FORMULATION & DELIVERY US 2024

BY OXFORD GLOBAL

Now In Its 6th Year!

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October 16 - 17 2024 | San Diego, CA

Enabling the swift progression of complex, alternative drug formats to market through safe, effective & targeted formulation and delivery strategies

8 Content Tracks

300+ Meeting Opportunities

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400+ Attendees

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50+ Industry-Leading Speakers Including...

ERIC MUNSON,
Professor and Head, Purdue University

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VP, Medical Affairs,
Rani Therapeutics

JAMIE TSUNG, Director, Head of DP Formulation, Alnylam Pharmaceuticals

DAVID LOYND,
Chief Executive Officer,
EnduRx Pharmaceuticals

JULIE ZHU,
Scientific Director,
GSK

JUSTIN COHEN,
Director,
Pfizer

LYNN KIRKPATRICK,
Chief Executive Officer, Ensysce Pharmaceuticals

RACHEL GROPPO,
Director, Lead saRNA Team, Johnson & Johnson Innovative Medicines

ESMAIEL JABBARI,
Professor,
University of South Carolina

WELCOME TO

Formulation & Delivery US 2024

Drug Formulation requires a delicate balance of scientific knowledge, technological expertise, and regulatory compliance. Researchers face the challenge of navigating the complex chemistry underlying compound stability, solubility, and bioavailability, all while ensuring formulations maintain efficacy and safety for patient use.

Formulation & Delivery US addresses these challenges head-on. By fostering exclusive networking opportunities among 400+ scientific experts and leading technology providers, the event offers a unique opportunity to bridge these knowledge gaps and translate research into practical solutions.

Jessica Thomson,
Portfolio Director, Drug Discovery & Development

3 High-Level Events in 1

Formulation & Delivery US features three co-located conferences:

- 6th Annual Formulation & Drug Delivery US Congress
- 6th Annual Inhaled & Nasal Drug Delivery US Congress
- 3rd Annual RNA Design & Delivery US Congress

You'll benefit from specialized programmes for each topic, as well as combined networking opportunities across the entire audience. In particular, the shared programme allows for knowledge-sharing between product development experts working on a wide variety of novel drug formats to remove bottlenecks and integrate new approaches into workflows.

Unlock The Latest News & Insights

Sign up for our monthly newsletter to keep up with all things Formulation & Delivery

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WHAT'S NEW

Benefits Of Attending

Why Attend?

- **Expand your perspective with our comprehensive agenda.** Across 9 tracks, explore case studies for diverse delivery routes, including oral, topical, injectable, inhaled, and nasal therapeutics
- **Engage in meaningful networking & partnership building.** Networking is at the heart of Formulation & Delivery. With our audience of 400+ decision makers and senior leaders, it's the perfect place to find your next strategic partner. Whether you're looking for a research collaborator, CDMO or technology partner, take advantage of over 11 hours of dedicated networking time to schedule private 1:1 meetings, catch-up over a coffee, and make the business connections you need for success
- **Unlock exclusive insights from top-level researchers in the field.** With 70+ speakers providing best practice case studies and real-world technical insights, the agenda is packed full of curated content across controlled release formulations, wearables & digital devices, immunogenicity, and more
- **Dive into targeted delivery systems for novel modalities, including RNA, gene therapy, ADCs and more.** Uncover targeted formulations for extrahepatic tissue and solutions for crossing the blood-brain barrier
- **Solve challenges and collaborate on-site with leading technology providers.** With new tools & platforms always under development, our exhibition hall highlights the most promising products to help you meet your research goals and progress your targets towards the clinic


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WHY PARTNER WITH

OXFORD GLOBAL?

At Oxford Global, our mission is to curate personalized experiences that foster community and inspire innovation.

We believe in the power of networking, connection, and knowledge to deliver quality products and services that exceed expectations. Partnering with Oxford Global means having a dedicated team committed to helping you achieve your goals and navigating the industry's ever-changing landscape.

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Benefit from guaranteed one-to-one face time with your key prospects, with detailed pre-meeting information provided to enable effective and productive conversations.

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Host Panel & Roundtable Discussions

Feature alongside key opinion leaders to discuss current hot topics and highlight your company's expertise.

Organise Workshops

Demonstrate best practice within the industry in front of your peers with case studies from your clients.

Exhibit your Products & Solutions

Promote your offerings and ensure delegates know where to find you with a prominent brand presence in the exhibition hall.

Digital Marketing & Lead Generation

Accessing the Oxford Global database, amplify your thought leadership and branding messaging through a post-event case study e-Book.

LEARN MORE

DRIVE INNOVATION & ACCELERATE RESEARCH

Who Is Partnering?

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NETWORK & KNOWLEDGE-SHARE

Attendees

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

- Formulation Science
- Drug Delivery
- Analytical Development
- Stability
- Inhalation
- Nasal Delivery
- Aerosol Science
- Device Development
- RNA Delivery
- RNA Design
- Lipid Nanocarriers
- Process Chemistry

Formal & informal meeting opportunities offer delegates the chance to discuss key solutions with leading service providers. Formal 1-2-1 meetings will be available to arrange prior to the event which take place during the dedicated networking breaks covering:

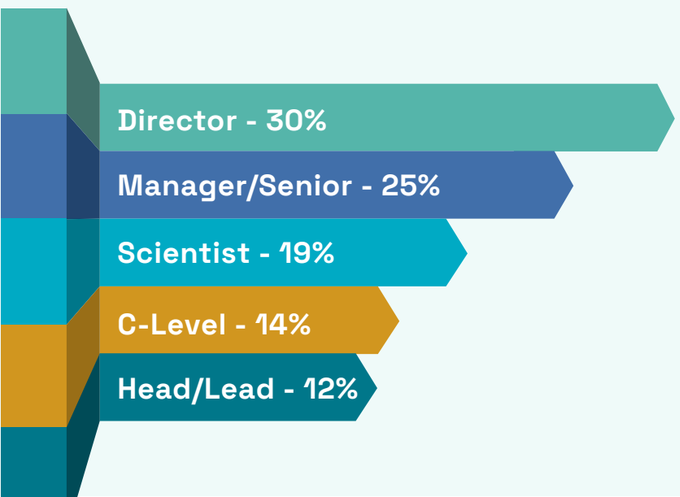
- Formulation Design
- Sustained Drug Delivery
- Stability Testing
- Excipients
- Solid State Characterization
- Nanocarriers & Lipids
- CRO/CMOs
- Raw Materials
- Sequencing & Assays
- Viral Vectors
- Analytical services
- Device Development

