

# FORMULATION & DELIVERY UK: IN-PERSON

21 - 22 September 2021 | London, UK

+ *Digital Day: 23 September 2021 | Online*

**250+**

LEADING PHARMA, BIOTECH AND  
ACADEMIC DELEGATES ATTENDING  
ON-SITE & VIRTUALLY

**50+**

PRESENTATIONS,  
CASE STUDIES AND  
DISCUSSIONS

**10+ HOURS**

OF INTERACTIVE SESSIONS –  
Q&As, PANEL DISCUSSIONS,  
ROUNDTABLES & WORKSHOPS

Conference Brochure

## KEY SPEAKERS INCLUDE



Theresa Scheuble  
Janssen



Stuart Madden  
Neurelis



Carsten Ehrhardt  
Trinity College Dublin



Abhishek Singh  
Janssen  
Pharmaceutica NV



Ijeoma Uchegbu  
UCL



David Cipolla  
Inmed

Book Online: [www.oxfordglobal.co.uk/formulation-delivery-series-uk/](http://www.oxfordglobal.co.uk/formulation-delivery-series-uk/)

Join the Conversation: [#FDDSeries2021](https://twitter.com/FDDSeries2021)

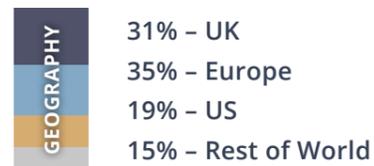
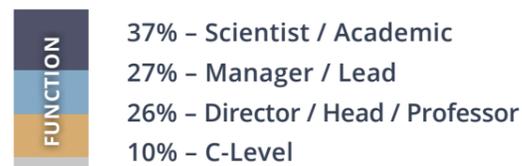




**250+ VPs, Directors & Senior Managers** will be attending on-site and virtually, coming from leading healthcare, biotech, pharma and research institutions in the following fields and more:

- Formulation Science
- Biologics Development
- Drug Delivery
- Stability
- Characterisation
- Analytical Science
- Combination Products
- Small Molecule Development
- Inhalation Drug Delivery
- Inhalation Devices
- Pulmonary Disease
- Respiratory Therapeutics

**2019's Attendee Profile**



**These companies and many more:**



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

- Formulation Design
- Formulation Development
- Process Optimisation
- Stability testing
- Bioanalysis
- Drug Delivery
- API and Excipient Production
- Solubility Enhancement
- Analytical Services
- Inhaler Technologies
- Dosing Technology
- Particle Engineering

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## SESSION TOPIC AREAS

**Formulation & Delivery UK: In-Person** features **2 days** of in-person cutting-edge presentations and knowledge-sharing, including **over 50** industry insights, sponsored presentations and think tank roundtable discussions followed by a dedicated **Digital Day** delivered through our online event platform.

