FORMULATION & DELIVERY SERIES UK

22 - 23 April 2020 | ILEC Conference Center, London, UK

6th Annual Formulation & Drug Delivery Congress
5th Annual Inhalation & Respiratory Drug Delivery Congress
NEW For 2020: Inaugural Biomanufacturing Congress

350+ DELEGATES FROM LEADING GLOBAL BIOTECH COMPANIES
110+ PRESENTATIONS, CASE STUDIES AND DISCUSSIONS
11 INTERACTIVE STREAMS ON THE LATEST INNOVATIONS

Conference Brochure

KEY SPEAKERS INCLUDE

Martina Röhm
Boehringer Ingelheim

John Patton
Aerami

Theresa Scheuble
Janssen

Alan Harris
Ferring

Katherine Miller
Orchard Therapeutics

Otmane Boussif
Novartis

Book Online: www.oxfordglobal.co.uk/formulation-delivery-series-uk/
Join the Conversation: #FDDUK20 | #IRDDUK20
Oxford Global is proud to present our Formulation & Drug Delivery UK Series, featuring 110+ presentations from leading industry experts and critical solution provider companies. Join over 350 attending delegates for scientific sessions and case studies at the forefront of pharmaceutical science and development, highlighting the latest innovation and trends for multiple therapeutic modalities.

6th Annual Formulation & Drug Delivery Congress: This crucial congress brings the latest developments in biopharmaceutical and small molecule formulation and drug delivery to you, covering a range of dosage forms and novel delivery modalities, including nanomaterials. Join experts in the characterisation and stability analytical sciences, and our unmissable workshop and panel discussion on patient-centric drug development.

6th Annual Inhalation & Respiratory Drug Delivery Congress: Our ever-popular inhalation congress brings together the premier experts working on the formulation and delivery of inhaled therapeutics, including preclinical modelling, simulation and characterisation, and the latest case studies and developments for novel therapeutics. Day 2 discusses novel delivery devices and combination products as well as the challenging issues of improving patient adherence and the regulatory and commercial challenges faced by inhaled and respiratory therapies.

Oxford Global’s inaugural Biomanufacturing Congress: Join pharmaceutical MSAT experts from across the globe as we discuss the latest developments, trends and strategies in the manufacture of complex biologics, upstream and downstream processing, and the development of cell and gene therapies. Crucial case studies in continuous manufacturing and automation, quality assurance and facility design make this the must-attend biologics manufacturing conference for 2019.

Building on the success of our 2019 event, the Formulation UK Series is bigger than ever, bringing a host of new streams and interactive elements alongside our popular event features. This event is not to be missed – we look forward to seeing you in London!
250+ VPs, Directors & Senior Managers from leading life sciences companies and research institutions in the following fields and more:

**Formulation**
- Combination Products
- Drug Delivery
- Biopharmaceutical Development
- Formulation Sciences
- Sustained Release
- Nanotherapeutics
- RNA Delivery

**Inhalation**
- Analytical Development
- Inhalation Drug Delivery
- Circulating Tumour Cells
- Respiratory Pharmaceutics
- Inhaled Dosage Forms
- Inhalation Devices
- Inhalation Formulation

**Biomanufacturing**
- Process Development
- Upstream & Downstream
- Continuous Manufacturing
- Automation
- Quality Control
- Facility Design
- Cell Therapy Manufacture

These companies and many more

For the full attendee list please contact marketing@oxfordglobal.co.uk

**2019’s Attendee Profile**
- 40% Europe
- 40% UK
- 13% Rest of World
- 32% Manager / Senior Scientist
- 15% Director
- 5% Commercial or BD
- 67% Pharma and Biotech
- 20% Academic Institution
- 13% Vendor Companies

**Network and Programme**

**Formal and informal meeting opportunities** offer delegates the chance to discuss key solutions with leading service providers:

**Formulation**
- Sustained/Controlled Release
- API Production
- Highly Potent Compounds
- Device Development
- Ocular Delivery
- Micronisation

**Inhalation**
- Extractable & Leachable
- Nasal Sprays
- Automation
- Suspension
- Dry Powder Inhalers
- Aerosols & MDIs

**Biomanufacturing**
- Viral Vector Manufacturing
- Bioreactors
- Quality Control
- Smart Facilities
- Continuous Manufacturing
- Process Analytical Technologies

**Recipharm**
**evotec**
**SCIEX**
**Wyatt Technology**
**Merck**
**Lonza**
**Advanced Instruments**
**MedPharm**
**Aptar**
**Celanese**
**UNCHAINED LABS**
**Pfantsiehl**
**Zerion**
**Munit**
**Cambrex**
**Occlugen**
**Quintiles Sciences**
**Arcinova**
**Upporton Pharma Solutions**
### Formulation & Drug Delivery

#### Day 1, Stream 1: Small Molecule Drug Formulation
- Recent progress in amorphous solid dispersions
- Advanced formulation strategies & methods
- Overcoming key formulation challenges for small molecules
- Excipient-ingredient interaction and compound development
- API challenges and solutions
- Formulating for paediatric concerns

#### Day 1, Stream 2: Biologics Drug Delivery Delivery of Oral Peptides
- New biologics drug delivery systems
- Disruptive drug delivery technologies and devices
- Injecting fragile molecules
- Advances in:
  - Ophthalmic drug delivery
  - Cell & gene delivery systems
  - Wearable/smart drug delivery devices

#### Day 1, Stream 3: Characterisation, Analytical Development & Innovative and Novel Medicines
- Part 1: Stability, Bioanalysis & Characterisation
- Stability testing and stability approaches for biologics
- Characterisation for antibodies
- Molecular level impact of formulation excipients
- Part 2: Nano & RNA therapeutic delivery
- The Nano-Panel with Professor Dobson
- Neuroprotective NanoBioTherapies for crossing the BBB
- Drug delivery using lipid nanoparticles

#### Day 1, Stream 4: Development & Formulation of Inhaled Therapies
- Aerosol Science
- Modelling & simulation in inhalation
- Characterising aerosol dynamics
- Particle engineering
- Inhaled delivery challenges
- Innovative formulation of therapies for COPD, IPF and infectious disease
- Case studies on alternative therapeutic areas:
  - Inhaled insulin
  - Inhaled vaccines & antibodies
  - Inhaled biologics

### Inhalation & Respiratory Drug Delivery

#### Day 1, Stream 5: Cell & Gene Therapy
- Biomanufacturing: Insights, Key Strategies & Novel Approaches
- Autoologous and allogeneic manufacture
- Overcoming scale-up challenges
- Manufacturing product lines for cell-based therapies
- Clinical to large scale process development
- Scaling-up development
- Regulatory trends
- Quality control assays
- Logistics, handling, storage (including cryopreservation)

### Biomanufacturing

#### Day 1, Stream 6: Upstream Processing, Smart Factories, Digitalisation, Tools & Technologies
- End-to-end process excellence
- Quality systems integration
- Monitoring and transfer of cell culture processes
- Increasing the speed of upstream bioprocessing with modelling techniques
- Optimising cell culture media for upstream bioprocessing
- Identifying and removing residual host cell proteins
- Emerging technologies in upstream bioprocessing
- Bioreactor selection, characterization and scale translation