Attended by these companies & many more:

AstraZeneca, AVANTI BIOSCIENCES, BRIGHT PEAK THERAPEUTICS, camurus., capstan therapeutics, Clexio Biosciences, CoNCERT Pharmaceuticals Inc., Genentech A Member of the Roche Group, Lilly, Pfizer, PTC THERAPEUTICS, Rani THERAPEUTICS, RELAY THERAPEUTICS, REGENERON, Spark THERAPEUTICS

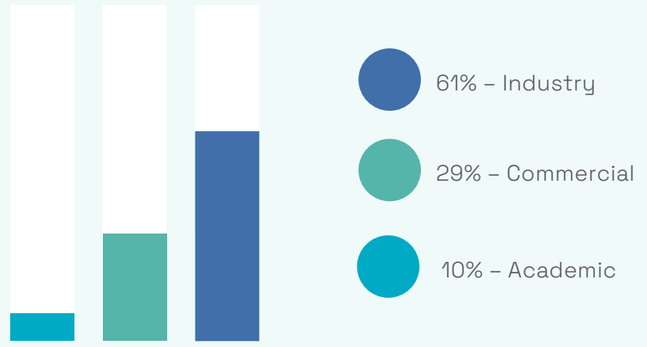
Previous Attendee Profile:

Function



Geography

Sector



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GAIN EXPERTISE FROM THOUGHT LEADERS

Confirmed Speakers

KEY SPEAKERS

Day Two | 15:15

JUSTIN COHEN,
Director, Pfizer

Day One | 12:25

JACQUES VAN DAM,
VP, Medical Affairs,
Rani Therapeutics

Day Two | 12:05

JAMIE TSUNG,
Director, Head of
DP Formulation,
Alnylam Pharmaceuticals

Day One | 09:00

LYNN KIRKPATRICK,
Chief Executive Officer,
Ensysce Pharmaceuticals

Day Two | 09:25

JULIE ZHU,
Scientific Director,
GSK

Day Two | 13:55

RACHEL GROPPO,
Director, Lead saRNA Team,
Johnson & Johnson
Innovative Medicines

LYNN KIRKPATRICK
Chief Executive Officer, Ensyce Pharmaceuticals

PETER PETROCHENKO
Associate Director in Regulatory Strategy, Regeneron

EVGENYI SHALAEV
Distinguished Research Fellow, AbbVie

ZHE WU
Principal Scientist, Johnson & Johnson Innovative Medicine

VIVEK GUPTA
Associate Dean & Associate Professor, St John's University

LENORA DIEYI
Process & Simulation Engineer – Investigator, GSK

JACQUES VAN DAM
VP, Medical Affairs, Rani Therapeutics

ERIC MUNSON
Professor and Head, Purdue University

ROBERT DUFF
Vice President, Switch Therapeutics

LAURA ROTOLO
Associate Scientist, Emory University

JOHN GLEESON
Associate Principal Scientist, Merck

SEVERIN SCHNEEBELI
Associate Professor, Purdue University

ESMAIEL JABBARI
Professor, University of South Carolina

JACK ROGERS
Director of Neurochemistry, Harvard University

WENHUA WANG
Senior Principal Scientist, Regeneron

SEAN HIRSCHLER
Principal Investigator, GSK

JULIE ZHU
Director, Biopharmaceutical Commercial Product Development, GSK

BRAD NILES
Chief Executive Officer, ARIZ Precision Medicine

DAVID LOYND
President and Chief Executive Officer, Endurx Pharmaceuticals

DAVID ULKOSKI
Associate Director, Korro Bio

JAMIE TSUNG
Director, Head of Drug Product Formulation, Alnylam Pharmaceuticals

IRVIN MAYERS
Professor, University of Alberta

ASH DUGAR
Senior Vice President, Dyne Therapeutics

THOMAS BRADSHAW
Chief Executive Officer, Neuronasal

MATTHEW LEVY
VP of Exploratory Research, Creyon Bio

RACHEL GROPPO
Director, Lead saRNA Team, Janssen

DEEPAK SAMPATH
Senior Vice President, Head of Research, Ultragenyx

YUCHEN FAN
Principal Scientist, Genentech

PRIT LAKHANI
Principal Scientist, Bristol Myers Squibb

DAVID JACKSON
Chief Executive Officer, Ceria Therapeutics

SREE NADKARNI
Biopharmaceutical Development (CMC) Consultant

KANIKA SURI
Scientist, Drug Product & Device Development, Takeda

ZHENYU GU
Senior Director of Analytical Sciences, Jasper Therapeutics

RAMMOHAN DEVULAPALLY
Director of Nonviral Delivery, Life Edit Therapeutics

YUN LIU
Scientist, Moderna

KINKINI ROY
Associate Director, Aviceda Therapeutics

JUSTIN COHEN
Director, Pfizer

VADIM KLYUSHNICHENKO
Vice President of CMC, California Institute for Biomedical Research

MANUEL SANCHEZ-FELIX
Vice President of Drug Delivery Search & Evaluation, Halozyme

HESONG HAN
Research Scientist, University of California, Berkeley

DAVID SLACK
Chief Executive Officer, Impilo Therapeutics

WORAPOL NGAMCHERDTRAKUL
Head of Research & COO, PDX Pharmaceuticals

CHANNABASAVAIAH GURUMURTHY
Professor and Director, University of Nebraska Medical Center

DAY ONE OVERVIEW

Wednesday 16 October 2024

Alongside the presentations, the conference features a host of roundtables and panels – enabling you to deep-dive into specific pain points and form meaningful connections. Day 1 sessions include:

- Considerations for Lyophilized Versus Liquid Formulations
- Overcoming Bioavailability Challenges
- CMC Challenges For New Modalities In The RNA Space

EXPLORE CURATED & INSIGHTFUL CONTENT

Agenda At A Glance

Track 1: Small Molecule Drug Formulation

- Controlled release formulations
- AI/ML in formulation development
- Utilizing novel excipients & addressing regulatory challenges

Track 2: Biologics & New Modalities Drug Delivery

- Oral delivery of biologics and novel modalities
- Overcoming challenges in the delivery of new modalities
- Devices, wearables, and patient centric approaches

Track 3: Stability, Characterization & Developability

- Aggregation, stability & characterization
- Advanced analytical controls
- Freeze-drying versus alternative approaches

Track 4: Inhaled and Nasal Therapies: Formulation. RNA Design, Formulation Strategies & Development

- Aerosol science: particle engineering including spray drying
- Innovations in liquid, dry powder formulation
- Crossing the BBB
- RNA synthesis & design
- Stability, CMC & raw materials
- RNA half-life and durability of response
- Immunogenicity challenges & prediction

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DAY TWO OVERVIEW

Thursday 17 October 2024

Alongside the presentations, the conference features a host of roundtables and panels – enabling you to deep-dive into specific pain points and form meaningful connections. Day 2 sessions include:

- Phase Appropriate Formulation
- Inhaled Biologics – Trends, Challenges & Opportunities
- Delivery of RNA Beyond The Liver

EXPLORE CURATED & INSIGHTFUL CONTENT

Agenda At A Glance

Track 1: Small Molecule Drug Delivery

- Delivering therapies through the BBB; brain delivery
- Timed & targeted delivery
- Long acting injectables & PK

Track 2: Biologics & New Modalities Drug Formulation

- Solid oral dose & high concentration biologics
- New modalities in formulation: ADCs, gene therapies
- Nanotechnology approaches

Track 3: RNA Delivery

- Delivering RNA beyond the liver
- Alternatives to LNPs
- Models for delivery
- In vitro/in vivo correlations

Track 4: Inhaled and Nasal Therapies: Delivery

- Novel approaches for pulmonary & nasal delivery
- Device Development
- Improving patient adherence and technique with product design

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DAY ONE: 16 OCTOBER 2024

SMALL MOLECULE DRUG FORMULATION

STABILITY, CHARACTERIZATION & DEVELOPABILITY

07:50 *Registration Opens & Welcome Refreshments*

08:50 **Oxford Global's Welcome Address**

Oxford Global's Welcome Address

09:00 **Using Clever Chemistry To Deliver Prescription Drugs With Oral Overdose Protection**

- Designer drugs that use body enzymes to 'turn on' and 'turn off' release: Introducing TAAP and MPAR
- TAAP: Clever chemistry controlling rate of release to achieve desired PK properties
- TAAP can improve drug performance, solubility, stability and gut delivery

LYNN KIRKPATRICK, Chief Executive Officer,
Ensyce Biosciences

The Role Of Water In Chemical Stability Of Amorphous Materials

- Molecular mobility and water role as a plasticizer were traditionally invoked to explain impact of water on physical and chemical stability of diverse pharmaceutical systems, both small molecules and biologicals
- It has been proposed more recently that structure of amorphous solids can also have a significant impact on chemical stability
- Structural aspects include water clusters in catalysis of various chemical reactions, change in hydrogen bonding pattern with dehydration, and water role in thermodynamic stability of higher-order structure of proteins

EVGENYI SHALAEV, Distinguished Research Fellow,
AbbVie

Q&A session & transition time between conference rooms

09:25 **Overcoming Formulation And Drug Delivery Challenges With Binder Jetting 3D Printing**

MIKE GOSSELIN, Vice President, Innovation & Development
Aprecia

Fast Track Formulation With Biologics Screening In A Snap

- As subcutaneous delivery of high-concentration biologics becomes more popular, optimizing their formulations becomes more complicated. Some excipients play better with one antibody, not another, or only help under specific conditions. Testing formulations at high protein concentration makes lower sample consumption and efficient assays a must-have. High-throughput, low volume solutions, designed for biologics, will speed up those formulation studies. Here, we present a case study on how to prepare monoclonal antibodies at high and low concentrations with some commonexcipients and screen for effects on quality, stability, and viscosity. The case study will illustrate how to produce all this data seamlessly, allowing the researcher to rate and rank formulations for their influence on the analyte and to quickly narrow down the optimal excipients

ROSS WALTON, Senior Applications Scientist
Unchained Labs

Q&A session & transition time between conference rooms

TRACK 1: SMALL MOLECULE DRUG FORMULATION	TRACK 2: BIOLOGICS & NEW MODALITIES DRUG DELIVERY	TRACK 3: STABILITY, CHARACTERIZATION & DEVELOPABILITY	TRACK 4: INHALED AND NASAL THERAPIES: FORMULATION
Track Chair: LENORA DIEYI, Process & Simulation Engineer – Investigator, GSK	**Track Chair:** PETER PETROCHENKO, Associate Director in Regulatory Strategy, Regeneron	**Track Chair:** SEVERIN SCHNEEBELI, Associate Professor, Purdue University	**Track Chair:** LAURA ROTOLO, Associate Scientist, Emory University
Balancing Biopharmaceutics, Stability And Manufacturability In LAI Suspension Formulation Design • This presentation will employ case studies of deviations and unexpected incidents to underscore the necessity of prioritizing manufacturability in formulation design. These case studies will illustrate that manufacturability should be considered on par with stability and biopharmaceutics. By doing so, it is feasible to design LAI suspension formulations that are not only effective and stable but also practical and efficient to manufacture on a large scale LENORA DIEYI, Process & Simulation Engineer – Investigator, **GSK**	**Utilizing Micro/Nanoscale Technologies To Support Cell Delivery For Tissue Regeneration** • Microparticles for expansion of adult stem cells for tissue regeneration • Nanogels for sustained protein delivery of morphogenetic proteins • Enzymatically cleavable nanogels for on-demand protein delivery • Tissue regeneration with spatially and temporally controlled delivery of tissue-specific morphogens ESMAIEL JABBARI, Professor, **University of South Carolina**	**Characterization Of Pharmaceutical Solids Utilizing Novel Analytical Techniques** • Preventing crystallization in amorphous solid dispersions (ASDs) is related to the solubility of the drug in the polymeric matrix, drug-polymer interactions, and the glass transition of the ASD • In this presentation the impact of each of these topics will be addressed, including strategies for preventing crystallization and how it relates to the commonly accepted Tg – 50 concept • Finally, new methods to understand the dynamics in ASDs using hydrogen bonding will be described ERIC MUNSON, Professor and Head, **Purdue University**	**In-situ Intranasal Gels For Enhanced Drug Delivery To The Brain** VIVEK GUPTA, Associate Dean & Associate Professor, **St John's University**

