

Agenda Day 1 Monday 11th March 2019

7:40 AM - 8:40 AM	Registration & Refreshments
8:40 AM - 8:50 AM	Chair's Opening Remarks Room 1 Mostafa Nakach, Head of Pharmaceutical Engineering, Sanofi
8:50 AM - 9:25 AM	How Next-Generation Biotherapeutics will Influence Formulation and Device Development Room 1 • Keynote • Biologics Kerstin Walke, Head of Pharmaceutical Development Biologicals, Boehringer Ingelheim
9:30 AM - 10:05 AM	Optimisation of Industrial Freeze Drying Cycle – Two Real Life Examples Room 1 • Case Study • Small Molecules Mostafa Nakach, Head of Pharmaceutical Engineering, Sanofi
	In-Silico Modelling to Support Protein Formulation Development Room 2 • Case Study • Biologics Patrick Garidel, Associate Director Protein Science, Boehringer Ingelheim
	Parenteral Sustained Release of Peptides – Getting it Right Room 3 • Case Study • Technology & Innovation Simon Bjerregaard, Senior Research Scientist, Ferring
	Facilitating Meaningful Differentiation of Products by Establishing a Culture of Innovation Room 4 • Case Study • Device Development Dr Stefan Holzner, Senior Director, Head of Device Development, Takeda
10:10 AM - 10:45 AM	Nanoparticle Formulation Development: A Closer look at Pharmaceutical Fabrication Methods Room 1 • Case Study • Small Molecules Ben Van Hove, Associate Director Drug Product Development, Oral Solid Dosage Forms, Janssen
	More Than Just Down-Scaling – Miniaturisation of Methods in a High-Throughput Setting Requires Creative Concepts and Holistic Thinking Room 2 • Case Study • Biologics Dr Martin Hüelsmeyer, Head of HTS Operations & Analytics NBE Formulation Sciences, Principal Research Scientist, AbbVie
	2D Inkjet Printing for Patient Centric and Translational Drug Delivery Room 3 • Case Study • Technology & Innovation Dr Amrit Paudel, Assistant Professor & Principal Scientist, Graz University of Technology, Research Center Pharmaceutical Engineering (RCPE)
	Drug Delivery Devices for Innovative Parenterals and Biosimilars: Patient-Centered Technical and Business Opportunities Room 4 • Case Study • Device Development Corinna Sonderegger, Head Portfolio Management Device Development & Commercialization, Novartis
10:45 AM - 11:45 AM	iSolve & Break
11:45 AM - 12:20 PM	Polyoxazoline: A Potent Alternative to PEG-based Formulations of Hydrophobic Drugs Room 1 • Case Study • Small Molecules Prof Rainer Jordan, Chair of Macromolecular Chemistry, School of Science, TU Dresden, Germany and Vice-President, DelAqua Pharmaceuticals Inc

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Mind the Gap - How to Assure Data Integrity in a High-Throughput Formulation Screening for Biotherapeutics

Room 2 • Case Study • [Biologics](#)

Sabine Eichling, Senior Scientist II, NBE High Throughput and Advanced Formulation Sciences Drug Product Development, AbbVie

Development of Polymeric Nanoparticles for Intravenous Administration

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

Dr Rebecca Booth, Senior Scientist, AstraZeneca

A Self Anchoring Microneedle Patch (StAMP) Offering Precise and Sustained Transdermal Drug Delivery

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

Manita Dangol, Senior Research Fellow, University College Dublin

12:25 PM - 1:00 PM

New Surfactants in Wet Ball Milling and an Innovative Embedding of Nanocrystals into a Granulate Matrix

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

Dr Matthias Rischer, Director Drug Delivery & Innovation Projects, Losan Pharma

Trehalose and Sucrose: Essential Components of Platform Biopharma Formulations

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

Dr Christian Lotz, General Manager EMEA, Pfanstiehl

Oral Thin Films – Tailoring Therapy Need

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

Dr Marco Emgenbroich, Corporate Senior Director, Head of Pharmaceutical Development I R&D, LTS Lohmann Therapy Systems

Rubber Components Selection for Optimal Drug Packaging

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

Simon Kervyn, Manager Materials Development, Datwyler

1:00 PM - 2:00 PM

Networking Lunch

Lunch & Learn Round Table with ADM SIO (*Advanced sign-up required*)

