



11th Global

# DDF Summit

## Drug Delivery & Formulation

**Agenda** ◊ Day 1 ◊ Monday 9th March 2020

7:40 AM - 8:40 AM

### Registration & Refreshments

8:40 AM - 8:50 AM

### Chair's Opening Remarks

Room 1

**Anand Subramony**, Vice President, External Innovation & Novel Technologies, AstraZeneca

8:50 AM - 9:25 AM

### Leveraging New Therapeutic Modalities to expand the Druggable Target Space

Room 1 • Keynote • **Technology & Innovation**

**Shalini Andersson**, Chief Scientist New Therapeutic Modalities, AstraZeneca

*Please note that this will be a remote presentation*

9:30 AM - 10:05 AM

### Pharmaceutical Salts and Co-crystal Development; from Conformer Selection to Continuous Manufacture: A Quality by Design Approach

Room 1 • Case Study • **Small Molecules**

**Steven Ross**, Research Associate in pharmaceutical processes Pharmaceutical, University of Greenwich

### Data Sciences meet Formulation Development: Workflow in Vaccine Formulation Development Using Integrative High Throughput/High Content Approaches

Room 2 • Case Study • **Biologics**

**Joao Miguel Freire**, Scientist Formulation Science & Technology (FST), Janssen

### AI in Formulation Development for Amorphous Dispersions

Room 3 • Case Study • **Technology & Innovation**

**Matthias Erber**, Laboratory head in Formulation Development Parenterals, Bayer

*Please note that this will be a remote presentation*

### Differentiation for Injection Devices: A Guide for Better Patient Safety

Room 4 • Case Study • **Device Development**

**Agathe Buffard**, Human Factors – Device Manager I, Novartis

*Please note that this will be a remote presentation*

10:10 AM - 10:45 AM

### Targeting Small Molecules to Lymph: Methods and Applications

Room 1 • Case Study • **Small Molecules**

**Daniel Bonner**, Vice President, PureTech Health

*Please note that this will be a remote presentation*

### Freeze Drying Process Design Using a Design Space Approach

Room 2 • Case Study • **Biologics**

**Benoit Koumurian**, Drug Product Process Engineer, Sanofi

### Clinically Relevant Drug Product Specifications

Room 3 • Case Study • **Technology & Innovation**

**Andreas Abend**, Director Analytical Sciences, MSD

*Please note that this will be a remote presentation*

### First-Time-Use Experience

Room 4 • Case Study • **Device Development**

**Rémy Kohler**, Human Factors Engineer, Device and Packaging Development, Roche

*Please note that this will be a remote presentation*

10:45 AM - 11:35 AM

### iSolve & Networking Break

- 11:35 AM - 12:10 PM Achieve Complex Drug Release Profiles for Solid Oral Dosage Forms**  
Room 1 • Solution Spotlight • [Small Molecules](#)  
Dr Carol Thomson, Chief Executive Officer, BDD Pharma
- Trehalose and Sucrose: Essential Components of Platform Biopharma Formulations**  
Room 2 • Solution Spotlight • [Biologics](#)  
Dr. Christian Lotz, General Manager, EMEA, Pfanstiehl
- Transdermal Therapeutic Systems – Still an Attractive Technology?!**  
Room 3 • Solution Spotlight • [Technology & Innovation](#)  
Dr. Marco Emgenbroich, Corporate Vice President Head of Pharmaceutical Development I R&D, LTS Lohmann
- MDR and Combination Products**  
Room 4 • Solution Spotlight • [Device Development](#)  
Richard Featherstone, Research Director, Human Factors Research and Design, Emergo by UL
- 12:15 PM - 12:50 PM Summary of Six Years of Progress in the Oral Biopharmaceutics Area – the EU/IMI project OrBiTo**  
Room 2 • Case Study • [Biologics](#)  
Bertil Abrahamsson, Senior Principal Scientist, AstraZeneca  
*Please note that this will be a remote presentation*
- Nanoparticles and Medicines Design**  
Room 3 • Case Study • [Technology & Innovation](#)  
Professor Andreas Schätzlein, Chair in Translational Therapeutics, UCL School of Pharmacy
- Injectability Modelling for Arbitrary Drug Delivery Devices**  