### DAY ONE - 21 SEPTEMBER 2021

#### Formulation & Drug Delivery

Stream 1: Improving Small Molecule Development & Formulation

Stream 2: Advanced Biologics Drug Delivery

#### Inhalation & Respiratory Drug Del.

Stream 3: Development & Formulation of Inhaled Therapies

### DAY TWO - 22 SEPTEMBER 2021

#### Formulation & Drug Delivery

Stream 1: Biotherapeutic Formulation Development

Stream 2: Small Molecule Drug Delivery Techniques & Technologies

Stream 3: Stability, Bioanalysis & Characterisation

#### Inhalation & Respiratory Drug Del.

Stream 4: Inhalation Devices & Combination Products

### DIGITAL DAY - 23 SEPTEMBER 2021

Presentations & interactive sessions on all above topics



CONFIRMED SPEAKERS – DAY ONE



**SU METCALFE**  
Chief Executive Officer,  
LIFNano Therapeutics



**HISHAM AL-OBAIDI**  
Lecturer, Pharmacy and  
Pharmaceutical Sciences, University  
of Reading



**AXEL BECKER**  
Senior Scientist,  
Merck KgaA



**CARSTEN EHRHARDT**  
Professor of Pharmaceutics,  
Trinity College Dublin



**TANVIR TABISH**  
Head of Formulation Development  
for Gene Therapy & Protein  
Modalities, Takeda



**NIKOLETTA FOTAKI**  
Reader in Biopharmaceutics,  
University of Bath



**DAN FRIEDRICHS**  
Principal Electronics Engineer,  
Minnetronix, Inc.



**KARL BOX**  
Chief Scientific Officer,  
Pion, Europe



**ABHISHEK SINGH**  
Senior Scientist, Pharmaceutical  
& Material Sciences, Janssen  
Pharmaceutica NV



**PETER BARNES**  
Head of Respiratory Medicine,  
Imperial College London



**IJEOMA UCHEGBU**  
Professor of Pharmaceutical  
Nanoscience,  
University College London



**STUART MADDEN**  
Chief Scientific Officer,  
Neurelis



**JONAS FAGERBERG**  
Head of Pharma R&D, Disruptive  
Materials Pharma



**JOËL RICHARD**  
Chief Development Officer,  
MedinCell



**FRANK KOPPENHAGEN**  
Senior Director, Aerosol Sciences,  
Translate Bio



**NICK SONG**  
Senior Principal Engineer,  
Takeda



**ADAM BYRNE**  
Asthma UK Senior Fellow and  
Lecturer in Chronic Lung Disease,  
Imperial College London



**KAMALINDER SINGH**  
Professor of Pharmaceutical  
Technology & Drug Delivery,  
University of Central Lancashire



**MAGDALENA KIERKOWICZ**  
Senior Scientist,  
UCB



**MARC B BROWN**  
Chair of Scientific Advisory Committee,  
MedPharm Ltd

CONFIRMED SPEAKERS – DAY TWO



**PATRICK GARIDEL**  
Head of Process, Purification and  
Pharma Development,  
Boehringer Ingelheim



**MOEIN MOGHIMI**  
Professor,  
University of Newcastle



**JENS BOUGHARDT**  
Head of PK Modeling,  
Boehringer Ingelheim



**DAVID CIPOLLA**  
Vice President of Research, Insmed



**SUPRIYADI HAFIZ**  
Senior Scientist Formulation,  
Merck



**ANNA RYDZIK**  
Associate Principal Scientist,  
AstraZeneca



**MAHMOUD AMERI**  
Vice President,  
Zosano Pharma



**MARIA MARLOW**  
Associate Professor,  
University of Nottingham



**HAMID MERCHANT**  
Senior Lecturer,  
University of Huddersfield



**MOHAMMAD NAJLAH**  
Professor of Pharmaceutics and  
Nanomedicine, Angelia Ruskin  
University



**ROBERT NIICHEL**  
Founder & Chief Executive Officer,  
SmartTab



**GEOFF SMITH**  
Professor,  
De Montfort University



**THERESA SCHEUBLE**  
Director, Janssen



**BEN FORBES**  
Professor in Pharmaceutics,  
King's College London



**ANNEKE HIMSTEDT**  
Associate Scientist,  
Boehringer Ingelheim



**CAROLIN REIHL**  
Principal Scientist,  
Merck KGaA



## LIVE AUDITORIUM



### Oxford Global Welcome Address & Chairperson's Opening Address

#### Event Opening Keynote: Physicochemical Profiling Of bRo5 Space In Drug Discovery

- Evolution of physicochemical properties in drug discovery
- Intra-molecular hydrogen bonds (IMHBs)
- PhysChem toolbox for characterization of drugs beyond Rule of 5 (bRo5)
  - Experimental polar surface area (EPSA)
  - $\Delta\log P/\Delta\log D$
  - Immobilized artificial membrane (IAM) binding
- Case study: identification of compounds bRo5 with good permeability

MAGDALENA KIERKOWICZ, Senior Scientist and Group Leader, **UCB**

#### Topical Medicines Development For The Treatment Of Inflammatory Skin Disease: Complexities, Risks And Opportunities

The development of a dermal product for the treatment of inflammatory skin disease is a complex process and there are many potential paths that can be taken. This lecture will consider the complexities and risks such approaches involve, the mitigation that should be considered and the contingencies that can be put in place. Areas of focus will be:

- Drug candidate selection
- Preformulation, formulation development and optimisation
- Performance testing including ex vivo skin disease models
- The patient, clinician and commercial reality

Professor MARC B BROWN PHD CCHEM FRSC, Founder, Board Director and Chair of Scientific Advisory Committee, **MedPharm Ltd**



### Networking Break & 1-2-1 Meetings x1



## LIVE AUDITORIUM

#### Nasal Drug Delivery: Opportunities And Challenges

- Anatomy of the Nose
- Advantages of Nasal Drug Delivery
- Challenges of Nasal Drug Delivery
- Regulatory Aspects
- Addressing the Challenges
- Nose to Brain Delivery

STUART MADDEN, Chief Scientific Officer, **Neurelis**



## BREAKOUT ROOM

#### Targeted Lung Delivery Of Antifungal Drug With Nebulised Surface-Active Hybrid Nanoparticles For Treatment Of Pulmonary Aspergillosis

- Pulmonary aspergillosis one of the major co-morbid infections in diseases like asthma, chronic obstructive pulmonary disease, tuberculosis, cancer, and Covid-19 caused by ubiquitous fungus, i.e., *Aspergillus fumigatus*
- Currently available antifungal regimen is restricted to oral and parenteral routes only, which limits the therapeutic availability of drugs in the lungs
- This presentation will cover the development of surface-active hybrid nanoparticles for pulmonary delivery of an antifungal drug

KAMALINDER SINGH, Professor of Pharmaceutical Technology & Drug Delivery,  
**University of Central Lancashire**



### LIVE AUDITORIUM

#### Extended Release Injectables: Polymer Design, Formulation And Processing For Success

- This presentation will provide scientists and technical stakeholders working in drug delivery with a detailed overview on an exciting extended release technology platform for parenteral applications based on bioresorbable polymers (lactide, glycolide, caprolactone chemistries and some novel PEGylated variants for newer/complex delivery needs)
- The session will explore control mechanisms, demonstrating how theoretical chemistry is coupled with formulation knowledge in different formulation formats including in-situ forming implants, microspheres/nanoparticles and pre-formed solid implants to successfully accomplish extended release drug delivery over periods of days, weeks and up to several months, Ashland will also highlight how customized and novel chemistries can be used to overcome technical development challenges for respective molecule delivery strategies
- Existing commercial products will be examined to highlight the breadth of release profiles achievable, types of molecules, indications, drug loading limits achieved to-date and successful formulation formats. Additionally, details on the technical challenges beyond formulation including processing, stability and sterilization will be discussed. Processing case studies involving hot melt extrusion (HME) optimization and more than ten different particle production technologies in the creation of microspheres and nanoparticles will be explained

Joining Virtually- SEÁN MCMAHON, Business & Technical Manager for Bioresorbable Polymers, **Ashland**



10:10  
-  
10:40



### BREAKOUT ROOM

#### INDiGO Case Study: The Benefits Of A Comprehensive And Integrated Drug/Formulation Development Capability

- Poorly water soluble free base API and salt screening resulted in few possible candidates with slightly better aqueous solubility and stability but with no increase in bioavailability compare to the free base API
- Good interaction between chemistry/discovery group, preclinical formulation group and animal science group help develop the API with better solubility
- The information obtained during the API development was then applied to develop an optimised formulation with good bioavailability for clinical use by the clinical formulation group

