Registration

BIOMANUFACTURING CONGRESS

Conference Room 4

Oxford Global Welcome Address

Chairperson's Opening Address

Keynote Address: Title TBA

OTMANE BOUSSIF, Global Head Cell & Gene Therapy Technical R&D,
Novartis

STREAM 5: CELL & GENE THERAPY BIOMANUFACTURING: INSIGHTS, KEY STRATEGIES & NOVEL APPROACHES

Stream Keynote Address:
Analytical Development For Cell & Gene Therapies (Title TBA)

KATHARINE A. MILLER, Vice President, Analytical Operations,
Orchard Therapeutics

Solution Provider Presentation

SPEAKER, Senior Representative,
Miltenyi Biotec

STREAM 6: UPSTREAM PROCESSING, SMART FACTORIES, DIGITALISATION, TOOLS & TECHNOLOGIES

Stream Keynote Address:
Upstream Process Transfer For Cell Culture

JOACHIM BÄR, Director, Cell Culture Development, Head of Process Transfer Upstream,
Boehringer Ingelheim

Morning Coffee & Refreshments, One to One Meetings x4, Poster Presentation Sessions

Biomanufacturing in Cell Therapy – Turning Innovative Science into Value For Patients

- Building cell therapy medicine foundation based initially on ophthalmology throughout value chain
- Leveraging current and future technologies and expertise to solve manufacturing scale and logistics challenges
- Understand and implement PSC-derived business model driving the most flexible and scalable product framework

JOSEPH LANING, Senior Director, Cell Manufacturing Operations,
Astellas

Bioreactor Selection For Large-Scale Cell Production

STEFFEN KREYE, Head of Lab, Upstream Process Development,
Bayer

Off-The-Shelf Cell-Based Cancer Immunotherapy

- Developing First-of-kind Cell Products using Clonal Master iPSC Lines
- Fate is pioneering a revolutionary approach to cell therapy – we use renewable master induced pluripotent stem cell (iPSC) lines generated from our proprietary iPSC platform to derive cell therapy product candidates that can be delivered off-the-shelf for the treatment of a large number of patients.
- Our cell therapy product candidate pipeline is comprised of immuno-oncology programs, including off-the-shelf NK- and T-cell product candidates derived from master iPSC lines
- Discuss challenges in cell culture scale up for allogeneic cell therapies with iPSC technology

RICHARD ANDERSON, Senior Director, MSAT,
Fate Therapeutics

Stress Factors For Biologicals In The Drug Product Manufacturing - Its Impact On Product Quality And Control Strategy

- Hold times for drug substance and drug product
- Process characterization studies

MARTINA RÖHM, Associate Director, Formulation & Process Development Late Stage, **Boehringer Ingelheim**

Solution Provider Presentation

Solution Provider Presentation

Lunch, One To One Meetings x3, Poster Presentation Sessions

STREAM 5: CELL & GENE THERAPY BIOMANUFACTURING: INSIGHTS, KEY STRATEGIES & NOVEL APPROACHES

Transforming Cell Therapy Product And Manufacturing Concepts With Gene Editing

- Lessons learned in manufacturing and clinical experience with allogeneic "off-the-shelf" CAR-T cell product candidates
- Process and manufacturing concepts for gene-edited cell therapies
- Going to the next level with gene-editing: industrializing designer cell therapies

TBA, Director,
Cellectis

A Swiss Timepiece: How To Build A Cell Therapy Manufacturing Site In 12 Months

- How to build
- Who to hire
- How to train cell processing associates

SIMONE STEINER, Production Unit Head, Cell & Gene Therapy,
Novartis

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Analytical Influence On Commercial Manufacture Of Autologous Gene Therapies

- Highlights the challenges and risks faced with current QC analytics and the direct impact on commercial price
- Highlights the impact on manufacturing logistics of Autologous gene therapies
- Discusses possible solutions to resolve these issues for commercialisation of Autologous gene therapies.

CHAMINDA SALGADO, Scientific Leader, Cell & Gene Therapy Platform CMC,
GlaxoSmithKline

Analytical Approaches For The Characterisation Of AAV Vectors

- Process manufacturing and Quality Control of AAV vectors
- VG titers- qPCR vs ddPCR
- Evaluation of genome integrity with 2D ddPCR

FABIEN DORANGE, Head of Analytical Development,
Genethon

Upscale Bioprocessing

- •Challenges in implementing a PAT strategy for complex upstream bioprocesses
- •Multivariate characterisation of cell biology during manufacture
- •Data analysis and modelling approaches
- •Real-time monitoring of lentiviral vector manufacture

MARC-OLIVIER BARADEZ, Senior Lead Scientist,
Cell and Gene Therapy Catapult

STREAM 6: UPSTREAM PROCESSING, SMART FACTORIES, DIGITALISATION, TOOLS & TECHNOLOGIES

HCP Analysis By LCMS To Support Process Development Of Biologics

- Removal of residual host cell proteins (HCPs) is a crucial step in the development of high-quality biopharmaceuticals
- The standard method for HCP detection is ELISA which is usually not capable to identify and quantify single HCPs
- Therefore, LC-MS-based methods capable of detecting and quantifying individual HCPs are becoming increasingly important for process design and testing of final drug substance
- Here, we present a platform approach for CHO and E.coli derived products to identify and relatively quantify HCPs during downstream processing and in the final drug substance