10:15 MORNING BREAK | 1-2-1 Meetings x4 | Poster Displays

DAY ONE: 16 OCTOBER 2024

	TRACK 1: SMALL MOLECULE DRUG FORMULATION	TRACK 2: BIOLOGICS & NEW MODALITIES DRUG DELIVERY	TRACK 3: STABILITY, CHARACTERIZATION & DEVELOPABILITY	TRACK 4: INHALED AND NASAL THERAPIES: FORMULATION
11:35	**Transforming Solid Form Selection From Art To A Predictable Science** • Crystallization is the most widely used separation and purification process in the pharmaceutical industry • At XtalPi, we have developed a combined computational and automated experimental platform, XtalGazerTM, which utilizes A.I./M.L. and physical models to design crystallization experiments for a given API molecule • XtalGazerTM can recommend potential coformers or counterions for co-crystal or salt screening crystallizations MICHAEL BELLUCCI, Senior Director of R&D, **Xtalpi**	**Silver Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*	**Silver Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*	**Exploring Capsule-Based DPIs. A Scientific Exploration Of The Properties And Performance Of Inhalation Capsules** • Inhalation drug delivery faces critical challenges affecting effectiveness. Explore DPIs, capsule formulations, and advanced methodologies, and understand factors influencing aerosolization to optimize drug delivery MAHMOUD FARAG, Scientific Business Development Manager, **Qualicaps**
	Q&A session & transition time between conference rooms			
12:00	**First In Human (FIH) Tablet Development For An Amorphous Unstable Prodrug With Enteric Coating Using An API Sparing Approach** • Formulation Development: Enteric-coated FIH tablets in three dose strengths were developed for an amorphous prodrug, focusing on stability in acidic and basic conditions, using a material science-based approach with micronized API and excipients. • Coating and Packaging: Seal and enteric coatings were optimized using limited active tablets bulked with placebos, while packaging configurations were tested for stability in different conditions. • Dissolution and Stability: Tablets showed no API release in pH 1.2 and 80% release in pH 6.8 within 20 minutes, with stability for at least 1 month across clinical batches. XIAOXIA (JESSICA) CHEN, Chief Technology Officer, **Crystal Pharmatech**	**Silver Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*	**Silver Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*	**Practical Considerations For Development And Scale-Up Of Spray Dried Powders For Inhalation** • When considering development of a spray-dried formulation for inhalation, the Target Product Profile (TPP) and physicochemical properties of the active should guide early decisions on manufacturing approach. • Key process parameters such as nozzle type, atomization ratio, process temperatures, and powder collection mechanism will also be highly influential on the target product. • For a spray-dried biologics formulation, additional considerations are given to feedstock preparation, vitrification, buffer level and target pH, atomization and drying parameters. ALAN WATTS, Director Innovation and Partnerships - Orally Inhaled Delivery, **Catalent**
	Q&A session & transition time between conference rooms			
12:25	**Impact Of Peptide Properties On Formulation Development Of The Antibody-Peptide Conjugates** • Antibody-peptide conjugates have drawn increased interests recently, with one example such as antibody-GLP1 peptide conjugate due to the substantial market potential. Peptide conjugation to a therapeutic antibody often alter molecular properties, which may pose formulation challenges. Case study focuses on the formulation development of two antibody-peptide conjugates will be presented to demonstrate how the peptide properties impact on solubility and stability WENHUA WANG, Senior Principal Scientist, **Regeneron**	**Successful Oral Delivery Of Biologics** • Patients and their physicians prefer orally delivered drugs to those that require administration by auto-injection. There are well over 350 currently available drugs that require parenteral administration. This presentation will focus on the most recent results of clinical trials demonstrating the safety and efficacy of a new oral delivery system for drugs currently requiring parenteral administration JACQUES VAN DAM, VP Medical Affairs, **Rani Therapeutics**	**New Insight Into The Oral Delivery Mechanism Of Peptide Drugs With Permeation Enhancers** • This presentation will describe a detailed molecular mechanism for oral peptide absorption with permeation enhancers. Our new mechanism is supported by all-atom molecular dynamics simulations and experimental data obtained with nuclear magnetic resonance (NMR) and dynamic light scattering (DLS). General implications to help improve oral peptide formulations with permeation enhancers will also be discussed SEVERIN SCHNEEBELI, Associate Professor, **Purdue University**	**Overcoming Bioavailability Challenges Within Inhalation** LAURA ROTOLO, Associate Scientist, **Emory University**
12:50	LUNCH BREAK & REFRESHMENTS	1-2-1 Meetings x3	Poster Displays	