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### Confirmed Speakers

<table>
<thead>
<tr>
<th>Professor</th>
<th>Institution</th>
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<tr>
<td>KORBINIAN LÖBBMANN</td>
<td>Professor, TU Dortmund University of Copenhagen</td>
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<tr>
<td>FLEX BAUER</td>
<td>Head and Scientific Director, Drug Product Development, Janssen</td>
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<tr>
<td>SONALI BOSE</td>
<td>Crystallisation, AstraZeneca</td>
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<tr>
<td>SOPHIE JANBON</td>
<td>Senior Scientist, American Regent</td>
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<tr>
<td>ROBERT HENNIG</td>
<td>Technical Project Leader &amp; Fellow, Novartis</td>
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<td>FINN BAUER</td>
<td>Associate Director, Merck KGaA</td>
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<tr>
<td>RAJ THAKUR</td>
<td>Professor of Solid-State Pharmaceutics, University of Copenhagen</td>
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<tr>
<td>SABINE THEILGES</td>
<td>Principal Scientist – Analytical Project Leader, Novartis</td>
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<tr>
<td>JONAS FAST</td>
<td>Head of Applied Research Activities, MedinCell</td>
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<tr>
<td>PATRICK BAUMHOF</td>
<td>Senior Scientist, Head of Research Unit, Sanofi</td>
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<td>THOMAS HAMM</td>
<td>Associate Professor, University of Copenhagen</td>
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<tr>
<td>MICHAEL SIEDLER</td>
<td>Founder, Board Member and Strategic Advisor, Aeraimi</td>
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<tr>
<td>TARIQ SETH</td>
<td>Co-Founder, Galacto Biotech and Former Chief Scientist Vice President Clinical Development Unit, AstraZeneca</td>
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<tr>
<td>OLIVER BRASS</td>
<td>Senior Vice President, Formulation &amp; Drug Delivery, CureVac</td>
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<tr>
<td>JOHN PATTON</td>
<td>Senior Vice President, Analytical Operations, Cellcatics</td>
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<tr>
<td>SIMONE STEINER</td>
<td>Production Unit Head, Cell &amp; Gene Therapy, Novartis</td>
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<tr>
<td>MARK TOMISHIMA</td>
<td>Head of NBE Formulation Development, AbbVie</td>
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### Formulation & Delivery Series UK: Agenda at a Glance
## Day Two: 23 April 2020

### Formulation & Drug Delivery

**Day 2, Stream 1: Biopharmaceutical Formulation**
- Pre-formulation & early phase development
- Late to commercial stage development
- Multi-dose protein formulation development and combination products
- Dosage form design and development

**Day 2, Stream 2: Small Molecule Drug Delivery & Manufacturing**
- Part 1: Small Molecule Drug Delivery
  - Targeted and sustained release drug delivery
  - Delivery of new therapeutic modalities and difficult targets
  - Oral solid & liquid delivery
  - Combination product delivery
  - Panel Discussion: Patient-Centric Drug Development
- Part 2: Drug Product Manufacturing
  - Continuous Manufacturing & CMC
  - Process Development
  - qBd and material properties

**Day 2, Stream 3: Inhalation Devices & Combination Products**
- Novel technologies for pulmonary & nasal delivery
- Innovative development of inhalation devices:
  - DPIs, MDIs & Generic Products
  - Connective health
    - Improving patient adherence and technique with product design
  - Digital health combination products
  - Challenges of bringing inhalation and respiratory drug delivery products to the market
  - Regulatory pathways for inhaled therapies
  - Manufacturing of delivery devices

### Inhalation & Respiratory Drug Delivery

**Day 2, Stream 4: Advances in Biologics Manufacturing, CMC & Continuous Biomanufacturing**
- Leadership & expertise: people at the heart of biomanufacturing
- Innovative factories of the future
- Contaminant reduction in continuous processing
- Adopting continuous processing in biomanufacturing
- Implementation and scale-up
- Stability analytical development
- Raw materials testing: novel approaches, strategies and processes
- CMC for breakthrough therapies

### Biomanufacturing

**Day 2, Stream 5: Downstream Processing**
- Part 1: Recent Technological Advancements, Automation and Latest Trends
  - Streamlining downstream bioprocessing
  - High-throughput process development for non-platform recombinant proteins
  - Single-use technologies
  - Technology Transfer
  - Ultrafiltration/diafiltration for downstream
- Part 2: Process Analytical Technologies For Biologics
  - Process Analytical Technologies (PAT)
  - Process characterization and laboratory support
  - New tools for analyzing subcellular states
  - Process scalability

### Confirmed Speakers

**Keynote Speaker:**
- **FREDERIC MATHOT**
  - Scientific Leader, Drug Product Development - Global Vaccines R&D, GlaxoSmithKline
- **CLEMENTS GUENTHER**
  - Director of Nonclinical Safety, Bayer AG
- **GIUSTINO DI PRETORO**
  - Associate Director, Group Leader, Drug Product Development, Johnson & Johnson
- **MATHILDE LORSCEIDER**
  - Senior Scientist, Formulation Technology, Pharmaceutical Development, Ipsen
- **MARTINA RÖHM**
  - Associate Director, Formulation & Process Development Late Stage, Boehringer Ingelheim
- **SHILPA THOSAR**
  - Associate Director, Commercial CMS Science Group, Takeda
- **CATHERINA HOULIHAN**
  - Site Control Strategy Lead, Sanofi Genzyme
- **NADAV NAVON**
  - Chief Operating Officer, Intec Pharma
- **KEYNOTE SPEAKER:**
  - **MARK MILTON-EDWARDS**
    - Managing Director, Ferring Pharmaceuticals
- **DECLAN LOWNEY**
  - Associate Director, Late Development Portfolio and Stability Sciences, Janssen
- **FERRER ALCIRA**
  - Professor of Molecular Medicine, University of Nottingham
- **FRANCESCA BUTTINI**
  - Associate Professor, University of Parma
- **CARSTEN EHRHARDT**
  - Professor in Pharmaceutics and Biopharmaceutics, Trinity College Dublin
- **PAUL HAGEDOORN**
  - Head of Inhalation Research Laboratory, University of Groningen

**Conference Sponsor:**
- **Intec Pharma**

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**CONFIRMED SPEAKERS**

### Formulation & Delivery Series UK: Agenda at a Glance

**Featured Workshop & Panel Discussion on Patient-Centric Drug Development**

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**Day 2, Stream 5:**
- Downstream Processing
  - Part 1: Recent Technological Advancements, Automation and Latest Trends
    - Streamlining downstream bioprocessing
    - High-throughput process development for non-platform recombinant proteins
    - Single-use technologies
    - Technology Transfer
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  - Head of Inhalation Research Laboratory, University of Groningen

**Conference Sponsor:**
- **Intec Pharma**
07:30 - 08:20
Registration

08:20
Conference Room 1
Oxford Global Welcome Address

08:25
Chairperson’s Opening Address

08:30 - 09:00
Co-Located Keynote Address: Intranasal Delivery Of Peptide Therapeutics – Current Challenges And Future Perspectives
- Common limitations and physiology constraints
- Aspects of non-clinical development related to nasal administration
- Currently marketed nasal peptide and drugs. Why so few? Why so poor bioavailability?
- Adding chemistry to nasal drug delivery design
ALAN HARRIS, Senior Vice President, Global R&D Life Cycle Management, Ferring Pharmaceuticals

STREAM 1: SMALL MOLECULE FORMULATION
Stream Chair: JOHN MCDERMOTT, Executive Director and Head, Drug Development Solutions (EMEA) Quotient Sciences

STREAM 2: BIOLOGICS DRUG DELIVERY
Stream Chair: CHRISTIAN SCHNEIDER, Program Specialist & Technical Customer Service, Celeneh

STREAM 3.1: STABILITY, BIOANALYSIS & CHARACTERISATION
Stream Chair: CHRISTIAN SIEG, Application Scientist, Wyatt Technologies