JOHN NKORNU, Senior Research Expert, Pharmaceutical Development, **Evotec**



10:40  
-  
11:40

### Networking Break & 1-2-1 Meetings x3

#### Risk Assessed Approach To Drug Product Development

- What is critical to a successful product launch?
- Finding the right solution to match the target product profile
- Risk assessment at request for quote stage
- Identifying key API Physicochemical properties impacting target product profile
- Using early science of scale tools to drive formulation and process selection
- Living umbrella risk assessment and mitigation strategies
- Risk assessment driving quality by design, tech transfer, scale up and commercial

ARUL BALASUNDARAM, Formulation Manager, **Recipharm**



11:40  
-  
12:10

#### PharmaShell® – Long Acting Injectable Formulations Aided By Inorganic Prolonged-Release Coatings Produced With Atomic Layer Deposition

- PharmaShell® consists of dense inorganic prolonged-release coatings, in the range of several nm in thickness, prepared on micronized APIs with precise thickness control
- The prolonged-release coatings are manufactured using a propriety process based on the gas phase technique Atomic Layer Deposition
- The products have low weight fraction coating with drug loads typically higher than 80 wt%.
- The prolonged-release coatings protect the encapsulated API until release at dissolution of the coating
- Depot lengths varying from one week to several months may be achieved by modulating the prolonged-release coating composition and thickness
- PharmaShell® can be used independently of drug solubility and also for biopharmaceuticals.

JOEL HELLRUP, Senior Formulation Scientist, **nanexa**



12:10  
-  
12:35

#### The Role Of Itaconate During Pulmonary Fibrosis

- Idiopathic pulmonary fibrosis (IPF) is a fatal lung disease in which airway macrophages (AMs) play a key role. Itaconate has emerged as a mediator of macrophage function, but its role during fibrosis is unknown
- Here, we reveal that itaconate is an endogenous anti-fibrotic factor in the lung
- Our data identify itaconate as critical for controlling the severity of lung fibrosis, and targeting this pathway may be a viable therapeutic strategy

ADAM BYRNE, Asthma UK Senior Fellow and Lecturer in Chronic Lung Disease, **Imperial College London**

#### Trojan Horse Delivery Of Nano-Engineered Cytokines

- Targeting of nano-engineered cytokines for control of inflammation
- Multiple sclerosis, cancer and pneumonia

SU METCALFE, Chief Executive Officer, **LIFNano Therapeutics**



## LIVE AUDITORIUM

### In Vivo Electroporation: An Engineering Solution To Drug & DNA Delivery

- There has been robust interest, recently, in human use of electroporation for delivery of large molecules and DNA
- In vivo electroporation devices can be realized as handheld devices which temporarily permeabilize cell membranes to allow delivery of cargo into cells
- This technique creates the potential for gene therapy and DNA vaccines, among other exciting therapies
- Developing an in vivo electroporation device has some technical challenges, but an experienced development partner can streamline this process

DAN FRIEDRICHS, Principal Electronics Engineer,  
**Minnetronix, Inc.**



12:35  
-  
13:05

### Lunch Break & 1-2-1 Meetings x3

13:05  
-  
14:05



## LIVE AUDITORIUM

### Absorption Driven Drug Formulation Concepts

- The Absorption Driven Drug Formulation (ADDF) concept will be discussed
- The solubility-permeability interplay and the role of free drug concentration as the driving force for absorption in the presence of excipients will be presented
- An example workflow illustrating the ADDF concept from candidate selection through to formulation development will be given

KARL BOX, Chief Scientific Officer  
**Pion, Europe**



14:05  
-  
14:35



## DISCUSSION ROOM

*The Discussion Room is Closed For 30 Minutes*



## BREAKOUT ROOM

### Reliable Osmolality Testing Of High Concentration mAb Formulations

- The osmolality of monoclonal antibody (mAb) formulations is typically determined using freezing point depression or vapor pressure osmometers
- The wider use of subcutaneous injections; an injection that requires less volume but increased concentration to alleviate patient pain and increase patient compliance has led to a trend in increasing mAb concentrations. This higher concentration, however, can pose analytical issues. Due to much higher viscosities being seen in drug formulations; it is critical to have an instrument that will measure concentration with optimal performance. Although freezing point depression
- Evaluation of the OsmoTECH® XT (freezing point) and Vapro® 5600 (vapor pressure) osmometers as a means of measuring concentrated protein formulations. In general, mean osmolality values were similar across a range of saline and monoclonal antibody concentrations. Key differentiations were observed in the accuracy of the salt standard measurements and the variance of the mAb measurements, both of which were preferable on the OsmoTECH XT. In addition, the OsmoTECH XT has key advantages in terms of usability and advanced data integrity features that facilitate implementation into GMP workflows

CAMERON L. BARDLIVING, PhD, Director,  
PD & Operations, Jefferson Institute for  
Bioprocessing, **Jefferson University**





#### LIVE AUDITORIUM

##### Developing Amorphous Solid Dosage Forms - Practical Considerations

- Development of Amorphous Solid Dispersions in industrial settings
- Patient centricity considerations

*Joining Virtually-* ABHISHEK SINGH, Senior Scientist, Pharmaceutical & Material Sciences, **Janssen Pharmaceutica NV**

##### Particle Engineering Of APIs – A Key Step To Improve DP Manufacturability?

- The talk will introduce general aspects of solid-state chemistry as potential key material attributes for APIs used in oral dosage forms
- Specifically, the concept of particle engineering is outlined and how this can be utilized to control and design particle properties of API
- A short case study is shown to illustrate how differences in API particle properties such as particle shape can impact on DP manufacturability behavior

*Joining Virtually-* AXEL BECKER, Lab Head Solid-State Characterization, **Merck KGaA**



#### DISCUSSION ROOM

##### COPD Workshop:

###### Presentation: Inhaled Therapy For COPD Now And In The Future

- Inhaled long-acting bronchodilators (LAMA and LABA) are mainstay of current management
- Triple fixed dose inhalers (ICS-LABA-LAMA) are useful for some patients
- New inhaled therapies are in development