Room 4 • Case Study • [Device Development](#)  
Nima Aghajari, Senior Simulation Engineer, Sanofi
- 12:50 PM - 1:50 PM Networking Lunch**
- 1:50 PM - 2:25 PM Improving Cancer Treatment using Nanomedicines: CriPec® and CPC634**  
Room 1 • Case Study • [Small Molecules](#)  
Rachel Hu, Senior Formulation Scientist, Cristal Therapeutics
- Challenges and Opportunities with Nanotechnology Applied to the Oral Administration of Peptides, Proteins and Biologics**  
Room 2 • Case Study • [Biologics](#)  
Alan S Harris, Senior VP GLOBAL R&D LCM, Ferring
- Re-thinking BioTED, a Technical Innovation Portfolio for Biologics**  
Room 3 • Case Study • [Technology & Innovation](#)  
Gregoire Schwach, E2E Home Leader Ocular and Drug Delivery, Roche  
*Please note that this will be a remote presentation*
- Interchangeability of Combination Products**  
Room 4 • Case Study • [Device Development](#)  
Mike Tate, Human Factors Manager, Boehringer Ingelheim
- 2:30 PM - 3:05 PM An Integrated Approach to Rapidly Advancing Poorly Bioavailable Compounds to the Clinic**  
Room 1 • Solution Spotlight • [Small Molecules](#)  
David Lyon, Senior Fellow, Research, Lonza
- New Silicone-Free Option for Delivery of Sensitive Biologics in Pre-Filled Syringes**  
Room 2 • Solution Spotlight • [Biologics](#)  
Russ Hornung, Business Development- Drug Delivery and Packaging, W.L. Gore & Associates
- Improving Compliance and Accuracy of Dosing in Paediatrics and Patients with Dysphagia**  
Room 3 • Solution Spotlight • [Technology & Innovation](#)  
Simon Hendry, BD Director, Adare Pharmaceuticals  
*Please note that this will be a remote presentation*
- New Coated Plungers for Syringes and Auto-Injector**  
Room 4 • Solution Spotlight • [Device Development](#)  
Simon Kervyn, Manager Materials Development, Datwyler  
Carina Van Eester, Platform Leader PFS and cartridges, Datwyler Sealing Solutions

## 3:05 PM - 3:55 PM **iSolve & Networking Break**

### 3:55 PM - 4:30 PM **Delivery to Market: Application of Multivariate Analysis to Production Processes**

Room 1 • Case Study • **Small Molecules**

**Paolo Avalle**, Associate Principal Scientist, MSD

### **Predictive Tools for the Development of Biologics: from Molecule Design to Formulation Stability Prediction**

Room 2 • Case Study • **Biologics**

**Patrick Garidel**, Associate Director Protein Science, Boehringer Ingelheim

### **Designer Nanomedicines for Cancer Immunotherapy**

Room 3 • Case Study • **Technology & Innovation**

**Professor Khuloud Al-Jamal**, Chair of Drug Delivery & Nanomedicine, King's College London

### **Dissolvable Microneedle Skin Patches for Vaccination**

Room 4 • Case Study • **Device Development**

**Anne Moore**, Professor, University College Cork

### 4:35 PM - 5:10 PM **Application of Thermodynamic and Kinetic Modeling in ASD Development for Primary Packaging Assessment**

Room 1 • Case Study • **Small Molecules**

**Kristin Lehmkemper**, Senior Scientist, AbbVie

*Please note that this will be a remote presentation*

### **Should I Mix for an Additional 5 min? Setting up the Mixing Parameters for Protein Drug Manufacturing with Computational Fluid Dynamics**

Room 2 • Case Study • **Biologics**

**Omar Naneh**, Senior scientist BPD DPD Operational Sciences, Novartis

### **Drug Delivery Across Biological Barriers for Combatting and Preventing Infectious Diseases**

Room 3 • Case Study • **Technology & Innovation**

**Claus-Michael Lehr**, Head of the Department Drug Delivery,

Helmholtz Institute for Pharmaceutical Research Saarland

### **3D Printing for the Fabrication of Transdermal Microneedles: In Vitro and in Vivo evaluation**

Room 4 • Case Study • **Device Development**

**Dennis Douroumis**, Professor in Pharmaceutical Technology and Process Engineering, Director of Centre for Innovation in Process Engineering and Research (CIPER), University of Greenwich

