**DAY ONE**

**07.45 - 08.30**
REGISTRATION

**08.30 - 08.40**
WELCOME & CHAIRPERSON’S OPENING REMARKS FOR DAY ONE
Dr. Uwe Gottschalk, Chief Scientific Officer, Lonza

**08.40 - 09.15**
Biomonitoring of the future – Which technologies for the benefit of the patient?
- Major transformation of BioManufacturing and emerging new and game-changing technologies, such as continuous E2E manufacturing, disposable equipment and digital plants.
- Which new technologies are just “passing fads” and which game-changing technologies will bring real benefit and added value to the patient?
- Technologies are sometimes incompatible or contradictory, e.g., disposable technology, requiring more manual handling, and plant digitalisation, aiming at self-driving operations.
- Is there a “one-size fits all” biomanufacturing plant of the future? Should the biotech industry work towards a common technology platform similar to that developed by the semi-conductor industry a few decades ago?

Thibaud Stoll, EVP Global Biotech Manufacturing, Merck Healthcare

**09.15 - 09.50**
The CMC challenges of innovative and breakthrough biological therapies
- Breakthrough therapies create opportunities & challenges for CMC development and manufacturing from both a technical and organizational view.
- Case study example on how Janssen CMC adapted to address a breakthrough program.
- CMC process scaling up & technology transfer.
- Specifications & regulatory filing with limited time.
- New modalities are often coupled with breakthrough products and the future is now with more to come!

John Knighton, VP, Janssen PDMS API Large Molecule, Janssen

**10.00 - 10.45**
COFFEE BREAK & MEETINGS

**10.40 - 11.15**
Integrating next-gen processes, technologies and operations to modernise biomanufacturing
- The growth of biologic therapeutic demands innovations in biomanufacturing to supply drug products in a more reliable and faster manner.
- Modernised approach to biomanufacturing in Biogen’s new facility with Next-Gen Manufacturing (NGM) integrations.
- Combing the NGM mode with modular, expandable facility design and automation.

Canping Jiang, Head of Manufacturing Sciences, Solothurn, Biogen

**11.20 - 11.55**
Disposable technology applications to support an evolving product pipeline
- Introduction of high potency Bispecific to standard product portfolio.
- Conventional cleaning methods not feasible.
- Design of disposable manufacturing options for 100% of upstream downstream unit operations.
- Develop calibration philosophy for disposable instruments.
- Deliver capability within 8 months to support clinical trial program.

Liz Dooley, Director Operations, Janssen Sciences Ireland UC

**11.55 - 12.25**
One to One Meetings
- Downstream/Upstream Process Technology Platforms.
- Specialised cell culture media.
- Single-use & Disposable Technologies.
- Smart Manufacturing Technologies - Technology Transfer.
- Facility Management & Integration.
- Capacity & Facility Design.
- Multi product facilities.
- Energy & Operational Efficiency.
- Lean/Transformational Change - Operational Excellence.
- Continuous Improvement / Manufacturing Processing.
- PAT & MES, Automation and Process Control Excellence.
- QBD.
- Quality Assurance & Quality Systems.
- Regulation - Rapid Release Testing.
- Finance / Inward & Foreign Investment.
- cGMP - Contract, External Manufacturing Services.
- Biogenerics/Biobetters.
- Personalised Medicines.
- Cell & Gene Therapy.
- Fill and finish.
- Cold chain.

**12.25 - 12.55**
Future trends perspectives and insights on biomanufacturing
- Major market trends, market growth and new modalities.
- Risk factors in biomanufacturing.
- Capacity planning: new approaches and technologies.
- Process intensification.

**12.55 - 13.45**
NETWORKING LUNCH
Leveraging predictive modeling to improve your development and validation efficiency
- Process validation using Latin Hypercube Sampling
- An alternative to traditional process validation to give higher accuracy and relevance, using less resources
- Which problem are we solving? heavy time consuming effort
- Why does this make sense? (data more relevant than DoE)

Ernst Broberg Hansen, Scientific Director, Novo Nordisk

Evaluation of different continuous chromatography systems for continuous capture
- The leading tool for transition to continuous biomanufacturing
- Different continuous chromatography technologies are currently available in the market, which differ in configuration, control elements
- Each technology comes with different benefits and limitations, selection of one can be based on requirements and feasibility
- Comparison of different systems with feasibility data and operational aspects