Management of Contaminants in Plant based Excipients

Moderated by: **Stephanie Bureau**, R&D Director, ADM SIO

Hervé Limouzin, Sales & Marketing Manager, ADM SIO

2:00 PM - 2:35 PM

Inhalable Dry Powders for the Improvement of Lung Pharmacokinetics in Preclinical *in-vivo* Experiments

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

Alessandro Fioni, DMPK Senior Scientist, Chiesi

Long Recombinant Homogeneous Linkers for Dual Protein Conjugations, to Replace Heterogeneous PEG

Room 2 • Case Study • [Biologics](#)

Thomas Hoeg-Jensen, Scientific Director, Novo Nordisk

DNA-Based Nanoassays for Biomarker Detection in Liquid Biopsy and Therapeutic Drug Monitoring

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

Loredana Casalis, Head of Nanoinnovation Laboratory, Elettra

Predicting the Future: Learning about Challenges with Injectable Formulations to Select Better Primary Packaging

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

James K. Mellman, Device Manager, Novartis

Agenda Day 1 Monday 11th March 2019

- 2:40 PM - 3:15 PM** **The Perks of a One Stop Shop: From Low Solubility APIs to High Performance Formulations**
Room 1 • Solution Spotlight • [Small Molecules](#)
Mafalda Paiva, Analytical Scientist, Team Leader Physical and Performance Characterization, Hovione
- How do I Quickly Develop First-in-Human (FIH) Dosage Forms and Bridge to Drug Products for Proof-of-Concept (POC)?**
Room 2 • Solution Spotlight • [Biologics](#)
Nikki Whitfield, Vice-President, CDMO Services, Quotient Sciences
- Simplifying Tablet Formulation Strategies with Avicel® SMCC and METHOCEL™ DC2**
Room 3 • Solution Spotlight • [Small Molecules](#)
Dr Carsten Huettermann, Senior Application Scientist, Leader Pharma SAFI Innovation EMEA, DuPont
- Combination Products – Global Regulatory Landscape**
Room 4 • Solution Spotlight • [Device Development](#)
Viky Gilles Daniel Verna, Co-Founder and VP, Confinis Corporation
- 3:15 PM - 4:15 PM** iSolve & Networking Break
- 4:15 PM - 4:50 PM** **Understanding Material Properties for HME Process Optimisation in ASD Formulations**
Room 1 • Case Study • [Small Molecules](#)
Samuel Kyeremateng, NCE Formulation Sciences Senior Scientist, AbbVie
- Root Cause Investigations for Visible Particles and Aggregation in Drug Containers – Case Studies**
Room 2 • Case Study • [Biologics](#)
Andreas Seidl, Head Global Analytical Characterization & Bioanalytics, Hexal (Novartis)
- New Generation of Safer Drug-Eluting Mesh Implants by Electrospinning and 3D Printing**
Room 3 • Case Study • [Technology & Innovation](#)
Dr Dimitrios A. Lamprou, Reader in Pharmaceutical Engineering, Queen's University Belfast
- Solid Lipid Solutions as Formulation Platform for Poorly Soluble Drugs**
Room 4 • Case Study • [Small Molecules](#)
Ruzica Kolakovic, Senior Scientist, Pharmaceutical Sciences, Drug Product Development, Janssen
- 4:55 PM - 5:30 PM** **Challenges and Opportunities for the next Generation of Oral Peptide Delivery**
Room 1 • Keynote • [Biologics](#)
Alan S. Harris, Senior VP, Global R&D Life Cycle Management, Ferring
- 5:30 PM - 5:35 PM** **Chair's Closing Remarks**
Room 1
Mostafa Nakach, Head of Pharmaceutical Engineering, Sanofi
- 5:35 PM - 6:35 PM** Drinks Reception in Exhibition Hall