### 5:15 PM - 6:00 PM **Cell & Gene Therapies: Current Status and Opportunities**

Room 1 • Keynote • **Biologics**

**Dr. Magdalena Obarzaneck-Fojt**, Drug Product Leader within Cell and Gene Technical Development, Novartis

### 6:00 PM - 6:05 PM **Chair's Closing Remarks**

Room 1

**Anand Subramony**, Vice President, External Innovation & Novel Technologies, AstraZeneca

## 6:05 PM - 7:05 PM **Drinks Reception**



11th Global  
**DDF Summit**  
Drug Delivery & Formulation

**Agenda** ○ Day 2 ○ Tuesday 10th March 2020

8:00 AM - 8:45 AM	<b>Registration</b>
8:45 AM - 8:50 AM	<b>Chair's Opening Remarks</b> Room 1 <b>Anand Subramony</b> , Vice President, External Innovation & Novel Technologies, AstraZeneca
8:50 AM - 9:25 AM	<b>Understanding Developability Assessment of Small Molecules</b> Room 1 • Keynote • <b>Small Molecules</b> <b>Sudhakar Garad</b> , Global Head of Chemical and Pharmaceutical Profiling, Novartis Institutes for BioMedical Research <i>Please note that this will be a remote presentation</i>
9:30 AM - 10:05 AM	<b>Bioavailability Enhancement in Early Formulation Development</b> Room 1 • Case Study • <b>Small Molecules</b> <b>Ildiko Terebesi</b> , Head of Drug Delivery Innovation, Bayer <i>Please note that this will be a remote presentation</i>
	<b>CMC aspect of Oligonucleotide Therapeutics</b> Room 2 • Case Study • <b>Biologics</b> <b>Aleksandra Dabkowska</b> , Associate Principal Scientist, AstraZeneca <i>Please note that this will be a remote presentation</i>
	<b>In Vitro Models of the Blood Brain Barrier and their use in Drug Delivery Studies</b> Room 3 • Case Study • <b>Technology &amp; Innovation</b> <b>Birger Brodin</b> , Professor, University of Copenhagen
	<b>Drug Product Challenges with Closed System Transfer Devices</b> Room 4 • Case Study • <b>Device Development</b> <b>Twinkle Christian</b> , Process Development Scientist, Drug Product Technologies department, Amgen <i>Please note that this will be a remote presentation</i>
10:05 AM - 10:55 AM	<b>iSolve &amp; Networking Break</b>
10:55 AM - 11:30 AM	<b>Analysis from the Tufts Center for the Study of Drug Development to Assess the Financial Benefits from Translational Pharmaceuticals®: A Platform for Accelerating Product Development</b> Room 1 • Solution Spotlight • <b>Small Molecules</b> <b>Andrew Lewis</b> , Vice President, Pharmaceutical Sciences, Quotient Sciences
	<b>Polysorbates for Biopharmaceuticals: An Unnecessarily Complex Mixture or Synergistic Blend?</b> Room 2 • Solution Spotlight • <b>Biologics</b> <b>James Humphrey</b> , Applications Specialist, Croda
	<b>Continuous Manufacturing and Influence of Excipient Variation</b> Room 3 • Solution Spotlight • <b>Technology &amp; Innovation</b> <b>Mara van Haandel</b> , Innovation Manager, DFE pharma
	<b>How to Unlock the Potential of Digital to Design Products for the Benefit of all Stakeholders</b> Room 4 • Solution Spotlight • <b>Device Development</b> <b>Clare Beddoes</b> , Senior Medical Innovation and Research Consultant, Cambridge Design Partnership <i>Please note that this will be a remote presentation</i>

# Agenda ○ Day 2 ○ Tuesday 10th March 2020

## 11:35 AM - 12:10 PM **Process Material Compatibility Study Concepts**

Room 1 • Case Study • [Small Molecules](#)

**Thomas Schmidt**, Principal Scientist, Novartis

## **Selecting Compound for Long Acting Injections and Available Technologies**

Room 2 • Case Study • [Biologics](#)

