Global Engage

2ND GLOBAL BIOPROCESSING, BIOANALYTICS & ATMP MANUFACTURING CONGRESS

DUBLIN, IRELAND

20-21 May 2019

#BioprocessingCongress

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WARM WELCOME

Global Engage

Global Engage is pleased to announce the **2nd Global Bioprocessing, Bioanalytics and ATMP Manufacturing Congress**, due to be held on 20th-21st May 2019 in Dublin, Ireland. Building upon the success of last year's meeting, this conference will once again provide an interactive networking forum for bioprocessing experts to examine the novel solutions and strategies that will improve the efficiency of biotherapeutic development.

Biopharmaceutical drug production has seen unparalleled growth in recent years and is now a core element of the pharmaceutical industry. However, there are still several bottlenecks within the manufacturing process, which need to be overcome. With complex biotherapeutics and advanced therapies showing huge potential for the future of medicine, new technologies and strategies are needed to produce these drugs efficiently whilst maintaining the high quality and standards required for them to enter the market.

Not only shall this meeting look at the manufacturing processes and regulatory challenges for biologics, the congress shall also feature a track dedicated to the complex manufacturing of cell and gene therapies. Attracting experts working in all areas of bioprocessing and process analytics, including cell line development, single-use technologies, continuous processing, automated systems, real-time monitoring, CMC/GMP practices, QbD strategies, purification optimisation, scale-down models and effective scale-up strategies, this conference will examine the latest developments in the technologies and methods used for biopharmaceutical production.

With a vibrant exhibition hall full of solution providers, showcasing their latest technologies and services, and a 30-strong speaker faculty comprising of individual presentations, roundtable sessions and senior-level panel discussions, this year's meeting will provide the opportunity to discuss current manufacturing and analytical challenges.

EXPERT SPEAKERS INCLUDE:

RAHUL SINGHVI
Chief Operating Officer, Global Vaccine Business Unit, Takeda Pharmaceutical Company Limited

DOMINIC CAROLAN
CEO, National Institute for Bioprocessing Research and Training (NIBRT), Ireland

CHRISTOPH HERWIG
Professor and Head, Research Division of Biochemical Engineering, TU Wien, Austria

CHARLOTTE MASY
Project Manager, Global Technical Support, GSK Vaccines

DAY 1

TRACK 1

Next-Generation Technologies

- Industry 4.0 and smart factories
- Single use technologies; the future of bioprocessing?
- Integrated continuous biomanufacturing
  - Technological developments
  - Continuous versus batch fed methods
  - High-throughput methods
  - Modular design possibilities
- Automation technologies and their applications
- Process modelling and analytics technologies
- Real-time monitoring and sensors

TRACK 2A

Upstream Method Development

- Cell culture modalities and choosing the right medium
- Microbial vs mammalian expression systems
- Cell line development and optimisation
- Intensified perfusion processes

TRACK 2B

Purification and Recovery Methods

- Tech transfer and scale up
- Improving purification and recovery methods: chromatography, centrifugation, filtration
- Process intensification methods
- Overcoming limited capacity in downstream development