Agenda Day 2 Tuesday 12th March 2019

- 8:00 AM - 8:45 AM** Registration & Refreshments
- 8:45 AM - 8:50 AM** **Chair's Opening Remarks**
Room 1
Mostafa Nakach, Head of Pharmaceutical Engineering, Sanofi
- 8:50 AM - 9:25 AM** **Drug Delivery – Recent Technology Trends and Solutions**
Room 1 • Keynote • [Small Molecules](#)
Dr Stefan Bracht, Vice President Head of Disruptive Technologies, Bayer
- 9:30 AM - 10:05 AM** **Modelling and Control of Fluid Bed Granulation Processes**
Room 1 • Case Study • [Small Molecules](#)
Sophie Martin, Process Engineer in Pharmaceutical Development, Sanofi
- Design of Long-acting GLP-1 Analogs Applicable for Once Weekly and Oral Dosing**
Room 2 • Case Study • [Biologics](#)
Jesper Lau, Vice President, Protein and Peptide Chemistry, Novo Nordisk
- Insights in Protein-Protein Interactions at High Protein Concentrations: The Relevance of Surrogate Parameters**
Room 3 • Case Study • [Technology & Innovation](#)
Josef Hartl, Scientist, Boehringer Ingelheim
- MDR – Notified Body Opinion – Article 117**
Room 4 • Case Study • [Device Development](#)
April Kent, M.Sc., B.Sc. Regulatory Affairs Manager, Combination products and IVDs, Amgen
- 10:05 AM - 11:05 AM** iSolve & Networking Break
- 11:05 AM - 11:40 AM** **Reactive Twin-Screw Melt Extrusion in Drug Delivery**
Room 1 • Solution Spotlight • [Small Molecules](#)
Feng Zhang, Assistant Professor, University of Texas at Austin
- Hydroxylpropyl β -cyclodextrin: A Promising Excipient for Protein Stabilisation**
Room 2 • Solution Spotlight • [Biologics](#)
Rajeev Gokhale, Head Global Pharmaceutical Sciences R&D, Head Asia R&D, Roquette
- Solid Dosage Forms for Heterogeneous Patient Groups: Challenges and Solutions**
Room 3 • Solution Spotlight • [Technology & Innovation](#)
Véronique Henner-Kulkarni, Technical Sales Manager, ShinEtsu
- Platform for Change and Improved Patient Experience**
Room 4 • Solution Spotlight • [Device Development](#)
Mike Hooven, President and CEO, Enable Injections, Inc.
- 11:45 AM - 12:20 PM** **Small is the New Big: Case Studies of two Nanotech Products from Lab to Market**
Room 1 • Case Study • [Small Molecules](#)
Dr Ajay J. Khopade, Vice President-R&D, Formulation Development (Non-Orals), Sun Pharma Advanced Research Co. Ltd.
- Challenging Transfer of a Fill & Finish Process for a Highly Fragile Bispecific mAb**
Room 2 • Case Study • [Biologics](#)
Stephanie Greco, Head of Laboratory in Formulation & Process Development, Sanofi
- Challenges and Opportunities to Include Patient Centered Design in Industrial Drug Development**
Room 3 • Case Study • [Technology & Innovation](#)
Leonie Wagner-Hattler, Formulation Scientist, F. Hoffmann-La Roche
- Micro Array Patches: Delivering High Drug Doses Transdermally**
Room 4 • Case Study • [Device Development](#)
Prof Ryan F. Donnelly, Chair in Pharmaceutical Technology, Queen's University Belfast

Agenda Day 2 Tuesday 12th March 2019

12:25 PM - 1:00 PM

How-to Use Oral Drug Delivery Technology Innovatively

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

Luigi Boltri, R&D Director, Innovation and Technology Liaison, Adare Pharmaceuticals

Hard-to-Stabilise Proteins and Peptides: Can Recombinant Human Albumin be an Effective Approach?

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

Eleonora Cerasoli, Senior Research Scientist, Albumedix

Reimagining your Orally Dispersible Tablets Formulation Excipients, Introducing a New Lactose Product (SuperTab® 500DT)

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

Mara van Haandel, Innovation Manager, DFE Pharma

Human Factors - Trends, Optimisation, ROI and the Future

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

Matthew Gottschalk, Director of Programme Development, Worrell

1:00 PM - 2:00 PM

Networking Lunch

Lunch & Learn Round Table with Capitsol a Ligand Technology (*Advanced sign-up required*)

What's New with Capitsol?