PETER BARNES, Head of Respiratory Medicine, **Imperial College London**

###### Panel Discussion: Challenges For COPD

- Improved and novel inhaled therapies
- Inhaled delivery challenges
- Unique challenges for COPD

PETER BARNES, Head of Respiratory Medicine, **Imperial College London**

STUART MADDEN, Chief Scientific Officer, **Neurelis**

CEES VAN RIJN, Professor, Nanotechnology and Microfluidics, **University of Amsterdam**



#### BREAKOUT ROOM

##### Delivering Nucleic Acid Medicines To The Brain

- NanoLigand Carriers (NLCs) for rapid and efficient intravenous delivery of nucleic acid medicines across the blood-brain barrier
- Intravenous targeting of neurons and microglia with NLCs
- Confirmation of NLC safety
- NLCs as universal vectors for nucleic acid therapy of neurological disorders

MOEIN MOGHIMI, Professor of Pharmaceutics and Nanomedicine, **University of Newcastle**

##### Long Acting Injectables: Challenges For Formulation Development Of Fragile Molecules

- Specific formulation challenges for fragile molecules (peptides and proteins)
- Successful technologies for long acting injectables and their limitations
- Competitive advantages of injectable in situ forming implant technologies
- Recent progress from BEPO long acting injectable formulation development

*Joining Virtually-* JOËL RICHARD, Chief Development Officer, **MedinCell**

14:35  
-

15:00  
-

15:25  
-

#### Networking Break & 1-2-1 Meetings x3

##### Panel Discussion: Formulation And Delivery For Nano-Based Therapies

- New formulation approaches
- Nano-based drug delivery approaches

**Moderator:** TONY LISTRO, Vice President of Technology, **Foster Delivery Science**

**Panellists:** MOEIN MOGHIMI, Professor of Pharmaceutics and Nanomedicine, **University of Newcastle**  
MOHAMMAD NAJLAH, Professor of Pharmaceutics & Nanomedicine, **Anglia Ruskin University**

##### Industry Presentation: Drug Formulation In Mesoporous Magnesium Carbonate

- Synthesis and refinement of mesoporous magnesium carbonate
- Loading of active pharmaceutical ingredients onto mesoporous magnesium carbonate
- In vitro and In vivo behavior of mesoporous magnesium carbonate formulations

*Joining Virtually-* JONAS FAGERBERG, Head of Pharma R&D, **Disruptive Materials Pharma**

##### Systemic Drug Delivery By Inhalation - Lessons Learned And Future Prospects

- Advantages and limitation of the pulmonary route to the systemic circulation
- Requirements for distal lung aerosol delivery
- Medicines for systemic inhalation therapy on the market and in the development pipeline
- Critical assessment of factors governing the success (or failure) of systemically inhaled products

CARSTEN EHRHARDT, Professor of Pharmaceutics, **Trinity College Dublin**

16:25  
-

# Formulation & Delivery UK: In-Person

DAY ONE: 21 SEPTEMBER 2021

IMPROVING SMALL MOLECULE  
DEVELOPMENT & FORMULATION

DEVELOPMENT & FORMULATION  
OF INHALED THERAPIES

ADVANCED BIOLOGICS DRUG  
DELIVERY



## LIVE AUDITORIUM

### Impact Of Material Behaviors On The Performance And Manufacturability Of Combination Products And Devices

- An overview of mechanics of polymeric materials used for combination products and devices
- Impact to design for manufacturability
- Impact to performance of combination products and challenges

16:50  
-  
17:15

*Joining Virtually -*  
NICK SONG, Senior Principal Engineer,  
**Takeda**



## DISCUSSION ROOM

### Panel Discussion: Formulation & Delivery For New Modalities

- New modalities and new drug delivery technologies
- Current challenges
- Formulation strategies

#### Panelists:

STUART MADDEN, Chief Scientific Officer,  
**Neurelis**

MAGDALENA KIERKOWICZ, Senior Scientist and Group Leader, **UCB**  
TANVIR TABISH, Head of Formulation Development for Gene Therapy & Protein Modalities, **Takeda**



## BREAKOUT ROOM

### Pulmonary Delivery Of mRNA Therapeutics For The Treatment Of Respiratory Disease

- Introduction to respiratory drug delivery
- Administration of local acting drugs
- Discussion of biologics for treatment of pulmonary disease including practical issues to consider

*Joining Virtually-* FRANK KOPPENHAGEN, Senior Director Aerosol Sciences,  
**Translate Bio**

### Precision Medicines The Nanoparticles Way

- Materials used to fabricate nanomedicines
- Nanomedicine manufacturing
- Nanoparticles and biodistribution
- Nanomedicine pharmacology

17:15  
-  
17:40

IJEOMA UCHEGBU, Professor of Pharmaceutical Nanoscience,  
**University College London**

### Roundtable Discussion: Anti-Infective Inhalation Therapy (Including Mucosal Vaccination)

- State of the art and future directions of inhaled antibiotics, antivirals and vaccines
- Novel formulations to treat lung infections
- Bottlenecks in product development and testing

CARSTEN EHRHARDT, Professor of Pharmaceutics,  
**Trinity College Dublin**

### Optimisation Of Solid Dispersions To Target Lung Infections

- The use of solid dispersions as carrier free particles for inhalation
- Tailored use of solid dispersions to target lung loci susceptible to infections caused by biofilms
- Novel applications of co-amorphous and co-crystals in inhaled formulations

HISHAM AL-OBAIDI, Lecturer, Pharmacy and Pharmaceutical Sciences, **University of Reading**



## LIVE AUDITORIUM

### Localised Drug Delivery Using Microneedles To Enhance Cancer Therapy

- Microneedle drug delivery
- Therapeutic application

17:40  
-  
18:05

MARIA MARLOW, Associate Professor, Formulation Science and Pharmaceutical Materials, **University of Nottingham**