DAY 2

TRACK 1

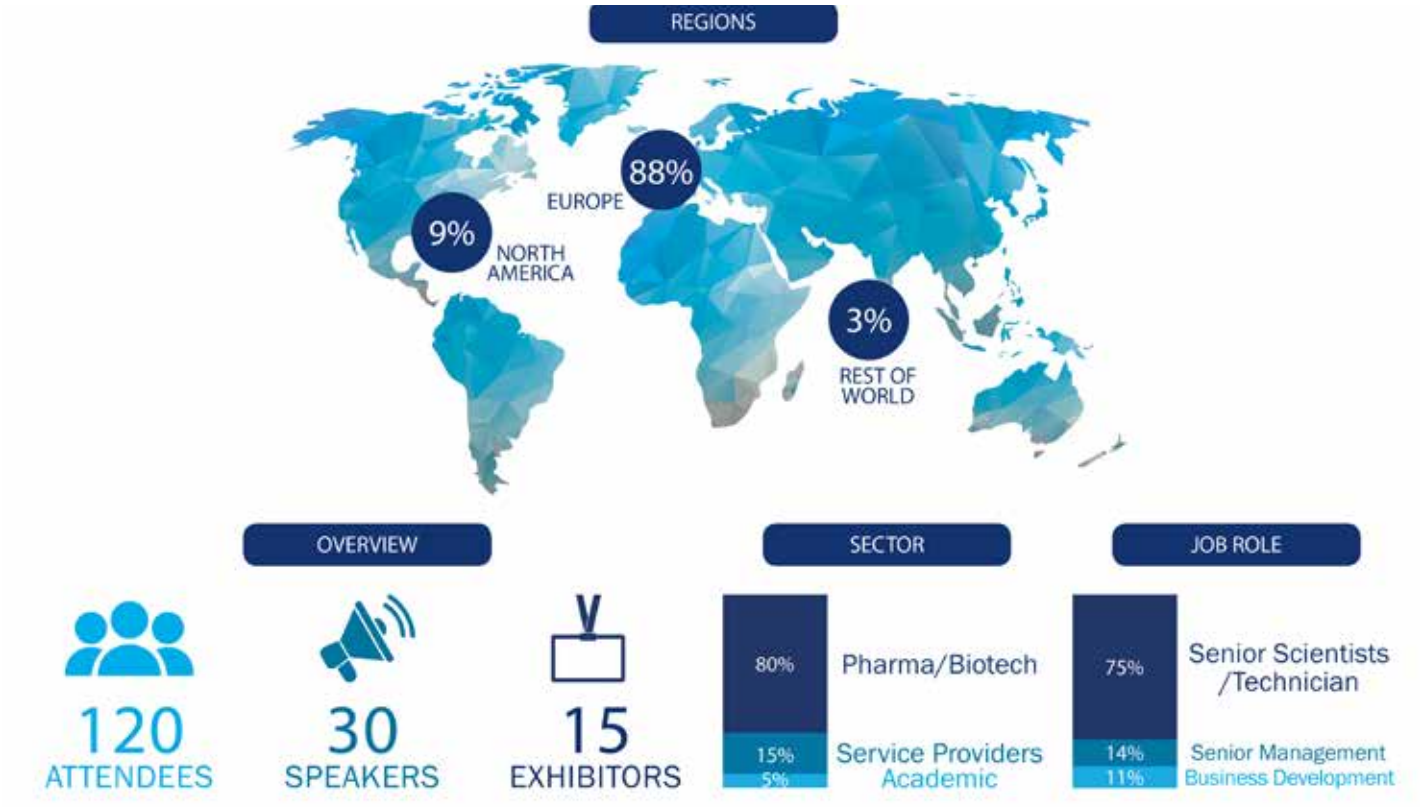
Manufacturing Cell and Gene Therapies

- Overcoming the regulatory challenges of ATMP manufacturing
- Analytical characterisation; process development, comparability assessments and stability testing
- CRISPR technology and other gene editing approaches
- AAV and lentiviral process development
- Quality control and CQA
- Autologous and allogenic products
- The need for closed, automated systems; upstream and downstream challenges
- **Panel Discussion:** Assay development and the challenge of characterisation for cell and gene therapies

TRACK 2

Quality Control, Analytics, and the Regulatory Landscape

- DOE and QbD strategies
- Process validation and the importance of prior knowledge
- Meeting GMP, PAT and CMC guidelines
- Protein characterisation and monitoring
- Bioassays and the determination of biological activity
- Data management and analysis
- Glycosylation and the introduction of mass spectrometry in the QC laboratory
- Outsourcing challenges
- Biosimilarity and comparability assessment
- Change control and analytical method transfer



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RAHUL SINGHVI
Chief Operating Officer, Global Vaccine Business Unit, Takeda Pharmaceutical Company Limited

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CEO, National Institute for Bioprocessing Research and Training (NIBRT), Ireland

JONATHAN CARTOUX
Field Application Engineer Life Sciences EMEA, Entegris

CHARLOTTE MASY
Project Manager, Global Technical Support, GSK Vaccines

RENATE KUNERT
University Professor, Department of Biotechnology, University of Natural Resources and Life Sciences, Austria

KIRSTEN STRAHLENDORF
Senior Scientist, BioProcess R&D Formulation and Stability, Sanofi Pasteur

SIAN RICHARDSON
Scientist, Ipsen

CHRISTOPH HERWIG
Professor and Head, Research Division of Biochemical Engineering, TU Wien, Austria

