protein expression and cell behavior. Topics of interest may include vector design, codon optimization, genome engineering and editing tools, synthetic circuits, bio-sensors, host cell selection, clone characterization and screening, clonal variation, clonality, omics- and large scale-data generation, high-throughput technologies, bioinformatics analysis and predictions.

2. Use of viral- and non-viral vectors for generating new therapeutic products and vaccines
Session chairs: Christian Claussen, Scott Estes

Key words: Cell-based vaccines, gene therapy, oncolytic viruses, delivery technologies, industrialization and scale-up

Session description: With only a handful of approved products but hundreds of ongoing clinical trials, the gene therapy field has gained considerable momentum. Likewise, interest in cell-based production of vaccines is growing for various indications. However, as emerging and rapid evolving modalities, both fields routinely encounter many technical obstacles that need to be overcome for the full potential of both to be realized into a broad range of therapeutic products capable of serving large patient populations. These include developing more efficient and automated scalable manufacturing processes to improved delivery and safety. In this session we explore advances made with both viral and non-viral gene therapy platforms as well as central advances when developing cell-based vaccines that begin to address these significant challenges.

3. Development of cell-based technologies and therapeutics
Session chairs: Paula Alves, Malin Parmer

Key words: Cellular engineering, scale-up methods, personalized medicine, stem cell therapy, immunotherapeutic approaches, CAR-T.

Session description: The field of cell therapy has advanced rapidly from promising clinical data to commercially approved products. As cell therapies encompass patient-specific to off-the-shelf products their manufacturing requirements are highly diverse and face major challenges impacting quality, safety and cost.

This session chairs invite abstract submissions in topics covering major trends for development of product platforms for novel cell therapeutics (e.g. hESC, iPSCs, T-Cells – CAR-T, TIL) from both academic and industrial perspectives, covering: 1) Upstream processing technologies from starting materials, cell selection, batch to batch consistency to bioreactors, disposable technology, scale-up/scale out, xeno-free culture media; 2) Downstream processes and novel bioprocess formats including cell separation, continuous/closed cell therapy products processing, automation, integrated USP and DSP, formulation, cryopreservation and point of care handling and 3) New developments in analytics to determine impact of process parameters on product critical quality attributes and development of better assays predictive of product potency enlarging to 3D cell-based assays, used also in drug discovery.

4. Cell culture process controls and analytics
Session chairs: Adrian Haines, Matthieu Stettler

Key words: Novel analytical methods, on-line monitoring tools, PAT, data feedback loops, real-time release

Session description: Animal cell technology products are expected to match very high quality and consistency standards. The product can be molecules or viruses produced by the cells or the cells themselves. The impact of performance of cell culture processes on product quality is investigated throughout all stages of process development from early clinical phases to process performance qualification for commercial operations. Innovative control elements and analytical tools are being developed to match the expected standards and to provide rapid and cost effective analyses and control of cultures and product quality. The focus of this session is to highlight and explore the technologies which are being developed to achieve this purpose. Aspects considered under this topic may include: process analytical technologies, state of the art analytics to confirm that cells/cellular process are controlled, and product quality is maintained, predictive models for cell culture applications, novel methods for monitoring and controlling cellular process on-line / at-line, multi-attribute analytical methods, on-line monitoring, real time release, next generation sequencing for in-process control

5. Cell culture process engineering, product quality and integration with downstream processing
Session chairs: Alan Dickson, Verena Lohr, Thomas Ryll

Key words: Media and feed strategies, fedbatch/perfusion strategies, continuous processing, process-controlled product quality

Session description: This session invites contributions focused on (1) areas associated with cell culture-based production technology, (2) holistic views linked to integration between upstream and downstream operations to develop efficient drug substance processes and (3) delivery of consistent product quality and yield. Proof of concept and/or troubleshooting studies that present significant novelty and uniqueness to serve as a role model for others are invited. Contributions are specifically encouraged on: Product quality modulation through integration of upstream and downstream processes; Media and feeding approaches to foster high cell mass, high productivity and consistent product quality; Aspects around fed-batch improvements, combination of fed-batch and perfusion technology and continuous production strategies; High volumetric productivity approaches, reaching beyond 2 g/L/d in a scale-able process format (pilot and production scales); Continuous process integration within downstream processing; Field reports from production processes of novel modalities and complex antibody formats. Contributions that offer real-world applications, exemplifying use in GMP manufacture, will be given priority.