Vince Antle, PhD, Senior Vice President of Technical Operations, Capitsol

JD Pipkin, PhD, Vice President, New Product Development, Capitsol

2:00 PM - 2:35 PM

Electrospinning of Biopharmaceuticals

Room 1 • Case Study • [Biologics](#)

Sune Andersen, Principal Scientist in Particle Engineering, Janssen

Oral Semaglutide: Realising the Potential of Oral Peptide Delivery

Room 2 • Case Study • [Biologics](#)

Stephen Buckley, Head of the Discovery ADME Department in Global Research, Novo Nordisk

Fill and Finish Process Development for Biologic Products: Derisking Approach

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

Marie Wacquet, Drug Product Process Development Unit Manager, Biologics, Sanofi

MDR Impact on Pharma Companies

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

Bjorg K. Hunter, Regulatory Manager, Devices, GSK

2:40 PM - 3:15 PM

Mesoporous Silica: An Option for Lquisolid Systems

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

Fred Monsuur, Excipient Development & TCS Manager, W.R. GRACE & Co.

End to End Solutions in Freeze Drying: From Cycle Audit through Formulation, Process Optimisation and Scale up

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

Dr Roberto Castangia, Global Head, Business Development and Innovation, Biopharma

New Silicone-Free Plunger Option for Delivery of Sensitive Biologics in Bare Glass Pre-Filled Syringes

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

Russ Hornung, Business Development – Drug Delivery, W.L. Gore & Associates, Inc.

Device Development Using In-Silico Techniques within an FDA Framework

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

Stephen Gilmore, Engineering Director, Crux Product Design

3:15 PM - 4:15 PM

Networking Break

Agenda Day 2 Tuesday 12th March 2019

4:15 PM - 4:50 PM **Importance of Establishing the Stability of Drug-Loaded Nanoparticles**

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

Cornelus van Nostrum, Associate Professor, Utrecht University

Biosimilars – Regulatory Primer for Formulation Scientists

Room 2 • Case Study • [Biologics](#)

Paul Chamberlain, Member, NDA Advisory Board, NDA Advisory Services Limited

Transporter-Mediated Brain-Targeted Prodrugs

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

Dr Kristiina M. Huttunen, Adjunct Professor (Docent) Finnish Academy Research Fellow, University of Eastern Finland

Human Factors Engineering for Medical Device Development

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

Rémy Vomscheid, Director, Device Development & Technologies, Ipsen

4:55 PM - 5:40 PM **EU Medical Device Regulations Impact on Combination Products – What to be Aware of Across Drug Delivery Development**

Room 1 • Panel Discussion • [Device Development](#)

Bjorg K. Hunter, Regulatory Manager, Devices, GSK

April Kent, M.Sc., B.Sc. Regulatory Affairs Manager, Combination products and IVDs, Amgen

Beat Steffen, Founder and Chief Executive Officer, Confinis

James K. Mellman, Device Manager, Novartis

Torsten Kneuss, QA Manager Combination Products, Bayer

5:40 PM - 5:50 PM **Chair's Closing Remarks, Poster Competition Award & End of Day 2**