18:05

**End Of Day One & Networking Drinks**



### LIVE AUDITORIUM

#### Photodegradation Of Therapeutic Antibodies

- Mechanical aspects of photodegradation
- Impact on specific light conditions
- What can we learn from a 1863-published paper?
- Selected cases studies

*Joining Virtually –*

PATRICK GARIDEL, Head of Process, Purification and Pharma Development, **Boehringer Ingelheim**

#### Trehalose And Sucrose: Essential Components Of Platform Biopharma Formulations And Covid-19 Applications

- Commercial Biotherapeutics Stabilized with Trehalose and Sucrose
- Key Issues in Biopharma Formulation Development
- Essential components of a "Platform Biopharma Formulation"
- Examples for utilizations and functionalities of Sucrose and Trehalose in Covid 19 related formulations/vaccines and techniques (m-RNA, Viral vectors, mAbs etc.)
- Understanding important physicochemical properties of Trehalose and Sucrose
  - Instability of sucrose at low pH – free glucose, protein glycation
  - Phase transition and crystallization of trehalose
  - Importance of Control of Glucose levels in Sucrose as well as Trehalose
- Purity, Quality, Consistency in Pfanstiehl's Trehalose and Sucrose
  - $\beta$ -glucans in sucrose – interference with endotoxin
  - Trace metal specifications for Sucrose and Trehalose
  - Upcoming compendial changes
- Advantages of Trehalose over Sucrose
- Pfanstiehl's Biopharma Stabilization Portfolio incld. newly launched L-Arginine and L-Histidine base and HCl

CHRISTIAN LOTZ, General Manager EMEA,  
**Pfanstiehl**



#### Networking Break & 1-2-1 Meetings x1



### LIVE AUDITORIUM

#### ChemoSeed®: An Implantable Drug Delivery Technology For The Localised Treatment Of High Grade Gliomas

- High grade gliomas are difficult to treat due to the presence of the blood brain barrier
- Current standard of care involve surgical resection with most recurrence occurring within 5mm of the original tumour
- This provides an opportunity to implant a drug delivery device to deliver a high local dose of chemotherapy to the resection margin
- ChemoSeed is an implantable drug delivery device designed to be implanted into the resection cavity of high grade gliomas
- This presentation will cover the development of ChemoSeed as well as the evaluation of its in vivo toxicity and efficacy using both a U87 cell line and a PDX mouse resection model

*Joining Virtually-* CHRIS MCCONVILLE, Associate Professor in  
Pharmaceutics, Drug formulation and Delivery,  
**University of Birmingham**



### BREAKOUT ROOM

#### DIAMOD®: In Vitro Gastrointestinal Dissolution With Physically Interconnected Permeation

- Scientific rationale, design and functioning of a dynamic in vitro model for predictive biopharmaceutical assessment of drugs (including solubility-permeability interplay)
- In vitro – in vivo correlation studies Demonstrating DIAMOD® through real-life cases

FÉDÉRIC MOENS, Director of R&D,  
**ProDigest**





### LIVE AUDITORIUM

#### Modeling And Simulation In Support Of Drug Product Development

- Benefits of modeling and simulation in drug development
- Recent advancements

NIKOLETTA FOTAKI, Reader in Biopharmaceutics, University of Bath



### DISCUSSION ROOM

#### Roundtable Discussion: Diverse Drug Delivery Techniques

- Discuss a variety of delivery forms and their unique advantages including microneedles and gels

MARIA MARLOW, Associate Professor, Formulation Science and Pharmaceutical Materials, University of Nottingham



### BREAKOUT ROOM

#### Non-Invasive Impedance Spectroscopy For Single-Vial PAT In Biopharmaceutical Freeze-Drying

- Non-invasive temperature measurement
- Phase behaviour of the solid/solute fraction
- True sublimation end point

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

10:40 - 11:05

11:05 - 12:00

### Networking Break & 1-2-1 Meetings x3

#### Light Scattering Tools For Screening And Characterizing Biologics And Nano-Formulations

- High-throughput screening of biologics for aggregation and stability by dynamic light scattering (HT-DLS)
- Screening of viral vectors and nano-formulations for size, polydispersity and titer by HT-DLS
- Quantification of protein and AAV CQAs by SEC coupled to multi-angle and dynamic light scattering (MALS/DLS)
- Detailed characterization of lipid nanoparticle formulations and viral vectors for size, concentration, encapsulation efficiency and payload by field-flow fractionation with light scattering (FFF-MALS/DLS)

KEVIN JACKSON, Technical Director, Wyatt Technology



12:00 - 12:30

The Discussion Room Will Open at 12.25

#### Engineering Drug Release In EVA Based Implants - Platform Tools & Predictive Modeling

- Basics of EVA copolymers: chemistry, structure, characteristics, regulatory
- Design variables to deliver of small molecule & peptides
- Examples
- Basics of release modelling
- Delivery of biologics

CHRISTIAN SCHNEIDER, New Business Development, Medical & Pharma EMEA, Celanese



#### Lipid-Based Nano-Carriers Of Disulfiram For Cancer Therapy

- Drug repurposing may become the most promising strategy in cancer treatment due to the high safety profile
- Disulfiram (DS), used safely for decades to treat alcoholism, has shown lethal activity against wide range of cancer cells including drug-resistant cancer stem cells (CSCs)
- The parenteral use of disulfiram for cancer treatment in clinic is limited by its bio-instability in the bloodstream
- The need to develop long-circulating nano-drug delivery system to protect DS in the bloodstream and enable targeted delivery is undiminished
- Lipid-based nano-carriers of disulfiram have shown a great potential for cancer therapy

MOHAMMAD NAJLAH, Professor of Pharmaceutics & Nanomedicine, Anglia Ruskin University