Topical Drug Delivery – Similarities And Differences Across The Delivery Routes
- Different topical routes of delivery
- Preformulation and formulation development
- Formulation characterisation
- Unique performance models available – Nasal routes of delivery
ROB TURNER, General Manager, MedPharm

Solution Provider Presentation
EMERGO by UL

Solution Provider Presentation

Defining Molecules For Long Acting Injectable And Potential Formulation Strategies
- Tech How to define the dose and duration for a compound to be implemented in a long acting injectable formulation
- Available formulation strategies for long acting injectables
RENÉ HOLM, Head and Scientific Director, Drug Product Development, liquids and Parenterals Janssen

BEPO®: A Bioresorbable In Situ Forming Depot Long-Acting Injectable With Flexible Drug Delivery Kinetics Modulation
- Presentation of BEPO® technology
- Tunable parameters for modulating the release kinetics
- Case studies with small molecules and macromolecules via different administration routes
ADOLFO LOPEZ NORIEGA, Head of Applied Research Activities, MedinCell

Early-To-Late Stage Characterisation For Antibody Therapeutics
- Phase appropriate characterization
- How to base the characterization needs on critical quality attributes
- Front-loading for project acceleration
CHRISTOPH ROESLI, Senior Fellow, Global Drug Development, Novartis Pharma AG

09:00 - 09:30
Saturday, 22 April 2023

09:30 - 10:00
Morning Coffee & Refreshments, One To One Meetings x4, Poster Presentation Sessions

09:30 - 10:00
Stream Keynote Address: Stabilization Of Poor Glass-Forming APIs With Mesoporous Silica
- Very few APIs with poor glass-forming ability (GFA-I) make it into commercial drug product formulations
- Strong re-crystallization tendency makes the development of a stable solid dosage form extremely challenging
- Mesoporous silica is an inert carrier material that stabilizes small molecule APIs in its amorphous form
- Case studies show stable formulation of different poor glass forming APIs with mesoporous silica benchmarking this technology against traditional amorphization technologies
FINN BAUER, Head of Solid Formulations R&D, Merck KGaA

Stream Keynote Address: Combination Products for Sub-cutaneous Delivery – Development and Compliance Considerations
- Linking Drug/Device Combination Products: Terminology Bridge for Drug and Device Development
- Development Considerations for Delivery Device Product Optimization and integration of Customer Needs
- Learnings around Bridging Studies from Clinical Commercial for Combination Products
- Compliance Considerations for Combination Products – De-mystifying Device Requirements
THERESA SCHEUBLE, Director, R&D, Johnson & Johnson Enterprise

Stream Keynote Address: Digitalisation Innovation For Lab Automation And FAIRization Of Analytical Data
MICHAEL SIEDLER, Head of NBE Formulation Development, Abbvie
Tablet formulations for polymer based amorphous solid dispersions (ASDs) are commonly developed on a case-by-case basis depending on the drug-polymer combination.

There is a lack of systematic investigations on how an incorporated API influences the material properties of an amorphous solid dispersion.

The presented work investigates the impact of different drugs and their drug loads on material properties of the obtained ASD with the focus on mechanical properties and disintegration behavior.

Where are the most pressing innovation gaps in C&GT delivery system?

How and where to maximize impact of delivery system in C&GT?

ROBERT HENNIG, Associate Director, Merck KGaA

HICHAM MAJD, Device Project Leader - New Technologies, Novartis

OLIVIER BRASS, Senior Scientist, Head of Research Unit, Sanofi

Delivery of highly viscous solutions: use of high-strength materials in injection devices for managing ever increasing spring loads.

Continuous drug delivery through smart wearables: high-flow materials for efficient molding of complex intricate geometries in compact devices.

Very long-acting depot formulations of small peptides and large proteins: innovating formulation concepts established in small molecule delivery for biologics.

CHRISTIAN SCHNEIDER, Program Specialist & Technical Customer Service, Celanese

Processability issues during drug product development are often triggered by drug substance variability or scale-up effects.

Powder rheological and mechanical properties are mostly not assessed at all or at least standard methods are missing. Therefore, we need to characterize our drug substances, excipients and powder blends in an appropriate manner and better understand how we can use these parameters to predict processability and optimize our formulations.

SONALI BOSE, Technical Project Leader & Fellow, Novartis

ARPAN DESAI, Associate Principal Scientist, AstraZeneca

CAROLIN AUCH, Principal Scientist, Merck KGaA

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<table>
<thead>
<tr>
<th><strong>STREAM 1: SMALL MOLECULE FORMULATION</strong></th>
<th><strong>STREAM 2: BIOLOGICS DRUG DELIVERY</strong></th>
<th><strong>STREAM 3.2: FORMULATION &amp; DELIVERY FOR NANO &amp; RNA THERAPIES</strong></th>
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<tbody>
<tr>
<td><strong>Dispersomes® - Next Generation Excipient Technology To Improve Small Drug Molecule Solubility</strong></td>
<td><strong>Solution Provider Presentation</strong></td>
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<tr>
<td>KORBINIAN LÖBMANN, Chief Scientific Officer, Zerion</td>
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<td><strong>Analysis From The Tufts Center For The Study Of Drug Development To Assess The Financial Benefits From Translational Pharmaceutics®: A Platform For Accelerating Product Development</strong></td>
<td><strong>Solution Provider Presentation: Reserved For Datwyler</strong></td>
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<td>JOHN MCDERMOTT, Executive Director and Head, Drug Development Solutions (EMEA), Quotient Sciences</td>
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<td><strong>Application Of Material Properties And Process Simulation to Hot-Melt Extrusion of Amorphous Solid Dispersion Formulations</strong></td>
<td><strong>Dosing Of Drug Products To The Geriatric Population And In Vitro Methodologies</strong></td>
<td><strong>Intracellular Delivery Of RNA By Transfection Reagent Based Nanoparticle Systems</strong></td>
</tr>
<tr>
<td>RACHEL C. EVANS, Senior Scientist, AbbVie</td>
<td>NATALIE SANDERSON, Senior Analytical Scientist, Global Product Development, AstraZeneca</td>
<td>DINA ZHANG, Director, Preformulation In Pharmaceutical Sciences, MSD</td>
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<td><strong>ASAP (Accelerated Stability Assessment Program) Methodology With Case Studies</strong></td>
<td><strong>Ocular Drug Delivery - Making Great Drugs Better</strong></td>
<td><strong>RNAntibody® As A Therapeutic Option</strong></td>
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<tr>
<td>SABINE THIELGES, Principal Scientist, Novartis</td>
<td>RAJ THAKUR, Chief Scientific Officer &amp; Reader in Pharmaceutics, Re-Vana Therapeutics/ Queen’s University Belfast</td>
<td>PATRICK BAUMHOF, Senior Vice President, Formulation &amp; Drug Delivery, CureVac</td>
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<td><strong>Afternoon Coffee &amp; Refreshments, One To One Meetings x3, Poster Presentation Sessions</strong></td>
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**6th Annual Formulation & Drug Delivery Congress**
**DAY ONE: 22 APRIL**
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speaker Comment</th>
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<tbody>
<tr>
<td>17:50</td>
<td>Crystallisation – A Matter Of Patience</td>
<td>SOPHIE JANBON, Senior Scientist, Team Manager and APS Crystallisation, AstraZeneca</td>
</tr>
<tr>
<td>18:20</td>
<td>Oral Delivery Of Biologics With An Unrivaled Formulation Technology</td>
<td>JAAW WIELING, Chief Executive Officer, BioOraliX</td>
</tr>
<tr>
<td>18:50</td>
<td>Small Molecule Injectable Formulations</td>
<td>BINDHU RAYAPROLU, Senior Scientist, American Regent</td>
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<tr>
<td>19:20</td>
<td>Opportunities And Challenges Of Protein Delivery Systems</td>
<td>PIERRE MAUDENS, Principal Scientist, Novartis</td>
</tr>
<tr>
<td>19:50</td>
<td>Long-Term Stability of Amorphous Solid Dispersions</td>
<td>GABRIELE SADOWSKI, Professor, TU Dortmund</td>
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<tr>
<td>20:10</td>
<td>Intestinal Permeation Enhancers In Oral Peptide Delivery Constructs</td>
<td>DAVID BRAYDEN, Professor of Advanced Drug Delivery, University College Dublin</td>
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<tr>
<td>20:30</td>
<td>Networking Drinks And End Of Day One</td>
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**STREAM 1: SMALL MOLECULE FORMULATION**