**Rene Holm**, Head and Scientific Director, Liquids & Parenterals, Janssen

*Please note that this will be a remote presentation*

## **Staying Ahead of the Game: Formulation Development Strategies for Biologics and Biosimilars**

Room 3 • Case Study • [Technology & Innovation](#)

**Sachin Dubey**, Deputy Director - Process Sciences I, Ichnos Sciences

*Please note that this will be a remote presentation*

## 12:15 PM - 12:50 PM **Continuous Melt Granulation of Thermally Labile Drugs**

Room 1 • Solution Spotlight • [Small Molecules](#)

**Tony Listro**, Vice President, Technology, Foster Delivery Science

## **Stable Liquid Formulations for Viral Vaccines and Gene Therapy Viral Vectors: Reality or Fantasy**

Room 2 • Solution Spotlight • [Biologics](#)

**Dr. Andreas Seidl**, Chief Operating Officer, LEUKOCARE AG

## **Fine Powder Methyl Cellulose and its Dry Binder Application**

Room 3 • Solution Spotlight • [Technology & Innovation](#)

**Dr. Andreas Sauer**, Technical Sales Director, SE Tylose GmbH & Co. KG

## **Computer Simulations for Subcutaneous Injections**

Room 4 • Solution Spotlight • [Device Development](#)

**Joel Gresham**, Simulation Expert & Life Sciences Lead, Crux Product Design Ltd.

**John Majewski**, Device Development Engineer, Gilead Sciences

## 12:50 PM - 1:50 PM

### **Networking Lunch**

Lunch and Learn roundtable:

Roundtable led by Captisol, a Ligand company

**Topic: Captisol a Globally Accepted Modified Cyclodextrin in 11 Approved Products. Come and Learn what's New.**

Moderated by: **Vince Antle**, Senior Vice President, Technical Operations

**JD Pipkin**, Vice President, New Product Development

## 1:50 PM - 2:25 PM

### **Lipid-based Excipients with Advanced Functionality**

Room 1 • Case Study • [Small Molecules](#)

**Dr. Sharareh Salar-Behzadi**, Principal Scientist, Research Center Pharmaceutical Engineering (RCPE)

### **Injection Pain with Biologics**

Room 2 • Case Study • [Biologics](#)

**Jonas Fransson**, Director of Drug Product Development, Swedish Orphan Biovitrum AB

*Please note that this will be a remote presentation*

## **Endocytosis for Drug Delivery: Driving the Internalisation and Intracellular Targeting of Therapeutics**

Room 3 • Case Study • [Technology & Innovation](#)

**Arwyn T. Jones**, Professor of Membrane Traffic and Drug Delivery, and Director of Research, School of Pharmacy and Pharmaceutical sciences, Cardiff University

## **Inhalation Devices – Device Selection for Drug/Device Combination Products**

Room 4 • Case Study • [Device Development](#)

**Bernhard Muellinger**, Vice President - Inhalation Technology, Vectura

**2:30 PM - 3:05 PM Advances in Dermal Drug Development – The Formulation and The Model**

Room 1 • Solution Spotlight • [Small Molecules](#)

**Charles Evans**, VP of Pharmaceutical Development, MedPharm

*Please note that this will be a remote presentation*

**Extending Shelf Life of Therapeutic Proteins with Hydroxypropyl  $\beta$ -Cyclodextrins – Mechanistic Understanding of Bevacizumab Stabilization**

Room 2 • Solution Spotlight • [Biologics](#)

**Shiqi Hong**, Senior Biopharma Scientist, Roquette

**Digital Assistant to Support Drug Product Development**

Room 3 • Solution Spotlight • [Technology & Innovation](#)

**Ferdinand Brandl**, Head of Laboratory, BASF SE, Nutrition and Health, Development Pharma Solutions

**How Devices and Services can be part of a Product's Life Cycle Management**

Room 4 • Solution Spotlight • [Device Development](#)

**Guillaume Brouet**, Vice-President - Analytical, Regulatory and Scientific Affairs, Aptar Pharma

**3:05 PM - 3:55 PM Networking Break**

**3:55 PM - 4:30 PM 3D Printing of Oral Solid Dosage Forms for Controlled Drug Delivery**

Room 1 • Case Study • [Small Molecules](#)