DENIS DECUBBER
Chairman Board of Directors, SalamanderU

CHRISTOPHER WILSON
DSP Expert, Ipsen

JENS LOHRMANN
Disease Area, Head Oncology, Technical R&D, Novartis

PIERRE MORETTI
Head of Process Development – Early Stage, Biopharma, GMS Development and Launch, Biotech Process Sciences, Merck Serono

CATHRINA HOULIHAN
Site Control Strategy Lead, New Product Industrialisation & Devices (NPID), Sanofi

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ROMAIN LE DEUN
GRA -CMC Senior Manager, Merck

STEWART CRAIG
Chief Manufacturing Officer, Orchard Therapeutics

PETR OBRDLIK
Technical Development New Biologic Entities, Analytical Dev., Novartis

KURTIS EPP
Senior Director, Process Development and Breakthrough Technologies CSL Behring

CORNÉ STROOP
Director Biologics & Vaccine Analysis, MSD

PAULINE RUDD
Professor and Principal Investigator, National Institute for Bioprocessing Research and Training (NIBRT), Ireland and Visiting investigator, Bioprocessing Technology Institute, A*Star, Singapore

HANI EL-SABBAHY
Biopharmaceutical Application Engineering Specialist, 3M Separation and Purification Sciences Division

STEPHEN LOCK
Marketing and Market Development Manager, SCIEX, CE EMEAI

PHILIPP AMSLER
Principal Scientist, Novartis

ALI ABUSNINA
Data Scientist, BI X Digital Lab, Boehringer Ingelheim

GARETH ALFORD
Engineering Lead, GSK

WENDY VAN EGMOND-DE WIT (Chair)
Manager QC, Janssen

CHAMINDA SALGADO
Scientific Leader, GSK

SÉBASTIEN DE BOURNONVILLE (Chair)
PhD Researcher at KU Leuven and Co-Founder, MyCellHub, Belgium

SENIOR REPRESENTATIVE
CPI

SENIOR REPRESENTATIVE
Avitide

08:00-08:50 Registration & Refreshments

08:50-09:00 **Global Engage Welcome Address and Morning Chair's Opening Remarks:** **Wendy van Egmond-de Wit,** Manager QC, Janssen

09:00-09:40

KEYNOTE ADDRESS:
RAHUL SINGHVI

Chief Operating Officer, Global Vaccine Business Unit, Takeda Pharmaceutical Company Limited

Challenges and Opportunities in Development of Innovative Vaccines for the 21st Century

Recent outbreaks of H1N1 influenza, Dengue, Chikungunya, SARS, MERS and Ebola are constant reminders of the threat of emerging infectious diseases to human life and the world economy. Vaccines can serve as an important defense against these threats, but development of innovative vaccines is complex, time consuming and expensive. This has led to consolidation of innovative vaccine players within the global pharmaceutical industry. In parallel, increasing demand for basic childhood vaccines, driven by supranational organizations such as UNICEF, PAHO and GAVI, has spurred growth of the vaccine industry within emerging economies. These trends are leading to partnerships between innovative multinational companies and developing country vaccine manufacturers, with the promise of greater output of innovative vaccines at affordable prices. These opportunities and associated challenges will be discussed in this presentation.

09:40-10:20

KEYNOTE ADDRESS:
DOMINIC CAROLAN

CEO, National Institute for Bioprocessing Research and Training (NIBRT), Ireland

Talent requirements for the next generation Biopharma workforce

- Changes that the new modalities are bringing to Biologics manufacturing.
- What this means for sourcing next generation talent.
- Brief NIBRT overview and solutions that work.

10:20-10:50

JONATHAN CARTOUX

Field Application Engineer Life Sciences EMEA, Entegriscation Engineer Life Sciences EMEA, Entegris

Preventing Single-Use Bag Failures in Frozen Applications Through Polymer Science

This presentation will discuss the unique characteristics that polymers bring to single-use bioprocessing applications. Included will be polymeric material performance data demonstrating toughness, purity, chemical resistance, gamma stability and cold temperature capabilities of single-use polymers along with guidance on how to leverage fluoropolymers to eliminate bag failures in frozen applications.

10:50-12:00 Morning Refreshments / One-to-One Meetings

TRACK 1: NEXT-GENERATION TECHNOLOGIES

12:00-12:30

CHARLOTTE MASY

Project Manager, Global Technical Support, GSK Vaccines

Implementation of single use systems in the closing of a sterile process

Some vaccines are sterile process from the very beginning of the upstream process. They are challenging for the introduction of Single Use Systems. The revamping of an upstream sterile process will be presented. This revamping includes closing of process, automation of some process step with the use of sensors. Challenges will be highlighted together with the solutions. Benefits of such a project will also be explained.