DAY ONE: 16 OCTOBER 2024

	TRACK 1: SMALL MOLECULE DRUG FORMULATION	TRACK 2: BIOLOGICS & NEW MODALITIES DRUG DELIVERY	TRACK 3: STABILITY, CHARACTERIZATION & DEVELOPABILITY	TRACK 4: RNA DESIGN, FORMULATION STRATEGIES & DEVELOPMENT
	Track Chair: LENORA DIEYI, Process & Simulation Engineer – Investigator, GSK	**Track Chair:** PETER PETROCHENKO, Associate Director in Regulatory Strategy, Regeneron	**Track Chair:** SEVERIN SCHNEEBELI, Associate Professor, Purdue University	**Track Chair:** ZHE WU, Principal Scientist, Johnson & Johnson Innovative Medicine
13:50	**Tailor-Made Paediatric Drug Development & Commercialisation Solutions** • In this presentation, Almac Pharma Services will discuss the critical aspects of age-appropriate dosage form development. We will evaluate the different dosage forms that are acceptable for various age groups, impacts of API properties on dosage form selection, along with several other aspects that need to be considered when developing an age-appropriate formulation KRISTA DIAZ, Director of Business Development, **Almac**	**Polysorbate Degradation Challenges And Risk Mitigation Strategies** • PS80 is a non-ionic surfactant routinely used in biotherapeutic formulations. PS80 prevents protein aggregates and protects proteins from denaturation from various stresses. However, there are challenges associated with PS80 as it is prone to degradation via oxidative or hydrolytic pathways. There are several root causes for PS80 degradation via oxidative pathway including transition metal contamination such as Fe and Cu. In this presentation we will discuss about mitigating risks with PS80 degradation using Pfanstiehl high purity, low endotoxin, low metal excipients SUDHAKAR VORUGANTI, Director, Business Development, **Pfanstiehl**	**Bronze Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*	**Biodegradable LNPs For mRNA Therapeutics And Vaccines** • COATSOME-SS: Tunable immunogenicity with biodegradable LNPs and rationally designed lipids SYED REZA, Scientific and Sales Consultant **NOF Corporation**
	Q&A session & transition time between conference rooms			
14:15	**Shape Of Innovation: Implantable Bioresorbable Dosage Forms** • Implants have gained popularity to create dosage forms to delivery APIs locally and sometimes without systemic side effects. They provide a more controlled, steady release of the API and improve patient compliance TONY LISTRO, VP, Technology and Site Lead **Sever Pharma Solutions**	**Innovative Strategies For Long-Acting Parenteral Drug Delivery** • The pursuit of long-acting drug delivery systems has accelerated in recent years, aiming to improve treatment outcomes for various diseases. While significant strides have been made, the controlled release of biologics and RNA remains a formidable challenge • The VitalDose® drug delivery platform can address these issues providing a versatile polymeric delivery system based on ethylene-vinyl acetate (EVA). This innovative matrix polymer offers a customizable solution for the sustained release of a wide range of molecules, from small molecules and peptides to complex biologics and RNA. By precisely adjusting factors such as drug loading, implant design, and polymer selection, we can tailor the release profile to meet the specific needs of a diverse range of therapeutic areas, including oncology, central nervous system disorders, ophthalmology, rare diseases, and women's health • Our EVA-based dose forms present a promising avenue for overcoming the limitations of traditional delivery methods, providing improved patient compliance, reduced dosing frequency, and enhanced therapeutic efficacy BRIAN WILSON, Business Development Leader, **Celanese**	**Bronze Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*	**Bronze Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*
	Q&A session & transition time between conference rooms			

DAY ONE: 16 OCTOBER 2024

TRACK 1: SMALL MOLECULE DRUG FORMULATION

14:40 — Strategies for RNA therapy for AD/PD with implications for treating SARS-CoV-2

- Our pipeline of translation blockers seeks to prevent neurodegeneration with potent drugs that interfere at high selectivity with these 5'untranslated regions (5'UTRs) of the neurodegenerative disease-associated transcripts, i.e. the amyloid precursor protein (APP) APP/amyloid of Alzheimer's disease (AD) and the Parkinsonian (PD) specific asynuclein. The translation of their mRNAs in neural cells are controlled by modified Iron-responsive Elements (IRE) RNA stem-loops. Our 5'UTR inhibitors limit APP-amyloid and asyn in the nanomolar range without off-target perturbations of iron homeostasis to treat the pathologies of neurodegeneration in neuroblastoma cell models and iPSC derived dopaminergic (DA) and cholinergic neurons. These translation inhibitors limit amyloid and toxic fibrils of asyn in the brains of key mouse models of AD and PD. We now discovered a line of therapy to inhibit APP translation linked to providing RNA-directed inhibitory actions to limit COVID by lowering the translation rates of the replicase in SARS-CoV-2

JACK ROGERS, Director of Neurochemistry, **Harvard University**

Q&A session & transition time between conference rooms

15:05 — Next-Generation Nano-Immunotherapy For Cancer Treatment

- We have developed a patented and versatile nanoparticle platform, Pdx-NP™, that overcomes the limitations of lipid nanoparticles in delivering therapeutics beyond the liver upon systemic administration. Pdx-NP™ is a mesoporous silica nanoparticle coated layer-by-layer with polymers and tumor/tissue-homing antibodies
- Pdx-NP™'s unique ability to co-deliver a variety of therapeutic classes—including oligonucleotides (siRNA & antisense), peptides, adjuvants, chemotherapeutics, small molecules, antibodies, cytokines, and proteins—has resulted in the development of several promising product candidates
- Our lead nano-immunotherapeutic candidates both destroy cancer cells and train the immune system to target and attack cancer. Efficacy has been shown in mouse models of NSCLCs, colorectal cancers, and other solid tumors

WORAPOL NGAMCHERDTRAKUL, Head of Research & COO, **PDX Pharmaceuticals**

15:30 — AFTERNOON BREAK | 1-2-1 Meetings x4 | Poster Displays

16:50 — Roundtable Discussion 1: Conjugation Design For Delivery

- Drug conjugate for different modalities
- Conjugate vehicle and linker design
- Target specificity & safety

Moderator: ZHE WU, Principal Scientist, **Johnson & Johnson Innovative Medicine**

Roundtable Discussion 2: Targeted Gene Therapy Delivery

- Viral versus non-viral delivery
- Targeted delivery and prevention of off-target effects
- Development of alternative delivery vehicles