**Roxanne Khalaj**, PhD Researcher, University of Greenwich

**What Can Really be Learned From Early Stage Interaction Measurements**

Room 2 • Case Study • [Biologics](#)

**Josef Hartl**, Scientist, Martin-Luther University Halle-Wittenberg

**Lipid-based Nanocarriers for Oral Peptide Delivery: Hype or Hope?**

Room 3 • Case Study • [Technology & Innovation](#)

**Andreas Bernkop-Schnürch**, Research Group Drug Delivery and Powder Technology, University of Innsbruck

**Integrated approach for Combination Product development**

Room 4 • Case Study • [Device Development](#)

**Davide Mercadante**, Senior Device Quality Engineer, Device Development Quality, Biogen

*Please note that this will be a remote presentation*

**4:35 PM - 5:10 PM Nanomedicine and Nanotechnology Impacts on Pharma**

Room 1 • Keynote • [Small Molecules](#)

**Christian Jones**, Chief Commercial Officer, Nanoform

*Please note that this will be a remote presentation*

**5:10 PM - 5:45 PM Polysorbate Degradation: Implications and Control**

Room 1 • Keynote • [Biologics](#)

**Kishore Ravuri**, Senior Group Leader, Early-Stage Pharmaceutical and Processing Development, Roche

**5:45 PM - 6:20 PM Nanomedicine, Emerging Opportunities in Immunooncology**

Room 1 • Keynote • [Technology & Innovation](#)

**Anand Subramony**, Vice President, External Innovation & Novel Technologies, AstraZeneca

*Please note that this will be a remote presentation*

**6:20 PM - 6:25 PM Poster Presentation Award**

**6:25 PM - 6:30 PM Chair's Closing Remarks**

Room 1

**Anand Subramony**, Vice President, External Innovation & Novel Technologies, AstraZeneca

**6:30 PM - 7:30 PM Drinks Reception**





11th Global

# DDF Summit

## Drug Delivery & Formulation

Agenda  Day 3  Wednesday 11th March 2020

8:30 AM - 9:00 AM **Registration**

9:00 AM - 9:05 AM **Chair's Opening Remarks**

Room 1

**Anand Subramony**, Vice President, External Innovation & Novel Technologies, AstraZeneca

9:05 AM - 9:40 AM **What is Pharmaceutical Engineering?**

Room 1 • Keynote • [Small Molecules](#)

**Jean-René Authelin**, Global Head of Pharmaceutical Engineering, Sanofi

*Please note that this will be a remote presentation*

9:40 AM - 10:15 AM **Creating a Digital Ecosystem that Improves Outcomes**

Room 1 • Keynote • [Device Development](#)

**Matthew Clemente**, Vice President, Device Development, Novo Nordisk

*Please note that this will be a remote presentation*

10:20 AM - 10:55 AM **A Convenient Formulation of Orodispersible mini-tablets for Pediatric Administration**

Room 1 • Solution Spotlight • [Small Molecules](#)

**Dr. Michael Black**, Head of Sales Pharma, BENEOPalatinit GmbH

**SynBiosys Microparticles for the Development of Long-Acting Injectable Formulations for Biological Therapeutics**

Room 2 • Solution Spotlight • [Biologics](#)

**Rob Steendam**, Chief Technology Officer, InnoCore Pharmaceuticals

**Novel Screening Tools for Hot-Melt Extrusion – Early Prediction of Formulation Performance**

Room 3 • Solution Spotlight • [Technology & Innovation](#)

**Thomas Kipping**, Head of Drug Carriers, Merck

*Please note that this will be a remote presentation*

**Innovation in Drug Delivery and the Value of 'Connectivity' to the Pharma Ecosystem**

Room 4 • Solution Spotlight • [Device Development](#)

**Mark A. Hassett**, Vice President of Business Development, Credence MedSystems

10:55 AM - 11:45 AM **Networking break**

11:45 AM - 12:20 PM **Processing Strategies to Prepare Poorly Soluble Drug Compounds by Nanotechnological Formulation Approaches**