Dominik Mittergradnegger, Associate Director Process Development Downstream, and Thomas Posch, Downstream Lead Process Development, Shire Austria

A new generation of Agarose Beads
- Next generation resin for downstream processing
- Advanced resin technology for continuous and batch manufacturing
- Increased process productivity & economy
- Ultra-high capacities on Protein A resin above 80 g/l

Panel Discussion: Development and implementation of an industry competitive first-in-human CMC strategy
- The timing from candidate selection until the first human administration is key for competitiveness
- An integrated approach across divisions
- Achieving this goal is focusing on the platformization of the early development stream

Moderator: Dr. Berthold Bödeker, Chief Scientist, Bayer AG
Panelists:
- Dr. Jochen Schaub, Director Late Stage Bioprocess Development, Boehringer Ingelheim
- Dr. Louis Boon, CSO, Biocerés
- Fabian Bindel, Lab Head in Upstream Process Development, Sanofi

Primary packaging solutions for biotech drugs
- Make personalised medicine a reality with R&D pipeline with biotech-based drugs
- Pay special attention to all the steps along the development process and value chain
- Protect the drug product throughout the shelf life to efficient processing and enable safe and easy drug administration
- Understand all aspects of primary packaging starting with purity of the raw materials to final container with drug product and administration
- Reduce the risk of drug container interaction and ensure safe and easy drug administration

Open Panel Discussion Technical life-cycle management and post-market authorisation changes
- Technical Life-cycle management activities and ICH Q12, more upfront planning required
- Post-market authorization changes, flexible manufacturing networks, however maintaining complexity at a reasonable level
- Treatment access for larger population groups, Biosimilars, and Cost pressure on Biologic

Moderator: Jesús Zurdo, Sr. Director Strategic Innovation, Lonza
Panelists:
- Markus Schneider, Head Biotechnology Excellence, Novartis Technical Operations
- Dr. Berthold Bödeker, Chief Scientist, Bayer AG
- John Knighton, VP, Janssen PDMS API Large Molecule, Janssen
- Didier Moerenhout, VP Manufacturing Science and Technology, Glenmark

Networking Drinks Reception
DAY TWO

08.30 - 08.35
CHAIRPERSON’S OPENING REMARKS FOR DAY TWO AND SUMMARY OF DAY ONE
Dr. Berthold Bödeker, Chief Scientist, Bayer AG

08.35 - 09.10
Project acceleration and breakthrough designation for biologics: Effect on early and late stage CMC development
- Strategies for streamlining CMC packages
- Minimising changes during development
- Front-loading versus fast to IND
- Accelerating/Compressing late stage development
- Effect of flexible plants, disposables and continuous processing
Dr. Berthold Bödeker, Chief Scientist, Bayer AG

09.10 - 10.45
Process Development
Chaired by Dr. Berthold Bödeker, Chief Scientist, Bayer AG

- Current innovative bioprocess technologies
  - Continuous integrated production of therapeutic proteins
  - Continuous Chromatography
  - Recombinant Technology
  - Massimo Morbidelli, Professor, ETH Zürich

- Process development and manufacturing of Antibody Drug Conjugates
  - Process development and challenges for different ADC platforms
  - Strategies for ADC manufacturing
  - Control of product heterogeneity
  - Improvement for future processes
  - Guy De Roo, Lead DSP Scientist, Syntheon

10.40 - 11.10
Downstream Purification and Automation Strategies for Microbial Expressed Proteins
- Microbial expression
- Downstream process development
- High Throughput Development
- Automation and parallelization
- Interdependencies between upstream and downstream development
- Dr. Cécile Brocard, Director Downstream Development, Boehringer Ingelheim

10.20 - 10.40
COFFEE BREAK & MEETINGS

10.40 - 11.10
Biosimilars
Chaired by Dr. Uwe Gottschalk, CSO, Lonza

- Biosimilars – Differentiation as a success factor
  - Regulators Perspective
  - Biosimilar Landscape
  - Differentiators for success: Manufacturing considerations
  - Technical Development Considerations
  - Interchangeability
  - Portfolio Selection
  - Andreas Herrmann, CEO & Founder, Valeriusbio