Moderator: DAVID LOYND, President and Chief Executive Officer, **EnduRx Pharma**

Roundtable Discussion 3: CDMO Selection And Management

- Required business and quality agreements
- Connecting technical parts with timeline, and budget
- Selection criteria and project management at CDMO

Moderator: VADIM KLYUSHNICHENKO, Vice President of CMC, **California Institute for Biomedical Research**

17:15 — Roundtable Discussion 4: RNA Design For Stability And Immunogenicity

- Optimization of RNA design: Sequence and Structure
- Target Product Profile (TPP) Considerations
- Deep Learning methods: Rational Design vs. Machine Learning

Moderator: DAVID ULKOSKI, Associate Director, **Korro Bio**

TRACK 2: BIOLOGICS & NEW MODALITIES DRUG DELIVERY

Oral Delivery Of Nucleic Acids

- Gastrointestinal diseases originate in the GI tract yet most macromolecules are administered parenterally
- GI tract offers immense opportunity for local delivery of therapeutics amongst other advantages
- Nucleic acids are emerging as a potent therapeutic modality with LNPs as the most potent transfection system
- To make LNPs amenable for GI delivery, the approaches will have to be re-evaluated

KANIKA SURI, Scientist, Drug Product & Device Development, **Takeda**

Digital Health Technologies For Injectables

- Digital Health Technologies advances in clinical trials
- Regulatory Challenges for verification and validation of DHTs
- Regulatory compliance for digital apps and smart features for marketed products

PETER PETROCHENKO, Associate Director in Regulatory Strategy, **Regeneron**

TRACK 3: STABILITY, CHARACTERIZATION & DEVELOPABILITY

Panel Discussion: Overcoming Bioavailability Challenges

- Tailoring formulations to optimize drug absorption and bioavailability.Addressing challenges such as poor solubility, permeability, and metabolism
- Leveraging advancements in nanotechnology, lipid-based formulations, and prodrugs

Moderator: VIVEK GUPTA, Associate Dean & Associate Professor, **St John's University**

Panelist:
MANUEL SANCHEZ-FELIX, Vice President of Drug Delivery Search & Evaluation, **Halozyme**

SEVERIN SCHNEEBELI, Associate Professor, **Purdue University**

Harnessing Digital Innovation For Enhanced Biopharmaceutical Risk Assessment

- Presentation discusses strategies to utilize digital tools to aggregate, analyze, and visualize biopharmaceutics risk assessment data from in vitro, in vivo, and in silico sources. Digitization has wide spectrum impact aiding scientist to management by reducing timeline &resource burn and enhance decision quality. Additionally, providing additional mechanism to optimize drug product for optimal bio-performance

PRIT LAKHANI, Principal Scientist, **Bristol Myers Squibb**

Q&A session & transition time between conference rooms

Facilitating Rapid High Volume Subcutaneous Drug Delivery

MANUEL SANCHEZ-FELIX, Vice President of Drug Delivery Search & Evaluation, **Halozyme**

TRACK 4: RNA DESIGN, FORMULATION STRATEGIES & DEVELOPMENT

Machine Learning For siRNA Design

- A structure-based machine learning model has been developed for siRNA activity. The model has the potential to be deployed in 3 different drug discovery scenarios
- Lead optimization: Use ML model to evaluate siRNA activity for a "new" chemical modification pattern to a studied gene target. Have knowledge on sequence for the target and the chemical modification has been studied for other gen target
- Hit identification: Use ML model to evaluate siRNA activity for a totally new gene target, but in a well-understood chemical modification pattern
- Accelerated hit identification: Use ML model to evaluate siRNA activity for a totally new modification pattern that have never been studied before

ZHE WU, Principal Scientist, **Johnson & Johnson Innovative Medicine**

Q&A session & transition time between conference rooms

Saturation Level Of RNA Backbone By Divalent Metal Ions Is Critical To Avoid Acute Neurotoxicity

- RNA delivery directly to the central nervous system (CNS) avoids the restrictions by the blood-brain barrier (BBB) but carries the risk of acute neurotoxicity, including seizures, tremors, hyperactive behaviors or death
- CASi formulation is tolerated in CNS
- Optimization of divalent metal saturation levels was the primary focus of this work