- Crystallisation – A Matter Of Patience
  - Presentation on AZ crystallisation process development approach
  - Case studies showing some key challenges encountered when developing crystallisation processes

**STREAM 2: BIOLOGICS DRUG DELIVERY**

- Oral Delivery Of Biologics With An Unrivaled Formulation Technology
  - Oral dosing of biologics is one of the major challenges in biopharmaceutical development, there are major hurdles that need to be dealt with. We have developed an innovative approach to manufacture formulations suitable for dosing biologics orally and manage these hurdles. For this new formulation, existing manufacturing technologies and various GRAS excipients have been utilized to obtain formulated monoclonal antibodies that are delivered to the GI tract in a capsule and subsequently taken up into circulation for systemic availability.
  - Omalizumab was the first Mab that we have tested this technology with in-vivo. Formulated omalizumab has been tested in 3 preclinical studies.
  - Various dosing levels and dosing routes were tested and compared.
  - The studies provided outstanding PK results for the oral formulation, with linear pharmacokinetics and high bioavailability.
  - We also demonstrated that omalizumab as a molecule remained intact and functional regardless the administration route, demonstrating the absence of a potential first-pass effect

**STREAM 3.2: FORMULATION & DELIVERY FOR NANO & RNA THERAPIES**

- Exploiting The Therapeutic Value Of LIF Using NanoTechnology
  - We are using NanoBioMedicine for targeted delivery of LIF, providing a transient, safe, scalable biomimetic "Stem Cell" with stemness properties for neuroprotection.
  - Multiple Sclerosis is our first indication, with clinical trial requirements in place.
Stream Keynote Address: Development Of A Freeze-Dried Antigen-Expressing Adenoviral Vector Platform

- Adenoviral vectors represent a vaccine delivery platform whereby the nucleic acid sequence encoding the immunogenic protein is incorporated into the adenoviral genome.
- The use of chimpanzee adenoviruses brings two main benefits. First, adenoviruses naturally elicit an immune response composed of antibodies and CD8+ T-cells. Second, humans have low preexisting immunity against chimpanzee adenoviruses.
- However, it has been a challenge to develop stabilizing formulations for simian adenoviral vectors which allow storage at acceptable temperatures (out of the freezer) with an adequate shelf life.
- The conjunction of key freeze-drying parameters with a specially developed matrix composition suited to simian adenoviruses allowed to reduce the infectivity loss from initially 2 log to ≤0.3 log during the lyophilization step when those formulation parameters were applied.

FREDERIC MATHOT, Scientific Leader, Drug Product Development - Global Vaccines R&D, GlaxoSmithKline

Solution Provider Presentation

unchained labs

Aptar

Morning Coffee & Refreshments, One To One Meetings x2, Poster Presentation Sessions

Pharmaceutical Development Of IgG Scaffold Based Multi-Specific Antibodies

- Insights on the design of early development phase drug product and formulation
- Challenges in the pharmaceutical development of very low concentration dosage forms for highly potent molecules

NAILA EL KECHAI, Drug Product Team Leader, Biologics Development, Sanofi

Tackling The Formulator Information Challenge

Human-curated databases enable formulators to efficiently source information

- Data is critical for formulation success. For efficient product development, formulators need access to information regarding existing formulations, the physical and chemical properties of particular ingredients (from melting point to pH to solubility, for instance), and the potential sources and costs of these ingredients.
- Developing innovative products – including pharmaceuticals, cosmetics, agrochemicals, and consumer goods – hinges upon acquiring good data up front in the formulating process. Human-curated research tools remove hurdles to allow formulators to do what they do best and focus on innovating.
- Learn from an industry expert on easier ways you can now source the data you need to have fewer iterative trials, save time and improve efficiency across every stage of the development process (from initial research to number of iterations