12:30-13:00

KIRSTEN STRAHLENDORF

Senior Scientist, BioProcess R&D Formulation and Stability, Sanofi Pasteur

Automation of Vaccine Formulations using Process Analytical Technology

Traditionally, vaccine formulation operations have been manual, which can lead to time-consuming individual tasks, lack of control, and hand-written data entry. This presentation will review the design and implementation aspects of an automated process to manufacture multi-component vaccines in a closed, single-use arrangement.

TRACK 2A: UPSTREAM METHOD DEVELOPMENT

12:00-12:30

RENATE KUNERT

University Professor, Department of Biotechnology, University of Natural Resources and Life Sciences, Austria

DoE-supported media formulations in high-density perfusion processes

Cell culture perfusion is among the most ambitious modes of running a bioprocess since cell concentrations exceed even 1x108 c/ml. At such high cell densities, the most challenging process parameters are the aeration of the culture and the feed supply. To provide the best culture medium for individual perfusion processes we apply a two-step DoE-supported screening of medium supplements in small-scale SpinTube bioreactors. In first batch experiments, we screen a distinct number of Cell Boost feeds to find an optimal combination in the chosen basal medium. This feed combination is used in a second DoE approach to fine-tune the spike concentration in so-called pseudo-perfusion cultures with daily medium exchange. Finally, the results of the small-scale experiment are transferred to a 500 ml bioreactor perfusion run

12:30-13:00

SIAN RICHARDSON

Scientist, Ipsen

Upstream process development of novel highly potent therapeutics: challenges and opportunities for development and clinical manufacture

Botulinum neurotoxin (BoNT), produced by Clostridium botulinum, is an effective treatment for several movement disorders. An increased understanding of the structure-function relationship of BoNT molecules provides opportunities to engineer recombinant (r) BoNTs with unique pharmacologic properties and therapeutic applications. This presentation describes the challenges and opportunities associated with process development and GMP manufacture for highly potent rBoNT products.

13:00-13:30

SENIOR REPRESENTATIVE
CPI
Title TBC

13:00-13:30

SENIOR REPRESENTATIVE
Avitide
Title TBC

13:30-14:30 Lunch

TRACK 1 (CONTINUED): NEXT-GENERATION TECHNOLOGIES

14:30-15:00

PIERRE MORETTI
Head of Process Development – Early Stage, Biopharma, GMS Development and Launch, Biotech Process Sciences, Merck Serono

Toward the implementation of Integrated Continuous Bioprocessing for NBE Manufacturing. From bench scale to GMP production

- In this presentation Merck KGaA will describe the key drivers toward adoption of "next-generation" processes.
- Intensified USP processes: from high cell density seeding to full perfusion
- Design of an integrated and automated continuous downstream processing and its scale up

15:00-15:30

CHRISTOPH HERWIG
Professor and Head, Research Division of Biochemical Engineering, TU Wien, Austria

Integrated digital twin solution for the bioprocess validation life cycle

- Integrated digital twins are a promising tool for leveraging data by turning it to knowledge along the product life cycle. They allow analyzing multi-parametric effects of process parameters between unit operations, help identify ranges for intermediate CQAs and demonstrate capability of process robustness, even at edges of the range of individual process parameters.
- Along with scale down models and comparability analyses, integrated digital twins identify triggers for safe scale up and tech transfer between sites.
- The digital twin technique can therefore be used continuously throughout the process lifecycle, serves as a platform knowledge management tool and assists process engineers in process characterization studies (PSC) and continued process verification (CPV) tasks.

15:30-16:00

SOLUTION PROVIDER PRESENTATION: DENIS DECUBBER
Chairman Board of Directors, SalamanderU

ATMP manufacturing has entered Industry 4.0

- What "Industry 4.0" means for ATMP manufacturing facilities
- Current obtained results in some companies:
  - Voice-controlled manufacturing process by using an electronic batch record (EBR) system with voice recognition and a voice synthesizer.The system is custom-made and reads out the master batch record (MBR) steps to the operator to guide him/her seamlessly through the production steps.
  - Real time remote-controlled manufacturing parameters' follow-up
  - Automatically generated batch records. The voice-controlled EBR system provides a real-time view of the process and all potential problems and deviations. The batch report is automatically generated in such a way that the batch record reviewer has no longer to analyze the complete batch record but can focus on the potential problems.
  - Centralized dashboards accessible in real time
- What comes next?
  - Optimized process control
  - Artificial intelligence