ROBERT DUFF, Vice President, **Switch Therapeutics**

Lipid Nanoparticles For mRNA Delivery

HESONG HAN, Research Scientist, **University of California, Berkeley**

Q&A session & transition time between conference rooms

Enabling In Vivo Gene Editing With Novel Lipid Nanoparticle

RAMMOHAN DEVULAPALLY, Director of Nonviral Delivery, **Life Edit**

17:40 — End of Day One & Drinks Reception

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DAY TWO: 17 OCTOBER 2024

	TRACK 1: SMALL MOLECULE DRUG DELIVERY	TRACK 2: BIOLOGICS & NEW MODALITIES DRUG FORMULATION	TRACK 3: RNA DELIVERY
	Track Chair: DAVID LOYND, President and Chief Executive Officer, EnduRx Pharma	**Track Chair:** WENHUA WANG, Senior Principal Scientist, Regeneron	**Track Chair:** WORAPOL NGAMCHERDTRAKUL, Head of Research & COO, PDX Pharmaceuticals
09:25	**Track Keynote Address:** Long-Acting Injectables - Biopharmaceutics And Product Design • Opportunities with Long Acting Injectables (LAIs) to design and deliver patient centric medicines • Mechanistic understanding of LAI product performance • Integrated biopharmaceutics concepts to drive differentiated LAI product design • Robust patient centric drug product design and development for LAIs SEAN HIRSCHLER, Principal Investigator, **GSK**	**Track Keynote Address:** Challenges In Developing Stable Biologics Formulation And Drug Product • There has been a lot of deep scientific understanding on Biopharm product development in the last two decades. However, making a stable and robust drug product is always a major challenge for formulation scientists. This presentation will focus surfactant optimization and share a few key learnings from case studies JULIE ZHU, Director, Biopharmaceutical Commercial Product Development **GSK**	**Track Keynote Address:** Design And Delivery Of PRDM2 siRNA For Cancer • ARIZ-047, our preclinical novel siRNA formulated in a calcium-phosphate drug delivery system with a tumor targeting ligand, targets a histone methyltransferase that is one of the early changes in cancerization of the cell • Our siRNA-conjugate delivery platform solves the siRNA delivery issue beyond liver cells with specificity for cancer cells, including lung cancer BRAD NILES, Chief Executive Officer, **ARIZ Precision Medicine**
	Q&A session & transition time between conference rooms		
09:50	**Old is still Gold: Multi-particulate Oral Drug Delivery** • Value in healthcare is the measured improvement in a patient's health outcomes for the cost of achieving that improvement. Numerous opportunities exist to help enhance the value proposition of pharmaceuticals, among which patient-centric product design, robust development, and efficient manufacturing play a significant role. Another opportunity exists by developing formulations that help improve patients' adherence to medication. Researchers estimate that the lack of medication adherence costs the U.S. healthcare system between $100 billion and $289 billion annually (Viswanathan, Golin et al. 2012). Modified-release (MR) oral dosage forms can help improve patient compliance by extending dosage forms, maintaining constant therapeutic drug concentrations in plasma, avoiding excessively high plasma concentration peaks, and reducing undesired side effects. • One approach to develop MR oral dosage forms is through multi-particulate oral drug delivery systems such as minitablets, pellets, and granules. Not only can multi-particulates be divided into desired doses without formulation and process changes, but they can also be blended to deliver simultaneously incompatible bioactive agents with different release profiles at the same site or at different sites within the gastrointestinal tract. In addition, technological advances in dosage form design, the advent of highly specialized equipment, and the popularity of controlled-release dosage forms as a means of drug delivery have made multi-particulates a viable and attractive alternative to single-unit dosage forms. This talk will share the state-of-the-art and a few case studies of multi-particulate oral drug delivery systems. BHAVISHYA MITTAL, Vice President, Product Development and Manufacturing **Bioduro-Sundia**	**Formulating The FutureOf Biotherapeutics: How Data Science Enhances The Development Of Highly Concentrated Liquid Formulations** • Leveraging molecular modeling and biostatistics in formulation design • Covering the full design space by integrating in-silico and in-vitro approaches • Case Studies and Practical Applications CORNELIUS POMPE, Chief Development Officer, **Leukocare**	**Vivofectamine Delivery Solutions – Advanced Lipid Nanoparticle (LNP) Technology** • Vivofectamine Delivery Solutions is a novel portfolio of biodegradable ionizable lipids, lipid nanoparticle (LNP) reagents and formulation services to enable your therapeutic development. Our products offer versatility, safety, and acceleration of your project timelines NEHA PARAYATH, R&D Manager, Clinical Delivery **Thermofisher Scientific**
10:15	MORNING BREAK — 1-2-1 Meetings x3 — Poster Displays		
11:15	**Right from the Start: Drug Product Design for Rapid Clinical Development** • Flexible and advanceable drug product design, right from the start, enables rapid clinical development without the need for time, material, and cost-intensive reformulation and subsequent bridging studies. Leveraging scalable parameters, we demonstrate how bench-scale techniques and platform MICAH TUTTLE, Senior Engineer, Product & Process Development **Seran**	**Silver Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*	**Silver Solution Provider Presentation** *For sponsorship opportunities please contact sponsorship@oxfordglobal.com*
	Q&A session & transition time between conference rooms		

DAY TWO: 17 OCTOBER 2024

	TRACK 1: SMALL MOLECULE DRUG DELIVERY	TRACK 2: BIOLOGICS & NEW MODALITIES DRUG FORMULATION	TRACK 3: RNA DELIVERY
11:40	**Unrealized Promise Of Peptide Targeted Nanosystem Delivery** • Peptide Drug Conjugates(PDCs) address limitations of ADCs head-on and open doors to more effective treatments. With superior tumor penetration, higher drug loading, reduced immunogenicity, greater ease of manufacture and storage, PDC's can deliver the right agent to the right place at the right time to improve efficacy and safety DAVID LOYND, President and Chief Executive Officer, **EnduRx Pharma**	**Leverage High-Throughput Screening And Analytics To Advance Nanoparticle Drug Delivery Systems** • Complex NP formulations need appropriate screening and optimization strategies • The formulation complexity also presents the challenge in characterization of quality attributes; • We pioneered high-throughput screening and analytical workflows tailored for NP formulation development • We also present data-mining strategies and SAR opportunities to further improve formulation development efficiency YUCHEN FAN, Principal Scientist, **Genentech**	**Targeted RNA Therapeutics Delivery Using Lanthanide Nanoparticles** • This presentation will highlight limitations of lipide nanoparticle (LNP) therapeutic RNA delivery as well as the improvements to drug loading and stability imparted by Ceria's novel lanthanide nanoparticle drug delivery platform. The audience will also learn about the performance of drug candidates derived from this platform to treat critical care conditions that share Cytokine Release Syndrome (CRS) DAVID JACKSON, Chief Executive Officer, **Ceria Therapeutics**
	Q&A session & transition time between conference rooms		
12:05	**Aptamers As Delivery Agents - Making Druggable Compounds** • Aptamers represent a unique class of targeting ligands with the potential to address these challenges. However, to date the field has been plagued by poorly characterized molecules and systems which fail to function reproducibly, hampering their use in drug development. We have developed stringent methods for validating aptamer function and robust methods for their development. More importantly, we have developed approaches that streamline the development of fully backbone stabilized druggable compounds that require little to no additional chemical optimizations. Using these approaches we have created multiple OBM delivery aptamers that successfully target and deliver both siRNA and ASO to cells in culture and animals. Learnings and relevant data will be discussed MATTHEW LEVY, VP of Exploratory Research, **Creyon Bio**	**Complex Formulations For Parenterals & Patient Considerations** JAMIE TSUNG, Director, Head of Drug Product Formulation, **Alnylam Pharmaceuticals**	**Preclinical And Clinical Development Of mRNA Therapeutics: Applications In Vaccines And Other Therapies** YUN LIU, Scientist, **Moderna**
12:30	LUNCH BREAK | 1-2-1 Meetings x3 | Poster Displays		
13:30	**Formulation Challenges For BCS Class IV Drugs** SREE NADKARNI, Biopharmaceutical Development (CMC) Consultant	**Panel Discussion:** Phase Appropriate Formulation • The importance of adapting drug formulations strategically at each phase of development to optimize safety, efficacy, and manufacturability • Challenges faced during different phases • How to ease formulation adjustments between phases **Moderator:** VADIM KLYUSHNICHENKO, Vice President of CMC, **California Institute for Biomedical Research** **Panelist:** JULIE ZHU, Director, Biopharmaceutical Commercial Product Development, **GSK** YUCHEN FAN, Principal Scientist, **Genentech**	**Panel Discussion:** Delivery Of RNA Beyond The Liver • Challenges related to systemic circulation, biodistribution, and cellular uptake • Alternatives to LNPs **Moderator:** JUSTIN COHEN, Director, **Pfizer** **Panelist:** YUN LIU, Scientist, **Moderna** KINKINI ROY, Associate Director, **Aviceda Therapeutics** DAVID SLACK, Chief Executive Officer, **Impilo Therapeutics**
	Q&A session & transition time between conference rooms		
13:55	**Enhanced Oral Bioavailability Of Small Molecules For Rare Diseases – Utility Of Lipid-based Delivery Systems** VIVEK GUPTA, Associate Dean & Associate Professor, **St John's University**		
	Q&A session & transition time between conference rooms		