12:30 - 12:55

#### Roundtable Discussion: Approaches To Assessing Developability Of Drug Candidates Early In Development

- Developability assessment
- New approaches and case studies

KATIE DAY, Associate Director, Formulation Science, AstraZeneca

#### Transdermal And Dermally-Applied Drug Delivery

- Transdermal Microneedle Delivery System provides
- Rapid delivery and pulsatile PK profile for improved efficacy
- Room temperature stable formulations
- Patient friendly alternative to injection

Joining Virtually- MAHMOUD AMERI, Vice President, Zosano Pharma

# Formulation & Delivery UK: In-Person

DAY TWO: 22 SEPTEMBER 2021

BIO-THERAPEUTIC FORMULATION  
DEVELOPMENT

INHALATION DEVICES &  
COMBINATION PRODUCTS

STABILITY, BIOANALYSIS &  
CHARACTERISATION

SMALL MOLECULE DRUG DELIVERY  
TECHNIQUES & TECHNOLOGIES



## LIVE AUDITORIUM

### Optimization Of Drug Formulations For Oral Inhalation - Perspectives Based On Integrative PK Modelling

- Optimised for oral inhalation strategies

*Joining Virtually-*

JENS MARKUS BORGHARDT, Head of Preclinical PK/PD Modelling, **Boehringer Ingelheim**  
ANNEKE HIMSTEDT, Research Scientist, **Boehringer Ingelheim**

12:55  
-  
13:20



## DISCUSSION ROOM

### Roundtable Discussion: Which Analytical Measurements Do You Use In Your Drug Formulation Process And Why?

PAUL BUTLER,  
Sales and Business Development Manager,  
**Advanced Instruments**



## BREAKOUT ROOM

*Delegates are welcome to attend co-located sessions*

13:20  
-  
14:15

## Lunch Break & 1-2-1 Meetings x3

### Oligonucleotide Conjugates For Targeted Delivery

- Challenges with targeted delivery of oligo conjugates
- New approaches for targeted delivery

*Joining Virtually-*

ANNA RYDZIK, Associate Principal Scientist,  
**AstraZeneca**

14:15  
-  
14:40

### Roundtable Discussion: Challenges In Drug Delivery Vector Analysis

KEVIN JACKSON, Technical Director,  
**Wyatt Technology**

### Surface Acoustic Wave Nebuliser

- An overview of current nebuliser technologies
- Limitation of nebuliser technologies
- Surface acoustic wave nebulisation
- Nebu-Flow acoustic nebuliser platform and its advantages

ELIJAH NAZARADEH, Fellow, **University of Glasgow**

14:40  
-  
15:05

### 3D Printed $\mu$ Needles For Transdermal Delivery

- Stereolithography (SLA) for miniature 3D printed microneedle
- Design features of 3D microneedles
- Advanced characterisation of microneedles
- Coupling of Microelectromechanical systems with hollow microneedles
- In vivo studies for drug delivery

DENNIS DOUROUMIS, Professor,  
Pharmaceutical Technology & Process  
Engineering, Director of CIPER,  
**University of Greenwich**

### Roundtable Discussion: How To Address Solubility & Permeability - Two Of The Critical Factors Affecting The Rate And Extent Of Drug Absorption Problems

JOHN NKORNU, Senior Research Expert,  
Pharmaceutical Development, **Evotec**

### Challenges In Bringing Inhaled And Respiratory Drug Products To The Market

- What are the regulatory considerations for inhaled combination products?
- What analytical tests are required for QC release and stability testing of inhaled combination products?
- When can characterization studies be conducted during development to replace routine QC testing?

*Joining Virtually-* DAVID CIPOLLA, Vice President of Research, **Insmad**

15:05  
-  
15:30

### Advancing Wireless Ingestible Drug Delivery Technologies

- The convergence of digital technologies and pharmaceutical delivery systems
- PK pre-clinical proof of concept study that demonstrates successfully administering, via radio frequency signalling, active ingredients to the chosen target site
- What this technology could hold for the future

*Joining Virtually-*  
ROBERT NICHIEL, Founder & Chief Executive Officer, **SmartTab**

### Panel Discussion: Overcoming Formulation Challenges (Large & Small Molecules)

- Designing formulation strategies
- Challenges to overcome

#### Moderator:

*Joining virtually -* JOËL RICHARD, Chief Development Officer, **MedinCell**

**Panelist:** RENE HOLM, Head and Scientific Director, Drug Product Development - Liquids & Parenterals, **Janssen**

*Joining Virtually-* THERESA SCHEUBLE, Director, **Janssen**  
LASSE STACH, Developability Team Leader, **GlaxoSmithKline**

### Degradation Of Complex Biological Formulations During Nebulization

- Nebulization might possibly damage biological formulations, resulting in loss of active pharmaceutical ingredients
- We studied two types of lung inhalation devices: vibrating mesh nebulizers and a special type of non-vibrating membrane nebulizers
- It is found that vibrating mesh nebulizers have about a ten times higher premature loss of complex biological formulations than non-vibrating membrane nebulizers

CEES VAN RIJN, Professor, Nanotechnology and Microfluidics, **University of Amsterdam**



### LIVE AUDITORIUM



### DISCUSSION ROOM

15:30  
-  
15:50

#### Networking Break

#### Combination Product Requirements For Drug Delivery Systems Evolving Regulatory Expectations

- Evolving routes of Administration
- Classifications of Combination Product types
- Risk Management Approaches
- Human Factors and Usability ConsiderationS