TRACK 2B: PURIFICATION AND RECOVERY METHODS

14:30-15:00

PHILIPP AMSLER
Principal Scientist, Novartis

Purification technologies to tackle complex therapeutic proteins during lead selection

Lead selection of therapeutic proteins requires careful characterization of a variety of molecule properties to reduce the risk for encountering unexpected obstacles during technical development. The developability assessment concept applied at Novartis combines information about expression, aggregation propensity, process fit, stability, physicochemical properties, and other parameters of potential candidates. The presentation will provide an overview of the concept and focus on examples for different purification approaches enabling the production and characterization of complex protein formats.

15:00-15:30

CHRISTOPHER WILSON
DSP Expert, Ipsen

Process Development Considerations for Novel Highly Potent Recombinant Proteins

- Challenges of working with highly toxic proteins
- Novel approaches to process development
- Case studies on DSP process development

15:30-16:00

SOLUTION PROVIDER PRESENTATION: HANI EL-SABBAHY
Biopharmaceutical Application Engineering Specialist, 3M Separation and Purification Sciences Division

Chromatographic Clarification Enables Removal of Problematic Host Cell Protein Contaminants Early in Downstream Processing

Over the last few years, a number of specific host cell proteins have been identified as being problematic due to their effect on the patient, on the product or simply because they are difficult to remove. This talk will explore the impact of Chromatographic Clarification compared to a conventional depth filtration on the removal of problematic HCPs during downstream processing. The data discussed was generated using advanced proteomic techniques to identify and quantify the host cell protein contaminants through clarification and capture.

16:00-16:50 Afternoon Refreshments / One-to-One Meetings

16:50-17:20

ALI ABUSNINA

Data Scientist, BI X Digital Lab, Boehringer Ingelheim

Data driven Integrated process Models for Optimizing a chain of biopharmaceutical processes

Solubilization, refolding, and capture are part of a biopharmaceutical process chain that are used in protein production. Identifying the optimal set of experimental conditions that maximize product volume, quality, and minimize production time along the whole chain (not only with one single process) is a challenging task for scientists. That is down to the complexity that underlies these processes, and also down to the large number of process conditions and combinations that scientists need to screen from. Resorting to data-driven modelling and utilizing historical data generated from these processes to build integrated process model (IPM) is an approach that Smart Process Design Team at Boehringer Ingelheim Digital Lab (BI X) is taking to address this multi process and multi-dimensional optimization problem. The approach is developing a data driven integrated process model that can be used as a fitness function for a genetic algorithm to find the optimal set of process parameters that maximizes product volume within the process chain.

17:20-17:50

GARETH ALFORD

Engineering Lead, GSK

Creating the Digitalized platform for Future Intensified Manufacturing

How can the next generation technologies in both the Digital and Manufacturing worlds combine to provide a platform to meet these challenges?

As a rule, we will encounter numerous business challenges in our industry, these include

- Development Pipeline Erosion & Patent Cliff impacts
- Affordability of medicines
- Processes must ensure quality, and the production of compliant material
- Paramount: always supply to patients

We will look at the intensification of manufacturing processes, and the impact these have on our existing manufacturing procedures, and where new digital techniques can be used to support an Agile platform from Development to Manufacturing.

16:50-17:50

ROUNDTABLE DISCUSSIONS:

Roundtables are informal, small-group interactive discussion on key topics in the field. Discussion leaders will introduce sub-topics/questions for discussion and roundtable attendees are encouraged to participate actively in the session.

Table 1: CMO management – challenges & insights for outsourcing complex biologics

JENS LOHRMANN

Disease Area, Head Oncology, Technical R&D, Novartis

- With limited biologics manufacturing capacities worldwide, how are pharma and biotech companies aiming to best support their portfolio with adjusted buy vs make strategies?
- Are differentiated strategies for "simple" biologics vs "complex" biologics becoming apparent?
- Special considerations for highly active compounds (ADCs)
- CDMO or CMO? Outsourcing of overarching development workflows vs. "just" API manufacturing?
- Balancing preferred partnerships with business continuity aspects
- The next challenges on the horizon: personalized medicine, local manufacturing requirements and beyond