MOLLY STRAUSBAUGH, Assistant Director, Product & Content Operations, CAS, A Division of the Americal Chemical Society
<table>
<thead>
<tr>
<th>Time</th>
<th>Stream 1: Biopharmaceutical Formulation</th>
<th>Stream 2.1: Small Molecule Drug Delivery</th>
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<tbody>
<tr>
<td>12:00</td>
<td>Trehalose And Sucrose: Essential Components Of Platform Biopharma Formulations</td>
<td>Solution Provider Presentation</td>
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<tr>
<td>12:30</td>
<td>• Commercial Biotherapeutics Stabilized with Trehalose</td>
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<tr>
<td></td>
<td>• Commercial Biotherapeutics Stabilized with Sucrose</td>
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<td></td>
<td>• Key issues in Biopharma Formulation Development</td>
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<td>• Essential components of a “Platform Biopharma Formulation”</td>
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<td>• Understanding important physicochemical properties of Trehalose and Sucrose</td>
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<td>• Instability of sucrose at low pH – free glucose, protein glycation</td>
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<td>• Phase transition and crystallization of trehalose</td>
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<td>• Importance of Control of Glucose levels in Sucrose as well as Trehalose</td>
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<td>• Purity, Quality, Consistency in Pfanzstiehl’s Trehalose and Sucrose</td>
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<td>• β-glucans in sucrose – interference with endotoxins</td>
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<td>• Trace metal specifications for Sucrose and Trehalose</td>
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<td>• Advantages of Trehalose over Sucrose</td>
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<td>• Pfanzstiehl’s Biopharma Stabilization Portfolio incl. newly launched L-Arginine and L-Histidine</td>
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<td></td>
<td>• Conclusions</td>
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<td>Tfanstiehl, Inc.</td>
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<td>12:30</td>
<td>Patient-Centric Formulation Development</td>
<td>Improving Diabetes Care Through Novel Formulation &amp; Delivery Platforms</td>
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<td>12:30</td>
<td>• Pediatric plans and realities</td>
<td>• SARAH HOWELL, Chief Executive Officer, Arecor</td>
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<td>13:00</td>
<td>• Chronic administration to heavily ill patients</td>
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<td>• Taste masking and concealing approaches</td>
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<td></td>
<td>DAINIUS MACIKENAS, Director, Formulation, Retrophin, Inc.</td>
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<td>13:00</td>
<td>Lunch, One to One Meetings x2, Poster Presentation Sessions</td>
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<tr>
<td>13:00</td>
<td>STREAM 1: Biopharmaceutical Formulation</td>
<td>STREAM 2.2: Drug Product Manufacturing</td>
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<tr>
<td>14:00</td>
<td>In-Use Challenges For Low Dose Administration Of Biologics</td>
<td>Early Phase Oral Dose Formulation</td>
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<td>14:30</td>
<td>• To enable safe and accurate administration to patients during clinical studies, a close collaboration between pharmaceutical development and the clinical team is needed early on in the development to reach the goal to establish a suitable and stable Drug Product (DP) formulation composition (concentration, excipients)</td>
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<td>• Further interaction with clinical operations is needed to find acceptable diluents and procedures for the in-use applications. The pharmaceutical developer performs in-use stability and simulated administration studies to design a safe and robust administration process and defined parameter space for regulatory filings and site guidelines</td>
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<td>• This presentation highlights critical input as well as expected output from in-use studies and challenges to consider, especially for low concentrations, low doses and low dose volumes</td>
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<td>JONAS FAST, Principal Scientist, Pharmaceutical Development &amp; Supplies, PTD Biologics Europe, F. Hoffman-La Roche AG</td>
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<tr>
<td>14:30</td>
<td>A Newly Identified Impurity in Polysorbate 80, the Long-Chain Ketone 12-Tricosanone, Forms Visible Particles in a Biopharmaceutical Drug Product</td>
<td>Small Molecules Delivery To Pediatrics Population: Challenges, Guidance And Formulation Innovation Landscape</td>
</tr>
<tr>
<td>15:00</td>
<td>• Visible particles in PS80 containing formulation</td>
<td>• Key challenges encountered by the pharmaceutical development for the oral delivery of small molecules drugs to the pediatrics population</td>
</tr>
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<td>• Free fatty acid particles</td>
<td>• Development decision tree to support a new pediatric project in the pipeline established based on regulatory guidelines, review of authorized excipients and other data bases</td>
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<td>• GC-MS identification</td>
<td>• Landscape of innovative formulation technologies and devices for accurate dose dispensing</td>
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<td>12-tricosanone</td>
<td>MATHILDE LORSCHIEIDER, Senior Scientist, Formulation Technology, Pharmaceutical Development, Ipsen</td>
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<td>VERONIKA HAMPL-RONGE, Principal Scientist, Novartis</td>
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<td>Time</td>
<td>Stream 1: Biopharmaceutical Formulation</td>
<td>Stream 2: Drug Product Manufacturing</td>
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<td>15:00 - 15:30</td>
<td><strong>Accelerated Predictive Stability For Bioproducts</strong></td>
<td><strong>Stress Factors For Biologicals In The Drug Product Manufacturing - Its Impact On Product Quality And Control Strategy</strong></td>
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<td>• Data in few months to predict few years stability behavior</td>
<td>• Hold times for drug substance and drug product</td>
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<td>• Using accelerated stability data to develop appropriate kinetic models</td>
<td>• Process characterization studies</td>
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<td>• Anticipate impact of cold chain breaks</td>
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<td>• Real time shelf-life monitoring during shipments</td>
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<td>• Accelerate ranking of formulations and batch-to-batch</td>
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<td>DIDIER CLENET, Senior Scientist, Formulation &amp; Stability - R&amp;D, Sanofi</td>
<td>MARTINA RÖHM, Associate Director, Formulation &amp; Process Development Late Stage, Boehringer Ingelheim</td>
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<td>15:30 - 16:00</td>
<td><strong>Challenges In Developability And Formulation For Complex, Highly Potent Immunotherapy Molecules</strong></td>
<td><strong>Challenges And Opportunities In Transfer Of Manufacturing Process Between Different Sites</strong></td>
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<td>• Immunocore’s novel bispecific biologics modality (ImmTACs) which have the potential</td>
<td>• Tech transfer challenges for small molecule processes</td>
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<td>to access multiple types of cancer antigens and combine high target specificity with high potency</td>
<td>• Opportunies and future of tech transfer for small molecules</td>
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<td>• Focus will be on the developability challenges in delivery of these complex</td>
<td>• Tech transfer challenges while working with CMOs</td>
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<td>immunotherapy molecules to patients</td>
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<td>• Formulating for the maintenance of safe, stable, low concentration dosing</td>
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<td>FRAYNE BIANCHI, Senior Scientist, Formulation &amp; Drug Delivery, Immunocore</td>
<td>SHILPA THOSAR, Associate Director, Commercial CMS Science Group, Takeda</td>
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<td>16:00 - 16:30</td>
<td><strong>Hard-To-Formulate Biologics</strong></td>
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<td>• What are BoNTs?</td>
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<td>• Challenges to BoNT formulations</td>
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<td>• Overcoming these challenges.</td>
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<td>SAIF SHUBBER, Formulation Team Leader, Ipsen</td>
<td>JANE SHAW, Global Head of Quality Management Systems For Solids Platform, Novartis</td>
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<td>16:30 - 17:00</td>
<td><strong>Mesoporous Silica For The Potential Oral Delivery Of Biologics</strong></td>
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<td>• Development of solid core drug delivery systems that involves immobilisation of</td>
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<td>biologics on mesoporous silica particles followed by coating with fatty acids</td>
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<td>• Immobilisation and coating provide enteric properties to the formulation capable of</td>
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<td>withstanding harsh gastric conditions and allowing the release in upper intestine</td>
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<td>• The coating performed via melt deposition method in supercritical CO2 (scCO2)</td>
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<td>ensures that the exposure to harsh processing conditions associated with traditional</td>
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<td>techniques can be avoided</td>
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<td>VIVEK TRIVEDI, Lecturer in Chemistry &amp; Drug Delivery, Medway School of Pharmacy, University of Kent</td>
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<td>17:00 - 17:30</td>
<td><strong>Site Control Strategy</strong></td>
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<tr>
<td>CATHRINA HOULIHAN, Site Control Strategy Lead, Sanofi Genzyme</td>
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<td>17:30 - End Of Conference</td>
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<tr>
<td>07:30</td>
<td>Registration</td>
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<td>08:20</td>
<td><strong>Inhalation &amp; Respiratory Drug Delivery</strong></td>
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<td>08:20</td>
<td>Conference Room: Oxford Global Welcome Address</td>
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<td>08:25</td>
<td>Chairperson’s Opening Address</td>
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<td>08:30</td>
<td>Keynote Address: Inhaled Insulin And Other Biologicals</td>
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<td>JOHN PATTON, Founder, Board Member and Strategic Advisor, Aerami</td>
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<td>09:00</td>
<td><strong>Stream 4: Development &amp; Formulation of Inhaled Therapies</strong></td>
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<tr>
<td>09:00</td>
<td>Stream Keynote Address: Inhaled Targeted-Inhibition Of Galectin-3 Dose Dependently Blocks Plasma Biomarkers In Patients With Idiopathic Pulmonary Fibrosis</td>
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<tr>
<td></td>
<td>1. Galectin-3 is a key regulator of fibrosis</td>
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<td>2. TD-139 is a specific Galectin-3 inhibitor formulated for inhaled treatment</td>
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<td>3. TD139 is safe and well tolerated in man</td>
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<td>4. TD-139 demonstrated dose dependent target engagement</td>
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<td>5. TD-139 specifically decreases in plasma biomarkers associated with IPF progression</td>
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<td>6. Suggesting inhaled TD-139 is a potential novel therapy for IPF</td>
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<td>TARIQ SETHI, Co-Founder, Galacto Biotech and Former Chief Scientist Vice President Clinical Development Unit, AstraZeneca</td>
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<td>09:30</td>
<td>Solution Provider Presentation</td>
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<td>10:00</td>
<td>Morning Coffee &amp; Refreshments, One To One Meetings x4, Poster Presentation Sessions</td>
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<tr>
<td>11:20</td>
<td>Aerosol Microphysics On Inhalation</td>
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<td>1. Aerosols are dynamic and evolve from the point of generation, during transport and prior to deposition in the respiratory tract</td>
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<td>2. Aerosol particles respond to changes in relative humidity and temperature dependent on their phase state (solution or crystalline) and size</td>
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<td>3. It is possible to formulate particles so that the aerosol responds in a preferred way, responding in phase, moisture content and size</td>
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<td>JONATHAN REID, Professor of Physical Chemistry, University of Bristol</td>
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<td>11:50</td>
<td>Isothermal Dry Particle Coating: A Novel Manufacturing Method For Delivering Difficult Drugs</td>
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<td></td>
<td>1. Principle of thin layer fluidisation</td>
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<td>2. Design of experiments for the formulation of fixed dose combinations</td>
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<td>3. Formulation and performance testing of high dose (higher than 5%w/w) formulations</td>
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<td>4. Potential for delivery of biologicals</td>
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<td>AFZAL MOHAMMED, Professor, Chair in Pharmaceutics, Aston University</td>
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<td>12:20</td>
<td>Solution Provider Presentation</td>
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<td>12:20</td>
<td>Lunch, One To One Meetings x3, Poster Presentation Sessions</td>
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<td>13:50</td>
<td>Mechanistic Profiling Of The Release Kinetics Of siRNA From Lipidoid-Polymer Hybrid Nanoparticles In Vitro And In Vivo After Pulmonary Administration</td>
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<td>CAMILLA FOGED, Professor of Vaccine Design and Delivery, University of Copenhagen</td>
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5th Annual Inhalation & Respiratory Drug Delivery Congress
DAY ONE: 22 APRIL