*Joining Virtually-* THERESA SCHEUBLE, Director,  
**Janssen**

15:50  
-  
16:15

#### Roundtable Discussion: From Lab To Production

ALAN HOLMES, Sales Manager,  
**Harro Höfliger**

#### Improving Protein Purification: Application Of Excipients In Downstream Processing

- The production of antibodies and Fc-fusion proteins involves several downstream processing unit operations
- The widely used purification template with Protein A chromatography, virus inactivation at low pH, and subsequent ion exchange chromatography steps is mostly able to remove impurities like aggregates, host-cell proteins, and viruses, which could affect the safety and efficacy of the product
- The low pH elution during Protein A chromatography, as well as during virus inactivation may induce aggregation
- Preventing protein aggregation during these unit operations instead of removing the multimeric forms during subsequent polishing steps would be a more efficient strategy.
- Excipients have shown that they can minimize aggregation levels in the final product formulation. For this reason, we have investigated the benefits of adding excipients during downstream processing on protein stability, chromatographic performance and viral inactivation

*Joining Virtually -*  
SUPRIYADI HAFIZ, Senior Scientist Formulation,  
**Merck**

16:15  
-  
16:40

#### Roundtable Discussion: Continuous Manufacturing And Quality By Design

- Modernising continuous manufacturing
- QbD approaches

WALKIRIA SCHLINDWEIN, Professor of Pharmaceutics,  
**De Montfort University**



### LIVE AUDITORIUM

#### Biopharmaceutics: The Key To Optimising Inhaled Medicines

- New techniques for respiratory drug transport
- Developing novel techniques

BEN FORBES, Professor in Pharmaceutics, **King's College London**

16:40  
-  
17:05

17:05

End Of Day Two



### VIRTUAL EVENT PLATFORM

#### Drug Delivery Technology To Marketed Product

- What we look for in a technology – evaluation criteria
- How we develop a technology – twists and turns along the way
- Successful examples

JANET HALLIDAY, Associate Vice President, FCT & External Drug Delivery Technologies, **Ferring Pharmaceuticals**

#### Creating A Feedback Loop - From Crystallization Optimization To Formulation Development

- Which powder characterization methods provide reliable and robust data for prediction of processability?
- How can we feed back and feed forward know-how generated during the DS crystallization and formulation development?
- Quo vadis - insights of new characterization methods to better understand API-exipient interactions and processability issues

CAROLINE REIHL, Principal Scientist, **Merck KGaA**

#### Microfluidic Techniques For Diagnostics And Advanced Therapies

- Formulation of Nanomedicines by microfluidics
- Manufacturing of lipid & polymeric nanoparticles
- 3D Printed chips
- Microfluidics for diagnostics & lab-on-a-chip

DIMITRIOS LAMPROU, Reader School of Pharmacy, **Queen's University Belfast**

#### *Session Wrap-Up: Live Q&A With Our Speakers*

DIMITRIOS LAMPROU, Reader School of Pharmacy, **Queen's University Belfast**

CAROLINE REIHL, Principal Scientist, **Merck KGaA**

#### Networking Break

#### Formulating For Innovative Delivery Routes

- Drivers of novel drug delivery systems
- Where are new drug delivery systems identified
- How can new drug delivery systems be evaluated and implemented in the strategies of large pharma

RENE HOLM, Head and Scientific Director, Drug Product Development - Liquids & Parenterals, **Janssen**

#### Powder Inhalation Formulation And Development

YAMINI SHAH, Associate Professor of Pharmaceutics and Pharmaceutical Technology, **L. M. College of Pharmacy**

#### *Session Wrap-Up: Live Q&A With Our Speakers*

RENE HOLM, Head and Scientific Director, Drug Product Development - Liquids & Parenterals, **Janssen**

YAMINI SHAH, Associate Professor of Pharmaceutics and Pharmaceutical Technology, **L. M. College of Pharmacy**

#### Lunch



### VIRTUAL EVENT PLATFORM

#### Panel Discussion: Challenges And Opportunities Of Inhaled Biologics

- The delivery of biologics via respiratory route has presented challenges
- Expected pathology, mechanisms of toxicity and immunogenicity induced by inhalation route
- Exciting opportunities such as pulmonary siRNA delivery against SARS-CoV-2
- Aspheric Microspheres

#### Moderator:

OLIVIA MERKEL, Professor of Drug Delivery, **University of Munich**

#### Panellists:

CARSTEN EHRHARDT, Professor, Inhalation Biopharmaceutics, **Trinity College Dublin**

PETER BARNES, Professor of Thoracic Medicine, **Imperial College London**

MARC SCHNEIDER, Professor, Chair of Biopharmaceutics and Pharmaceutical Technology, **University of Saarland**

#### Peptide & Protein Therapeutic Drug Delivery

- Anatomy of the nose
- Advantages of nasal drug delivery
- Challenges, Limitations and strategies to overcome these regulatory aspects

KULDEEP BANSAL, Principal Scientist, **Abo Akademi University**

#### 3D Microfabrication Of Injection-Free Microneedles For Single-Administration Vaccines

- Injection free vaccine delivery
- Single-time administration
- Additive micro-manufacturing
- Microneedles
- Transdermal delivery

THANH NGUYEN, Associate Professor of Mechanical Engineering, **University of Connecticut**

#### Session Wrap-Up: Live Q&A With Our Speakers

KULDEEP BANSAL, Principal Scientist, **Abo Akademi University**

THANH NGUYEN, Associate Professor of Mechanical Engineering, **University of Connecticut**

End of Day

# A NEW CONFERENCE EXPERIENCE

## The digital revolution has hit conference organisation

...and just because we're returning to In-Person events doesn't mean a return to the traditional set-ups. It's why we're excited to welcome you to our new and improved In-Person conferences: maintaining the high-quality presentations and networking that you expect from an Oxford Global event but harmonised with digital elements and new formats to optimise attendee experience.

## Register Online

Formulation & Delivery: In-Person can be attended in-person or via our virtual events platform.

MORE INFORMATION



You now have more chances than ever to shape your daily agenda around the exact types of sessions you enjoy. Our **AUDITORIUM** is the place to be for our keynote talks, where you can hear high-level strategy and aspirational case studies from the biggest names impacting the industry, from pharma giants and academic innovators through to technology providers ready to help you achieve your research goals.