Table 2: Sharing Practices/Preferences with Sterile Filter Integrity Testing of Drug Product

KIRSTEN STRAHLENDORF

Senior Scientist, BioProcess R&D Formulation and Stability, Sanofi Pasteur

Table 3: Setting meaningful potency and purity specifications

BART VAN MONTFORT

Scientific Director, Analytical Development, Janssen

Setting potency and purity specifications for cell or gene therapy products is often not straightforward. Quite often the mode of action is influencing complex systems such as the immune system or cellular pathways and it is challenging to correlate the in vivo situation to an in vitro assay. Moreover, in many cases a half potent lot is not the same as a lot with only half of the active ingredient. This round table is about sharing experiences and thoughts on how to set meaning full potency and purity specifications (method and acceptance criteria) for cell and gene therapy products.

17:50-18:20

FRANK THIELMANN

PMO & Operational Excellence Platform Leader, Biologics, Novartis

Trends in Biopharmaceuticals and their perspectives in the Pharma market

- Disease areas and biotherapeutics
- Regulatory differences between small and large molecules
- Market perspectives of different types of biopharmaceuticals

18:20 Chair's Closing Remarks / End of Day 1

18:20-19:20 Networking Drinks Reception

08:20-09:00 Refreshments

09:00-09:40

CATHRINA HOULIHAN

Site Control Strategy Lead, New Product Industrialisation & Devices (NPID), Sanofi

Control Strategy Creation & Integration

- Control Strategy – the basic concepts
- Understanding the Regulations; The Industry Landscape; Why the patient is core
- Control Strategy – development/acronyms
- Regulation and Acronyms (and more!); Qbd Principle application; Risk based application
- Control Strategy – lifecycle integration and management
- Product Lifecycle Management; Example Document Structures; Multi-product/multi-platform challenges
- Control Strategy – Site Integration & Use
- Creating the Vision; Opportunities & Challenges

09:40-10:10

CORNÉ STROOP

Director Biologics & Vaccine Analysis, MSD

MS is ready for QC. Are you? Role and possibilities of Mass Spectrometry in QC labs

Mass spectrometry (MS) in quality control (QC) labs is a much debated subject at this time. In my presentation, I will show that there is no reason for unease, as long as we consider important questions and requirements. We have to ask ourselves about alternatives, which instrumentation and which methods. For requirements, we should consider instrument qualification, available expertise, training, method transfer, and software applications. It is worthwhile to realize that use in QC labs is not limited to release and stability testing. And with some examples, I hope to make the case that MS is indeed ready for QC routine testing. But you and your QC lab might not yet be.

10:10-10:40

SOLUTION PROVIDER PRESENTATION:

STEPHEN LOCK

Marketing and Market Development Manager, SCIEX, CE EMEAI

Applications of CE from QC and Characterisation to Cell Line Screening

CE is a flexible analytical platform for the analysis of biopharmaceuticals. Recent innovations have focused on fast, simplified workflows to address challenges throughout development and production. In this talk we will cover two of the many areas that CE is currently being used by the biopharmaceutical industry

- CE-MS a new level of characterization for mAbs and its future in DMPK analysis
- CGE Glycan analysis a replacement for HILIC which can meet the throughput demands for cell line screening

10:40-11:50 Morning Refreshments / One-to-One Meetings

TRACK 1: MANUFACTURING CELL AND GENE THERAPIES

Chair:

11:50-12:50

HOUR PANEL DISCUSSION:

Assay development and the challenge of characterisation for cell and gene therapies

ANGELA KEIGHTLEY (Chair)

Director, Assay Development, BlueRock Therapeutics

QASIM RAFIQ

Associate Professor in Cell and Gene Therapy Bioprocess Engineering, UCL, UK

FRANCESCA ROSSETTI

Analytical Methods Development Manager, MolMed

BART VAN MONTFORT

Scientific Director, Analytical Development, Janssen

TRACK 2: QUALITY CONTROL, ANALYTICS AND THE REGULATORY LANDSCAPE

Chair: **Sébastien de Bournonville,** PhD Researcher at KU Leuven and Co-Founder, MyCellHub, Belgium

11:50-12:20

ROMAIN LE DEUN

GRA-CMC Senior Manager, Merck

Accelerated Development Schemes: Regulatory Challenges and Opportunities for CMC

Regulatory mechanisms have been developed to promote a faster commercialization of drugs targeting serious or life-threatening diseases for which no existing treatment exists. These advances make CMC requirements on the Critical Path for products eligible to Accelerated Development programs. We will explore in this session what are the tools we can use to facilitate the CMC development of products under Accelerated Development; what are the main hurdles and which mechanisms could help overcoming them; maintaining the objective to meet patients' needs in best delays.