STREAM 4: DEVELOPMENT & FORMULATION OF INHALED THERAPIES

Accurate Dosimetry Predictions For Evolving Liquid Aerosol Mixtures
• Aerosol evolution as challenge in accurate dosimetry predictions
• Aerosol dosimetry requires joint experimental and computational efforts
• AeroSolved developed as computational fluid dynamics (CFD) package for complex aerosol simulations
• Linking aerosol dosimetry with physiologically based pharmacokinetic (PBPK) modeling
ARKADIUSZ KUCZAJ, Manager, Aerosol Research and Dosimetry, Philip Morris International

Solution Provider Presentation

Pharmacometric Approaches To Evaluate Pulmonary Selectivity Of Orally Inhaled Drugs – Is Inhalation Meaningful For All Respiratory Diseases And All Inhaled Drugs?
• Pharmacometric analyses represent mathematical approaches, which allow evaluating systemic (plasma) as well as pulmonary concentration-time profiles
• It will be presented how the combination of preclinical data and pharmacometric analyses allow to learn about the pulmonary selectivity of potential drug candidates
JENS BORGHARDT, Principal Scientist Modelling & Simulation, Boehringer Ingelheim

Pulmonary Drug Delivery Of Macromolecules
AYCA YILDIZ, Associate Professor, Istanbul Universitesi

Networking Drinks And End Of Day One

DAY TWO: 23 APRIL

STREAM 1: BIOPHARMACEUTICAL FORMULATION

Stream Keynote Address: Development Of A Freeze-Dried Antigen-Expressing Adenoviral Vector Platform
• Adenoviral vectors represent a vaccine delivery platform whereby the nucleic acid sequence encoding the immunogenic protein is incorporated into the adenoviral genome
• The use of chimpanzee adenoviruses brings two main benefits. First, adenoviruses naturally elicit an immune response composed of antibodies and CD8+ T-cells. Second, humans have low preexisting immunity against chimpanzee adenoviruses
• However, it has been a challenge to develop stabilizing formulations for simian adenoviral vectors which allow storage at acceptable temperatures (out of the freezer) with an adequate shelf life
• The conjunction of key freeze-drying parameters with a specially developed matrix composition suited to simian adenoviruses allowed to reduce the infectivity loss from initially 2 log to ≤0.3 log during the lyophilization step when those formulation parameters were applied
FREDERIC MATHOT, Scientific Leader, Drug Product Development - Global Vaccines R&D, GlaxoSmithKline

STREAM 3: INHALATION DEVICES & COMBINATION PRODUCTS

Connected Inhalers
MARK MILTON-EDWARDS, Head of Product & Health Solutions - Digital Health, Teva

FORMULATION & DRUG DELIVERY UK CONGRESS
Stream Chair: TBA

STREAM 1: BIOPHARMACEUTICAL FORMULATION

Stream Keynote Address: Development Of A Freeze-Dried Antigen-Expressing Adenoviral Vector Platform
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FREDERIC MATHOT, Scientific Leader, Drug Product Development - Global Vaccines R&D, GlaxoSmithKline

STREAM 3: INHALATION DEVICES & COMBINATION PRODUCTS

Connected Inhalers
MARK MILTON-EDWARDS, Head of Product & Health Solutions - Digital Health, Teva

For sponsorship opportunities please contact sponsorship@oxfordglobal.co.uk
5th Annual Inhalation & Respiratory Drug Delivery Congress
DAY TWO: 23 APRIL

STREAM 3: INHALATION DEVICES & COMBINATION PRODUCTS

09:30 - 10:00
Solution Provider Presentation

10:00 - 11:00
Morning Coffee & Refreshments, One To One Meetings x3, Poster Presentation Sessions

11:00 - 11:30
Digital Inhalers: Recent, Future Studies And A New Way To Manage Asthma And COPD Patients
GUILHERME SAFIOTI, Global Medical Director, Teva Digital Respiratory, Teva

11:30 - 12:00
Solution Provider Presentation

12:00 - 12:30
Solution Provider Presentation

12:30 - 13:00
Effect Of Device Design On The In Vitro Performance Of Capsule-Based Dry Powder Inhalers
HLACK MOHAMMED, Analytical Science & Technology Director, GlaxoSmithKline

13:00 - 14:00
Exhibition Area
Lunch, One To One Meetings x3, Poster Presentation Sessions

14:00 - 14:30
Applying The TRIZ Methodology To Medical Device Innovations
• What is TRIZ?
• Five Stage TRIZ Model for Medical Device Innovations
• Application of TRIZ to Combination products
RENE DATHE, Head Medical Devices Quality Development, Novartis

14:30 - 15:00
Health Informatics For Asthma And COPD
• What data resources are available on asthma and COPD?
• How can these be used to help design treatment strategies?
• Introduction to BREATHE, the HDRUK respiratory digital innovation hub
IAN HALL, Professor of Molecular Medicine, University of Nottingham

15:00 - 15:30
In Vitro Dissolution Methodologies For Generic Product Development
FRANCESCA BUTTINI, Associate Professor, University of Parma

15:30 - 16:00
Exhibition Area
Afternoon Coffee & Refreshments, One To One Meetings x3, Poster Presentation Sessions

16:00 - 16:30
In Vitro And Ex Vivo Models For Drug Deposition Studies
CARSTEN EHRHARDT, Professor in Pharmaceutics and Biopharmaceutics, Trinity College Dublin

16:30 - 17:00
How Patient Technique Influences Deposition; With A Case Study On Parkinson’s Disease
PAUL HAGEDOORN, Head of Inhalation Research Laboratory, University of Groningen

17:00
End Of Conference
Biomanufacturing Congress
DAY ONE: 22 APRIL

07:30 Registration

08:20 Conference Room 4
Oxford Global Welcome Address

08:25 Chairperson's Opening Address

08:30 - 09:00
Keynote Address: Title TBA
OTMANE BOUSSIF, Global Head Cell & Gene Therapy Technical R&D, Novartis

09:00 - 09:30
STREAM 5: CELL & GENE THERAPY BIOMANUFACTURING: INSIGHTS, KEY STRATEGIES & NOVEL APPROACHES
Stream Chair: TBA, Senior Representative, Miltenyi Biotec

Stream Keynote Address: Analytical Development For Cell & Gene Therapies (Title TBA)
KATHARINE A. MILLER, Vice President, Analytical Operations, Orchard Therapeutics