To delve more deeply into recent updates and novel work done in a specific field, our **BREAKOUT ROOMS** provide themed talks around a particular area of interest. Ideal for gaining insights into the new technologies, modalities and techniques about to impact your workflow, they also allow you to advance your understanding of multiple different topics that cross-over with your expertise.



Prefer to join the conversation via interactive discussions, and keen to benefit from the high levels of networking enabled at in-person events? Our **DISCUSSION ROOM** is jam-packed with panels, roundtables and workshops to encourage as much knowledge-sharing as possible. Join for a specific theme or stay for a full day of debate – who knows where the conversations may lead.



Our agendas are now fully **COLOUR-CODED** so that you can see which room you need to be in for the tracks of interest to you – and don't worry, the room themes only ever change at a breaktime, so you'll be able to grab a coffee, re-charge, and then follow your sessions of interests into the next room.



That's not all... Reflecting the move to a more online conference world, our In-Person events now include an increased amount of digital content and experience: from live streaming of certain auditorium talks, allowing you to catch them digitally, through to a host of online-only content on our **DIGITAL DAY**, bringing you closer to your global peers from the comfort of one location and with instant content accessibility. We've also introduced a variety of industry-leading new event technologies, including an intuitive digital system for question-asking, so that no matter where you are, you're able to submit your questions on the app to benefit as much as possible from the speakers' expertise.

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## CONFIRMED 2021 EVENTS

### Biologics Series

[www.oxfordglobal.co.uk/biologics/](http://www.oxfordglobal.co.uk/biologics/)

-  **Biologics Europe: Online**  
26 - 27 April 2021 | BST (UTC+1)
-  **Oligonucleotides: Chemistry & Therapeutics Symposium**  
28 April 2021 | BST (UTC+1)
-  **Biologics UK: In-Person**  
06 - 07 September 2021 | London, UK
-  **Biotherapeutics US: Online**  
17 - 18 November 2021 | EST (UTC-5)

### Biomarkers Series

[www.oxfordglobal.co.uk/biomarkers/](http://www.oxfordglobal.co.uk/biomarkers/)

-  **Biomarkers Week: Online**  
17 - 21 May 2021 | BST (UTC+1)
-  **Advancing Biomarker Analysis Europe: Online**  
14 - 16 September 2021 | BST (UTC+1)
-  **Biomarkers UK: In-Person**  
08 - 09 November 2021 | Manchester, UK
-  **Digital Biomarkers US Symposium**  
07 December 2021 | EDT (UTC-4)
-  **Biomarkers US: In-Person**  
07 - 08 February 2022 | San Diego, USA

### Cell Series

[www.oxfordglobal.co.uk/cell/](http://www.oxfordglobal.co.uk/cell/)

-  **Gene Therapy Europe: Online**  
05 - 06 May 2021 | BST (UTC+1)
-  **Cell UK: In-Person**  
28 - 29 October 2021 | London, UK
-  **3D Cell Culture Symposium**  
02 December 2021 | GMT (UTC+0)

### Discovery Series

[www.oxfordglobal.co.uk/discovery/](http://www.oxfordglobal.co.uk/discovery/)

-  **Virtual Symposium: Targeted Protein Degradation & PROTAC**  
16 - 17 February 2021 | GMT (UTC+0)
-  **Organoid Discovery Symposium**  
13 April 2021 | BST (UTC+1)
-  **Discovery Week: Online**  
01 - 04 June 2021 | BST (UTC+1)
-  **Discovery UK: In-Person**  
26 - 27 October 2021 | London, UK
-  **Discovery Chemistry US: Online**  
15 - 17 November 2021 | EST (UTC-5)

 In-Person Event  Online Event  Online Symposium

### Formulation & Delivery Series

[oxfordglobal.co.uk/formulation/](http://oxfordglobal.co.uk/formulation/)

-  **Formulation & Delivery Europe: Online**  
20 - 21 April 2021 | BST (UTC+1)
-  **RNA Therapeutics & Delivery US: Online**  
29 - 30 June 2021 | EDT (UTC-4)
-  **Formulation & Delivery UK: In-Person**  
21 - 22 September 2021 | London, UK
-  **Formulation & Delivery US: In-Person**  
01 - 02 February 2022 | San Diego, USA

### Immuno Series

[www.oxfordglobal.co.uk/immuno/](http://www.oxfordglobal.co.uk/immuno/)

-  **Oncolytic Viruses Symposium**  
25 May 2021 | BST (UTC+1)
-  **Immuno Week: Online**  
06 - 09 July 2021 | BST (UTC+1)
-  **Immuno UK: In-Person**  
13 - 14 October 2021 | London, UK
-  **Immuno US: In-Person**  
07 - 08 February 2022 | San Diego, USA

### NextGen Omics Series

[www.oxfordglobal.co.uk/omics/](http://www.oxfordglobal.co.uk/omics/)

-  **Spatial Biology Europe: Online**  
14 - 16 April 2021 | BST (UTC+1)
-  **Spatial Biology US: Online**  
27 - 30 September 2021 | EST (UTC-5)
-  **NextGen Omics UK: In-Person**  
04 - 05 November 2021 | London, UK
-  **NextGen Omics US: In-Person**  
25 - 26 January 2022 | Boston, USA

### PharmaTec Series

[www.oxfordglobal.co.uk/pharmatec/](http://www.oxfordglobal.co.uk/pharmatec/)

-  **Pharma Data Congress: In-Person**  
02 - 03 September 2021 | London, UK
-  **SmartLabs Congress: In-Person**  
08 - 09 September 2021 | London, UK
-  **Pharma Manufacturing Europe: Online**  
01 - 02 December 2021 | GMT (UTC+0)
-  **PharmaTec Networking Dinners**  
October / November / December 2021

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



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