DAY TWO: 17 OCTOBER 2024

TRACK 4: INHALED & NASAL THERAPY: DESIGN & DELIVERY

Panel Discussion: Inhaled Biologics – Trends, Challenges & Opportunities

- What are the main obstacles in developing inhaled biologics
- Regulatory challenges

Moderator: ALAN WATTS, Director Innovation and Partnerships - Orally Inhaled Delivery, **Catalent**

Panelist:

VIVEK GUPTA, Associate Dean & Associate Professor, **St John's University**

LAURA ROTOLO, Associate Scientist, **Emory University**

THOMAS BRADSHAW, Chief Executive Officer, **Neuronasal**

TRACK 2: BIOLOGICS & NEW MODALITIES DRUG FORMULATION

Developing Complex In Vitro Models To Guide Oral Peptide Formulation Development

- Oral delivery of bro5 molecules such as peptides are complicated by their impermeability and requirement for intestinal permeation enhancers to achieve clinical efficacy. Current in vitro tools fail to predict clinical performance and therefore we aimed to develop a complex in vitro "Gut-on-a-Chip" model for this purpose
- Initial validation of this model was conducted using a range of BCS I-IV small molecule drugs in Caco-2 cells cultured on Transwells (gold-standard FDA approved model) or microfluidic Chip model. The predictivity of Chip was comparable to the Transwell model (r2 = 0.41–0.79 vs r2 = 0.59–0.83) while reducing culture time by 3x
- The efficacy of two intestinal permeation enhancers we assessed in these models, and Chip model required increase concentration to elicit efficacy in line with pre-clinical models. We assessed the inclusion of FaSSIF and FeSSIF in the apical chamber, and epithelium cultured in Chips was more resistant to perturbation by these physiologically-relevant buffers. Absorption of Octreotide with these two enhancers was much lower in Chip than Transwells which trends with ex vivo and preclinical models

JOHN GLEESON, Associate Principal Scientist,
Merck

TRACK 3: RNA DELIVERY

Potency Assays For Self-Amplifying RNA

- Discuss methods for assessing potency of saRNA molecules

RACHEL GROPPO, Director, Lead saRNA Team
Janssen

14:20

Q&A session & transition time between conference rooms

TRACK 4: INHALED & NASAL THERAPY: DESIGN & DELIVERY

The Effects Of Automatic Substitution Of A Canadian Reference Product Inhaler With A Subsequent Entry Product Inhaler: A Real-World Study

- A second entry Salmeterol/Fluticasone dry powder was available in Alberta, Canada in May 2020
- Forced switching at the level of the pharmacy of a less expensive secondary entry product for the innovator product is standard in Alberta
- We used linked health administrative databases to assess the effects of a forced switch upon inhaler adherence and clinical outcomes

IRVIN MAYERS, Professor,
University of Alberta

TRACK 3: RNA DELIVERY

Discovery Of A mRNA Therapeutic For The Treatment Of Glycogen Storage Disorder Type III

- Overview of Glycogen Storage Disorder Type III disease biology
- Optimization of mRNA encoding glycogen debranching enzyme (GDE) as primary modality and target
- Preclinical pharmacology in vitro and in vivo

DEEPAK SAMPATH, Senior Vice President, Head of Research,
Ultragenyx

14:45

Q&A session & transition time between conference rooms

Intranasal Delivery For CNS Treatment

THOMAS BRADSHAW, Chief Executive Officer,
Neuronasal

A Novel Non-viral Platform For Delivering Therapeutic mRNAs

- Viral vectors or lipid nanoparticles have been the most commonly used tools for delivering mRNA but they have several limitations Introduction to an endogenous protein based platform that was developed recently called 'SEND' (for 'selective endogenous encapsidation for cellular delivery'). In this talk, I will present proof of principle study to show that SEND-VLP can potentially be used as a gene therapy tool to deliver therapeutically important mRNAs

CHANNABASAVAIAH GURUMURTHY, Professor and Director,
University of Nebraska Medical Center

15:10

15:35 **End of Congress**

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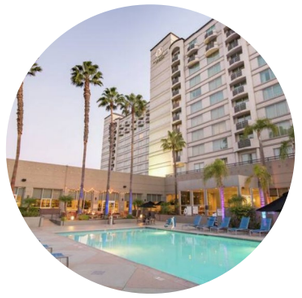

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Additionally, we kindly remind all attendees to only book their accommodation if they are registered for the event. This ensures that accommodations are available for those who have officially secured their attendance.

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