09:30 - 10:00
Solution Provider Presentation

SPEAKER, Senior Representative, Miltenyi Biotec

09:30 - 10:00
STREAM 6: UPSTREAM PROCESSING, SMART FACTORIES, DIGITALISATION, TOOLS & TECHNOLOGIES
Stream Chair: TBA

Stream Keynote Address: Industry 4.0 Topics In Commercial Manufacturing
PAUL HANSON, Senior Director, Technical Operations, Takeda

10:00 - 11:20
Morning Coffee & Refreshments, One to One Meetings x4, Poster Presentation Sessions

11:20 - 12:20
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

11:20 - 12:20
Upstream Process Transfer For Cell Culture

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

11:50 - 12:20
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

11:50 - 12:20
Bioreactor Selection For Large-Scale Cell Production

STEFFEN KREYE, Head of Lab, Upstream Process Development, Bayer
**STREAM 5: CELL & GENE THERAPY BIOMANUFACTURING: INSIGHTS, KEY STRATEGIES & NOVEL APPROACHES**

**Applying Machine Learning in Bioprocess Development Strategies**

13:50 - 14:20

MARK TOMISHIMA, Senior Director, CNS Bioprocess, BlueRock Therapeutics

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

14:20 - 14:50

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

**Solution Provider Presentation**

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

**HCP Analysis By LCMS To Support Process Development Of Biologics**

12:50 - 13:20

M. Fuchs, Principal Scientist, Novartis

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

13:50 - 14:20

W. O. Loughu, Principal Scientist, Ipsen

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**Transforming Cell Therapy Product And Manufacturing Concepts With Gene Editing**

16:50 - 17:20

R. Baptista, Director, Process & Analytical Development, Cellectis

**Analytical Influence On Commercial Manufacture Of Autologous Gene Therapies**

17:20 - 17:50

Ch. Salgado, Scientific Leader, Cell & Gene Therapy Platform CMC, GlaxoSmithKline

**Analytical Approaches For The Characterisation Of AAV Vectors**

17:50 - 18:20

F. Dorange, Head of Analytical Development, Genethon

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Delegates are Welcome to Attend the Co-Located Sessions
Upscale Bioprocessing

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

Networking Drinks & End of Day One

Delegates are Welcome to Attend the Co-Located Sessions

BIOMANUFACTURING CONGRESS

Keynote Address: Leadership And Expertise: People At The Heart Of Biomanufacturing

CLAUS TOLLNICK, Managing Director, Ferring Pharmaceuticals

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

Stream Chair: TBA

Stream Keynote Address: Biologics Stability Analytical Development

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

Solution Provider Presentation

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

Stream Chair: TBA

Stream Keynote Address: High-Throughput Process Development For Non-Platform Recombinant Proteins

- Microbial expression
- Downstream Process Development
- High-Throughput Process Development
- Automation & parallelization

CÉCILE BROCARD, Director, Downstream Development, Bioprocess Science, Boehringer Ingelheim

Solution Provider Presentation

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09:00 - 09:30

09:30 - 10:00

10:00 - 10:30

11:00 - 11:30

11:30 - 12:00

12:00 - 12:30

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

Shifting Biomanufacturing From Exploratory Research To Implementation And Scale-Up

JESSICA BARTLEY, External Site Operations Lead, Servier

Solution Provider Presentation

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Advancing Downstream Process Development Through Data Analyses And In-Silico Models

ALEXANDER WIEDENMANN, Associate Director, Protein Science and Lab Head, Boehringer Ingelheim

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

### Development & Manufacture Of A New bbmAb

- Bivalent IgG1 like bispécifique 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 bi spécifique is targeting two major infl ammasome eff ectors IL-1β and IL-18

MICHAEL BARDROFF, Associate Director NBC Project Management, Novartis

### Challenges And proposed Solutions For Building Manufacturing Quality/Compliance At A Green Field Project

RAMZAN TABASUM, Head of Site Manufacturing Quality and Compliance Management, CSL Behring

### Breakthrough Therapy Means No Break For CMC

CHONGHUI GUI, Head of CMC, Agios Pharmaceuticals

### 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

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

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

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

- An introduction to Th rough 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

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

### Title TBA

- UWE DEMELBAUER, Head of DS Process Development, Novartis

### 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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**STREAM 5.2: DOWNSTREAM PROCESSING: PROCESS ANALYTICAL TECHNOLOGIES FOR BIOLOGICS**

### 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

### 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

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**End Of Conference**
ILEC Conference Centre
IBIS London Earl's Court
47 Lillie Road, London, SW6 1UD, UK
Tel: +44 (0)20 7666 8470

The ILEC Conference Centre is best known for the formidable flexibility and large capacity of its conference hall. Based in the heart of West London and only a short ride away from London's greatest landmarks, the venue is an ideal location for UK and overseas visitors.

The hotel is easily accessible by rail, car, and air. Detailed travel directions can be found at: [www.oxfordglobal.co.uk/formulation-delivery-series-uk/](http://www.oxfordglobal.co.uk/formulation-delivery-series-uk/)

Oxford Global has secured a number of bedrooms at the IBIS London Earls Court at a reduced conference rate:

**Tuesday 21st April 2020** – £112 including VAT and breakfast

**Wednesday 22nd April 2020** – £112 including VAT and breakfast

*£10 supplement per night for double occupancy*

Should you wish to book a room, please [click here](http://www.oxfordglobal.co.uk/formulation-delivery-series-uk/).

You will need to create an account and provide credit card details for payment, in order to book your accommodation. The final cut-off date to book these bedrooms is 22nd March 2020 – any bookings after this date are subject to availability and rates. Please note all bookings are made through the hotel and all enquiries regarding your bookings should be made directly to Ibis.
**Delegate Details**

Please complete fully and clearly. Please photocopy for additional delegates.

Please tick which event(s) in the Series you are interested in:
- Formulation & Drug Delivery Congress
- Inhalation & Respiratory Drug Delivery Congress
- Biomanufacturing Congress

Title: _______________________ Forename: ___________________ Surname: ____________________
Job Title: ________________________
Company/Organisation: ____________________________
Email: ___________________________
Address: __________________________
Postcode: _________________________
Country: _________________________
Direct Telephone: ________________ Direct Fax: ______________
Mobile: _________________________ Switchboard: _______________
Signature: ______________________ Date: _______________________

**Registration Fees: 3 events in 1**

I would like to attend: (Please tick as appropriate)

**Industry Delegates (Biopharma, Pharma or Biotech Companies)**
- 2-day pass £899 plus VAT
- 1-day pass £599 plus VAT
  
  **Day 1**
  - Day 2

**Academic Delegates**
- 2-day pass £520 plus VAT
- 1-day pass £320 plus VAT
  
  **Day 1**
  - Day 2

**Vendor Delegates**
(CROs, Consultants, Technology and Service Providers)
- Series Only £1750 plus VAT
- Poster Presentation £250 plus VAT

**PROMOTIONAL LITERATURE DISTRIBUTION**
- Distribution of your company's promotional literature to all Series attendees £999 plus VAT

**Terms & Conditions of Booking**

Agreed Terms between the Organiser (Oxford Global Marketing Ltd) and the Delegate

**Delegate Booking Fee**
The Delegate Booking Fee includes lunches and refreshments throughout the Series, presentations and panel sessions, scheduled one-to-one meetings and networking/social events, Senior and speaker notes. Delegates may attend free of charge, all sessions arranged by the Organiser.

An admin surcharge of £50 plus VAT will be applied to payments settled following the receipt of an invoice. This charge will not be applied to payments settled online.