- Selected outcomes from the EMA/FDA Workshop.
- Lessons Learned from product approved following Breakthrough Designation.
- Other ideas to explore...

Keywords: Post-Approval Protocols, Stability, Specifications, Process Characterization and Validation, Control Strategy, Continued Development to Commercial Process.

12:20-12:50

KURTIS EPP

Senior Director, Process Development and Breakthrough Technologies CSL Behring

PACMP & QbD – An Efficient Path to Change Approval

Using a QbD approach, CSL Behring received pre-approval for a Comparability Protocol to support a manufacturing process site change (same facility, new production area). Leveraging the QbD approach to process development in the original dossier, CSL successfully claimed that the planned change would not influence CQAs in order to avoid submission of further

11:50-12:50

Continued

12:20-12:50

downstream comparability assessment (e.g., process comparability, DS stability profile comparison. Obtaining binding agreement from the regulatory authorities helped to ensure a clear understanding of the comparability data package required to support the major change. Based on this experience, CSL now has greater confidence that the QbD approach will continue to facilitate further process changes in the product lifecycle, especially as more product/ process knowledge and data are gained.

12:50-13:05

SOLUTION PROVIDER PRESENTATION

12:50-13:05

15 MINUTE SOLUTION PROVIDER PRESENTATION:
SENIOR REPRESENTATIVE
Gyros Protein Technologies
Title TBC

13:05-14:05 Lunch

14:05-14:35

STEWART CRAIG
Chief Manufacturing Officer, Orchard Therapeutics
Tackling the CMC Challenges for Rare Disease Gene Therapies

- Considerations in manufacturing process design, development and implementation for lentiviral vectors and gene-modified stem cell products
- Comparability considerations for the product lifecycles

14:05-14:35

PAULINE RUDD
Professor and Principal Investigator, National Institute for Bioprocessing Research and Training (NIBRT), Ireland and Visiting investigator, Bioprocessing Technology Institute, A*Star, Singapore
Applications of new software to improve the speed and quality of multi-attribute data analysis for glycopeptide and released glycan separations
Traditional challenges for glycan analysis can be addressed by a range of technologies that are automated, high throughput, sensitive and quantitative. To give a more complete detailed analysis of intact glycoforms a combination of technologies such as LC/MS/CE are required. These enable the analysis of intact glycoproteins, glycopeptides and glycolipid head groups. The bottleneck now lies in data interpretation so this talk focuses on the application of four new software programmes: (i) GlycopeptideGraphMS (for the detailed identification of Glycopeptides which is data base and platform independent) (ii) GlycoStore (an international resource including experimental glycan data bases and metadata) (iii) Glycoanalyser (software to aid interpretation of exoglycosidase array digestions) and (iv) MAGMap (a programme giving a confidence score to an assignment based on multiple attributes).

14:35-15:05

CHAMINDA SALGADO
Scientific Leader, GSK
Analytical impact on the commercialisation of autologous gene therapies

- For Autologous Gene Therapies the analytical testing is a critical path activity following commercialisation of the product
- The 1 batch per dose is a huge logistical challenge for high patient number indications, for manufacture, testing and release.
- The cost of analytical testing (FTE contribution) may be the single largest cost of goods that must not be ignored.

14:35-15:05

PETR OBRDLIK
Technical Development New Biologic Entities, Analytical Dev., Novartis
Early phase bioanalytics for complex therapeutic proteins and IgG conjugates
Since several years, the biologics development landscape is moving away from monoclonal antibodies and IgG fusion proteins towards new protein formats and protein conjugates. Such molecules have often a complex mode of action (MoA) and the critical quality attributes of the drug molecule may not be fully understood. These features pose new challenges on the selection and development of representative potency assays for quality control of the final drug product. This presentation will show examples of development of potency assays and bioanalytical strategies applied for such new generation biologics.

15:05-15:35

BENJAMIN GYSI
Director Site Projects, Takeda
Takeda – Stem Cell Program & Project

15:35 Conference Close

Hotel Riu Plaza The Gresham Dublin
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www.gresham-hotels.com/en

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