- Using SPOT™ Technology in our CHOBBC® Platform and our USP Modulation toolbox to reduce cost of goods for Biosimilar Development
  - SPOT™ technology in our CHOBBC® platform
  - Upstream process modulation to meet CQAs
  - Costs of Goods reduction
  - Metabolic Engineering of Cell Lines
  - Dr. Louis Boon, CSO, Bioceros

11.10 - 11.40
End-to-End Processing of Biopharmaceuticals – Options for scale-up and/or scale-out strategies
- End-to-end processing may embrace batch, continuous or hybrid technologies
- Single-use technologies enable proven scale-up and then scale-out
- Significant productivity improvements may be achieved through effective process design
- Using a toolbox approach to develop and scale-up a process enables productivity improvements across a broad range of advanced biologics modalities

11.40 - 12.00
Chromassette®: A stackable chromatography cassette enabling next-generation bioprocessing
- A stackable, single-use and pre-packed chromatography cassette with a supported bed (Chromassette®) is a novel product concept in DSP, addressing the current key challenges in manufacturing
- Chromassette combines the separation capabilities of chromatography resins with the convenience of a pre-packed, modular cassette as shown in a range of

12.00 - 12.40
Improving single use bioreactor design and process development
- Improve performance and control when operating under these special conditions
- Impacts of enhanced energy transfer-Implementing bottom heat exchange, alternate impeller positions, and considering agitation dissipation rates
- How new technology improves equipment utilisation, scheduling efficiency, inventory logistics, and reactor harvest consistency?
Implementation and validation of a single-use mixing system for virus inactivation with solvent / detergent

- Virus inactivation by solvent Detergent treatment
- Single Use System
- Scale-down model for S/D Virus inactivation
- Steps of the validation (temperature mapping; Homogeneity study, ...)
- Impact of the EU Reach regulatory authority on S/D IV processes

David Balbuena, Head of Manufacturing / LFB Biomanufacturing, LFB Biotechnologies

A Robust and Stable Molecularly Imprinted Polymers for Bioprocessing

- Molecularly imprinted polymers (MIPS) have broad application as affinity reagents in sensing, diagnostics, analysis and separation
- MIPS are synthetic alternatives to antibodies – they are robust and stable and can operate in extreme physicochemical conditions
- Viable alternative for purification of biotherapeutics with potential for extensive reuse
- With significantly lower production costs, our initial testing indicates the potential to transform the antibody purification process
- We are developing a MIP alternative to Protein A, available for licensing from 2019

Richard A. Mineo, Vice President, Encova

Next generation manufacturing for expanding portfolio of biologics

- Hybrid Model
- Modular and single-use technologies
- Flexible fed-batch cell culture
- High-performance purification
- Single pass TFF (SPTFF)

Nripen Singh, Associate Director, BMS

Open Panel Discussion: With next gen manufacturing technologies and processes and strategies emerging what gains are being realised for profitability, productivity and quality in future facilities?

- Assessing the benefits and drawbacks of the latest manufacturing technology trends
- How Single-use equipment can help achieve performance improvements, both for downstream purification and for manufacturing productivity overall
- Process and Product Considerations for Flexible Manufacturing
- How Process Technology Platforms can be used to Optimize areas and parameters in upstream processing and automation opportunities to improve productivity and quality
- Process intensification strategies in USP and DSP shortening process time

Moderator: Uwe Gottschalk, CSO, Lonza
Panellists: Canping Jiang, Head of Manufacturing Sciences, Solothurn, Biogen
Nripen Singh, Associate Director, MS&T Downstream, Bristol-Myers Squibb
Stefan Schmidt, Head, Operations (COO), BioAtrium AG, a Sanofi and Lonza Joint Venture

Continuous processes for antibody-drug conjugate manufacturing

- Continuous conjugation processes utilizing flow reactors are capable of generating ADCs with identical product quality to conventional batch processes
- Space-time yield optimization of continuous conjugation processes can maximize product output while minimizing equipment footprint and potent compound containment requirements
- Single-pass tangential flow filtration enables continuous ADC purification and formulation

15.00 - 15.10
COFFEE BREAK

15.10 - 15.40
Next generation manufacturing for expanding portfolio of biologics

15.40 - 16.10
Open Panel Discussion: With next gen manufacturing technologies and processes and strategies emerging what gains are being realised for profitability, productivity and quality in future facilities?

16.10
CHAIRPERSON’S CLOSING REMARKS

16.15
CLOSE