Vendor Delegates will not be eligible for one to one meetings unless they purchase a sponsorship meetings package. These can only be purchased directly from Oxford Global Marketing Ltd and not via the online booking facility.

**Acceptance of a Complimentary Pass**
If you are offered a free delegate pass and you are unable to attend the Series, you may nominate a substitute of equal standing in terms of business and financial responsibility. A substitute delegate must be nominated within a week of cancellation and must be approved by the Organiser in advance in order to avoid a non-attendance charge of £200 plus VAT being applied.

Your complimentary delegate place is not officially confirmed until we have had chance to check that you qualify for the complimentary pass. Please do not make any travel arrangements before we have confirmed acceptance of your application. We will not be liable for any expenses incurred.

**Delegate Registration Form**
Delegate must complete the online delegate registration form issued by the Organiser on receipt of the Delegate Booking Form. This information will only be used for the organisation of the Series, for material produced for Delegates and Sponsors and to facilitate the networking sessions.

**Cancellation and Curtailment**
If a Registered Delegate is unable to attend the Series, he/she may nominate a substitute of equal standing within their Company. A substitute delegate must be nominated within a week of cancellation and must be approved by the Organiser in advance in order to avoid cancellation charges being applied. Delegates and vendor delegates are subject to the following charges and refunds upon withdrawal or cancellation.

<table>
<thead>
<tr>
<th>Period Prior to Event</th>
<th>Charge or Refund</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than 6 months</td>
<td>0% 25% reduction</td>
</tr>
<tr>
<td>6 to 3 months</td>
<td>50% 75% reduction</td>
</tr>
<tr>
<td>Less than 3 months</td>
<td>Full cancellation 0% refund</td>
</tr>
</tbody>
</table>

**Data Protection**
The data controller is the organiser (Oxford Global Marketing Ltd). The Organiser may disclose such personal information as name, company, job title, telephone and email address to Registered Event Sellers (Solution Providers) and other Delegates but solely for the purposes of the Series. Registration details will be retained and used in accordance with our [privacy policy](http://www.oxfordglobal.co.uk). If you wish to opt out please email info@oxfordglobal.co.uk

**Miscellaneous**
The Organiser will determine the scope and content of Series events, seminars, workshops and activities throughout the Series.

The Organiser reserves the right to cancel the Series without liability to Delegate's Company or individual Delegate. If for any reason the Organiser has to cancel or postpone this Series, the Organiser reserves the right to transfer this booking to another Series within the same sector to be held within twelve months. Should another Series in the same sector not be available within this period, the Booking Fee will be refunded.

For promotional purposes, there may be professional photography and video production taking place during the Series. Delegates who do not wish to be filmed or recorded should advise the Organiser by email to [marketing@oxfordglobal.co.uk](mailto:marketing@oxfordglobal.co.uk) prior to the event.

These terms and conditions are binding upon the delegate submitting a registration form.

I agree to the above Terms and Conditions

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**How to Pay** (choose one of the following payment options)

**Number of delegates:**
- Industry del(s)  
- Academic dels(s)  
- Vendor del(s)  

**Special Offer: 3 for 2**
Offer is only valid on the Series and for those registering at Industry or Academic rates

Please choose one of the following payment options:

- **CREDIT CARD:**
  An Oxford Global representative will contact you directly following return of contract / booking form to process card payment.
  If payment will be made by a colleague within your company, please complete the following:

  **Card Payment Contact Name:** ______________________
  **Phone Number:** ________________________

- **INVOICE:**
  Invoice Address (if different from above) ______________________

*Please note there is a £50 plus VAT handling charge for payment via invoice*
## FORTHCOMING EVENTS

### Biologics Series

**UK**
- 13th Annual Proteins & Antibodies Congress  
  27 - 29 April 2020 | London, UK
- 7th Annual Peptides & Oligonucleotides Congress  
  27 - 29 April 2020 | London, UK
- 2nd Annual Bispecifics in Discovery & Development Congress  
  27 - 29 April 2020 | London, UK

**US**
- 5th Annual Biomarkers & Precision Medicine USA Congress  
  15 - 16 October 2020 | San Diego, USA

### Immuno Series

**UK**
- 5th Annual Advances in Immuno-Oncology Congress  
  21 - 22 May 2020 | London, UK
- Autoimmunity & Immunology Congress  
  21 - 22 May 2020 | London, UK
- 3rd Annual Advances in Immuno-Oncology USA Congress  
  15 - 16 October 2020 | San Diego, USA

### PharmaTec Series

**UK**
- 18th Annual Pharmaceutical IT & Data Congress  
  24 - 25 September 2020 | London, UK
- 4th Annual Artificial Intelligence in Drug Development Congress  
  24 - 25 September 2020 | London, UK

**US**
- 2nd Annual SmartLabs & Laboratory Informatics Congress  
  24 - 25 September 2020 | London, UK

### R&D Series

**EU**
- 21st Annual Drug Discovery Summit  
  26 - 27 May 2020 | Berlin, Germany
- 8th Annual Drug Design and Medicinal Chemistry Congress  
  26 - 27 May 2020 | Berlin, Germany
- 2nd Annual Neuroscience Drug Discovery Congress  
  26 - 27 May 2020 | Berlin, Germany

### Cell Series

**UK**
- 9th Annual Cell Culture & Bioprocessing Congress  
  06 - 07 October 2020 | London, UK
- 7th Annual Regenerative Medicine & Advanced Therapy Development Congress  
  06 - 07 October 2020 | London, UK
- 6th Annual Cell & Gene Therapy Manufacturing Congress  
  06 - 07 October 2020 | London, UK

### Formulation & Delivery Series

**UK**
- 6th Annual Formulation & Drug Delivery Congress  
  22 - 23 April 2020 | London, UK
- 5th Annual Inhalation & Respiratory Drug Delivery Congress  
  22 - 23 April 2020 | London, UK
- Biomanufacturing Congress  
  22 - 23 April 2020 | London, UK

**US**
- 3rd Annual Formulation & Drug Delivery USA Congress  
  17 - 18 March 2020 | San Diego, USA
- 3rd Annual Inhalation & Respiratory Drug Delivery USA Congress  
  17 - 18 March 2020 | San Diego, USA

### Biomarkers Series

**UK**
- 15th Annual Biomarkers Congress  
  18 - 20 February 2020 | Manchester, UK
- Genomic Markers Congress  
  18 - 20 February 2020 | Manchester, UK

**US**
- 5th Annual Biomarkers & Precision Medicine USA Congress  
  15 - 16 October 2020 | San Diego, USA

### NextGen Omics Series

**UK**
- 12th Annual Next Generation Sequencing & Clinical Diagnostics Congress  
  05 - 06 November 2020 | London, UK
- 8th Annual Single Cell Analysis Congress  
  05 - 06 November 2020 | London, UK
- 6th Annual Genome Editing Congress  
  05 - 06 November 2020 | London, UK
- 2nd Annual Digital PCR Congress  
  05 - 06 November 2020 | London, UK

**US**
- 6th Annual Next Generation Sequencing USA Congress  
  07 - 08 April 2020 | Boston, USA
- 6th Annual Single Cell Analysis USA Congress  
  07 - 08 April 2020 | Boston, USA
- 4th Annual Genome Editing USA Congress  
  07 - 08 April 2020 | Boston, USA

### COMPLIMENTARY RESOURCES

Visit [www.oxfordglobal.co.uk/hub/](http://www.oxfordglobal.co.uk/hub/) to gain access to our complimentary resources, including Webinar Recordings, Videos, Speaker Q&As, Newsletters, Reports, and much more!