MICHAEL FUCHS, Principal Scientist,
Novartis

The Systematic Study Of The Large-Scale Fermentation Rnvironment Using A Two-Compartment Scaled-Down Model: A Study In The Development Of A Cadaverine Bioprocess

- Understanding the challenges of mimicking the large-scale fermenter environment
- Important scale-down models used in bioprocess development will be highlighted

WILLIAMS OLUGHU, Principal Scientist,
Ipsen

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Synthetic And Systems Biology Based Strategies For Cell Factory Design

DAVID C. JAMES, Professor of Chemical & Biological Engineering,
Unviersity of Sheffield

Characterisation And Scale Translation Of A Parallel Mini-Bioreactor System (microMatrix) For Cell Culture Process Development

FRANK BAGANZ, Associate Professor, Biochemical Engineering,
University College London

Delegates are Welcome to Attend the Co-Located Sessions

Afternoon Coffee & Refreshments, One To One Meetings x3, Poster Presentation Sessions

Networking Drinks & End Of Day One

BIOMANUFACTURING CONGRESS

Keynote Address: Developing, Qualifying And Validating Analytical Methods For Novel Biologics

The presentation will cover the analytical strategies deployed for the characterization of novel biologics (mainly bispecific antibodies) and the analytical approaches taken for release, stability and characterisation.

DECLAN LOWNEY, Associate Director, Late Development Portfolio and Stability Science, Large Molecule Analytical Development,
Janssen

STREAM 4: ADVANCES IN BIOLOGICS MANUFACTURING, CMC & CONTINUOUS BIOMANUFACTURING

Stream Keynote Address:
Shifting Biomanufacturing From Exploratory Research To Implementation And Scale-Up

JESSICA BARTLEY, External Site Operations Lead,
Servier

Solution Provider Presentation

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Development & Manufacture Of A New bbmAb

- Bivalent IgG1 like bispecific format with no engineering in the variable domains
- One of the parental antibodies contains a lambda and the other a kappa light chain and both have hetero-dimerization mutations in the Fc part
- The presented bispecific is targeting two major inflammasome effectors IL-1β and IL-18

MICHAEL BARDROFF, Associate Director NBC Project Management,
Novartis

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Breakthrough Therapy Means No Break For CMC

CHONGHUI GUI, Head of CMC,
Agios Pharmaceuticals

STREAM 5.1: DOWNSTREAM PROCESSING: RECENT TECHNOLOGICAL ADVANCEMENTS, AUTOMATION AND LATEST TRENDS

Stream Keynote Address:
Control Strategy At The Interface Of Drug Substance To Drug Product

- Controls and control strategy on the interface drug substance drug product
- Challenges on the interface DS/DP especially if DS QA´s have and impact on DP and also the read out of the analysis is on DP level
- 3 showcases to demonstrate the bullets above

UWE DEMELBAUER, Head of DS Process Development,
Novartis

Solution Provider Presentation

ADVANCED INSTRUMENTS

Morning Coffee & Refreshments, One To One Meetings x3, Poster Presentation Sessions

Process Development And cGMP Manufacture Of Nature's Most Potent Toxins

- Introduction to botulinum toxin therapeutics; A wonder of nature but manufacturing challenge
- Case Study
- Opportunities and Future Manufacturing Strategie

PHIL MARKS, Bioprocess Engineering Manager,
Ipsen

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Lunch, One To One Meetings x3, Poster Presentation Sessions

STREAM 4: ADVANCES IN BIOLOGICS MANUFACTURING, CMC & CONTINUOUS BIOMANUFACTURING

Differentiated Product Concepts Of Biopharmaceuticals Through Innovative Formulation Approaches

- Product differentiation is essential to succeed in competitive markets
- Formulation and smart devices are key to product differentiation
- Novel approaches to formulation enable superior product characteristics
- Exploiting unique characteristics of excipients in formulation design

JAN JEZEK, Chief Scientific Officer,
Arecor

STREAM 4: ADVANCES IN BIOLOGICS MANUFACTURING, CMC & CONTINUOUS BIOMANUFACTURING

Metabolomics – A Promising Tool Analyzing Subcellular States To Optimize Antibody Formation With CHO Cells

- Compartment-specific metabolomics
- Identification of mitochondrial shuttle activities
- Correlation between maximizing antibody formation, ATP formation and shuttle activities

RALF TAKORS, Professor & Director of Biochemical Engineering,
University of Stuttgart

Impedance Spectroscopy: Recent Developments As A Process Analytical Technology For Pharmaceutical Freeze-Drying

- An introduction to Through Vial Impedance Spectroscopy (TVIS)
- TVIS applications for the In situ determination of critical process parameters

GEOFF SMITH, Professor of Pharmaceutical Process Analytical Technology,
De Montfort University

Afternoon Coffee & Refreshments, Poster Presentation Sessions

Separation Of Fine Chemicals, Pharmaceuticals And Biomolecules By Chromatographic And Absorption Processes

JOSÉ PAULO MOTA, Professor of Chemical & Biochemical Engineering,
Nova Universidade Lisboa

Continuous Flow Production Of High Value Isoprenoids Using Engineered S. Cerevisiae

- De novo pathways to bypass cell regulation
- Using engineered consortiums to divide pathways in a continuous way
- Incorporating in situ product recovery tools

J LEONARDO SOLIS, Assistant Professor,
University of Edinburgh

End Of Conference