Room 1 • Case Study • [Small Molecules](#)

**Werner Hoheisel**, Group Lead Formulation Technologies, InVivo

*Please note that this will be a remote presentation*

**Mesoporous Silica Particles; Simple yet Powerful Tool for the Delivery of Biomolecules**

Room 2 • Case Study • [Biologics](#)

**Dr Vivek Trivedi**, Lecturer, Formulation Science Department of Pharmaceutical, Chemical and Environmental Sciences, University of Kent

**In Progress, Unique Identifiers on Dosage Forms to Prevent Counterfeits and Falsified Medicines**

Room 3 • Case Study • [Technology & Innovation](#)

**Sven Stegemann**, Professor for Patient Centric Drug Development and Manufacturing, Graz University of Technology

**Risk Management for Drug-Device Combination Products**

Room 4 • Case Study • [Device Development](#)

**Torsten Kneuss**, QA Manager Combination Products, Bayer

*Please note that this will be a remote presentation*

**12:25 PM - 1:00 PM Computer-aided Formulation Development for Small Molecule Drugs and Biologics**

Room 1 • Solution Spotlight • [Small Molecules](#)

**John C. Shelley**, Schrödinger Fellow, Schrödinger

**Translating Inhaled and Nasal Technologies for the Delivery of Biologics**

Room 2 • Solution Spotlight • [Biologics](#)

**David Ward**, Formulation and Manufacturing Lead, Intertek

**The Accordion Pill®: Unique Oral Delivery to Enhance Pharmacokinetics and Therapeutic benefit of Challenging Drugs**

Room 3 • Solution Spotlight • [Technology & Innovation](#)

**Ronny Reinberg**, Vice President Technology Affairs, Intec Pharma

*Please note that this will be a remote presentation*

**1:00 PM - 2:00 PM Networking Lunch**

**2:00 PM - 2:35 PM Multivariate Analysis in the Pharmaceutical Industry**

Room 1 • Case Study • [Small Molecules](#)

**Mike Tobyn**, Research Fellow, Bristol-Myers Squibb

*Please note that this will be a remote presentation*

**Characterization of Protein Based Medicines using Drop Coat Deposition Raman Spectroscopy**

Room 3 • Case Study • [Technology & Innovation](#)

**Anna Luczak**, Senior Scientist, Bristol-Myers Squibb

**Biocompatibility Testing of Medical Devices and Drug Device Combination Products**

Room 4 • Case Study • [Device Development](#)

**Dr. Clemens Günther**, Director Nonclinical Safety CC, Bayer

*Please note that this will be a remote presentation*

**2:40 PM - 3:15 PM Formulation and Evaluation of Midazolam loaded Hydrogel as a Carrier for Nose to Brain Drug Delivery**

Room 1 • Case Study • [Small Molecules](#)

**Muhammad Akhtar**, Associate Professor at Faculty of Pharmacy and Alternative Medicine, The Islamia University of Bahawalpur

**Nanogels for the Intracellular Delivery of Proteins and Peptides**

Room 2 • Case Study • [Biologics](#)

**Rene van Nostrum**, Associate professor, Utrecht University

**Sustained Release Intra-Vaginal Drug Delivery Systems based on Ethylene-Vinyl Acetate: Formulation and Physicochemical Considerations**

Room 3 • Case Study • [Technology & Innovation](#)

**Amrit Paudel**, Assistant Professor & Principal Scientist, Graz University of Technology, Research Center Pharmaceutical Engineering (RCPE)

**Aggregation Propensity and Beneficial Solution Conditions in Antibody Formulations from a Thermodynamic Perspective**

Room 4 • Case Study • [Technology & Innovation](#)

**Dr. Christoph Brandenbusch**, Group Leader, TU Dortmund

**3:15 PM - 3:50 PM CMC Strategies to Accelerate Proof-of-Concept and late-stage development for Oral Drugs in the Biotech Industry**

Room 1 • Keynote • [Small Molecules](#)

**Jatin Patel**, Executive Director, CMC, Constellation Pharmaceuticals

**3:50 PM - 3:55 PM Chair's Closing Remarks**

Room 1

**Anand Subramony**, Vice President, External Innovation & Novel Technologies, AstraZeneca