Room 1

Mostafa Nakach, Head of Pharmaceutical Engineering, Sanofi

5:50 PM - 6:50 PM Drinks Reception in Exhibition Hall

Agenda Day 3 Wednesday 13th March 2019

- 8:00 AM - 8:50 AM Registration**
- 8:50 AM - 8:55 AM Chair's Opening Remarks**
Room 1
Mostafa Nakach, Head of Pharmaceutical Engineering, Sanofi
- 8:55 AM - 9:30 AM Formulation & Device Lifecycle Management**
Room 1 • Keynote • [Device Development](#)
Beate Bittner, Senior Portfolio Strategy Director, Roche
- 9:35 AM - 10:10 AM 3D Printing as an Investigative Tool in Particle Detachment**
Room 1 • Case Study • [Small Molecules](#)
Tim Rouse, Senior Scientist, Chiesi
- Polysorbate Degradation: Implications and Control**
Room 2 • Case Study • [Biologics](#)
Satya Krishna Kishore Ravuri, Senior Group Leader, Early-Stage Pharmaceutical and Processing Development, Roche
- Biopharmacy of New Chemical Entities for Oral Route Administration: Contributions of Predictive Tools to Confirm Developability and Support Proof of Concept Clinical Studies**
Room 3 • Case Study • [Technology & Innovation](#)
Guillaume Louit, Biopharmacy Team Leader, Sanofi
- Benefits and Challenges from Pharmaceutical Industry Perspective**
Room 4 • Case Study • [Device Development](#)
Torsten Kneuss, QA Manager Combination Products, Bayer
- 10:15 AM - 10:50 AM Silica Carrier for Solubility Enhancement – Graduating from Lab to Production Scale**
Room 1 • Solution Spotlight • [Small Molecules](#)
Dr Gudrun Birk, Lab Head Controlled Release, Merck
- Soteria®: Delivery of Antibodies in an Easy to Swallow Oral Pill**
Room 2 • Solution Spotlight • [Biologics](#)
Vipul Yadav, Director of R&D, Intracel Pharma
- Targeting Specific Patient Populations for Distinct Oral Dosing Formulation Challenges – Flexible Technology is Key**
Room 3 • Solution Spotlight • [Technology & Innovation](#)
Sven Stegemann, Director, Pharmaceutical Business Development, Lonza
- 10:50 AM - 11:50 AM Networking Break**
- 11:50 AM - 12:25 PM Control Strategy Approaches in Continuous Manufacturing of Oral Solid Dosage Forms**
Room 1 • Case Study • [Small Molecules](#)
Jacqueline Maximilien, Senior Scientist, Drug Product Development-Oral Solid Dosage Forms, Janssen
- Bispecifics Drug Product Development; Challenge of Low Concentration Analysis and Formulation**
Room 2 • Case Study • [Technology & Innovation](#)
Sachin Dubey, Head of Formulation and Analytical Development, Glenmark
- API Solvates and Hydrates**
Room 3 • Case Study • [Technology & Innovation](#)
Gabriele Sadowski, Professor for Thermodynamics, TU Dortmund University

Agenda Day 3 Wednesday 13th March 2019

Harnessing the Power of the Digital Exhaust and Digital ATM in Wellness Programs

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

Graham B Jones, Director of Innovation, Novartis

12:30 PM - 1:05 PM

Transmucosal Delivery – Using the Mucofilm® Technology to Bypass the First Pass Effect

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

Dr Sebastian Braun, Head of Science & Technology, tesa Labtec GmbH

Early Evaluation of Clinical Performance for Modified Release Products

Room 2 • Case Study • [Technology & Innovation](#)

Dr Carol Thomson, Chief Executive Officer, BDD Pharma

Risk Mitigation in Topical Product Development

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

Rob Turner, Vice President of Business Development and Innovation, MedPharm

1:05 PM - 2:05 PM

Networking Lunch

2:05 PM - 2:40 PM

Crystallisation Kinetics in ASDs

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

Christian Lubbert, Postdoc Pharmaceutical Formulations, TU Dortmund University

In-use Studies: Some Case Studies

Room 2 • Case Study • [Biologics](#)

Héloïse Audat, Head of Late Stage Formulation Development Unit, Biologics, Sanofi

Digital Design of Pharmaceutical Products and Processes

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

Johannes Khinast, Director, Research Center Pharmaceutical Engineering

Benefits of Early Integration of Human Factors: A BYDUREON® BCise case study

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

James Meehan, Associate Principal Scientist – Human Factors, AstraZeneca

2:45 PM - 3:20 PM

Smart Delivery of Actives by Polyrotaxanes Providing New Options for the Treatment of Niemann-Pick Type C Disease

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

Gerhard Wenz, Professor, Saarland University

Kerstin Egele, Doctoral Researcher, Institute of Organic Macromolecular Chemistry, Saarland University

Characterisation of Subvisible Particles: Old Challenges and Newest Improvements

Room 2 • Case Study • [Biologics](#)

Anacelia Ríos Quiroz, Scientist – Group Leader Particle Lab Biologics, Roche

Impact of ABC Transporters at the Blood Brain Barrier

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

Gert Fricker, Professor, University of Heidelberg

Formulation Design and Evaluation of Low Dose Aspirin Loaded Wafers for Oral / Buccal Delivery in Geriatric Patients With Dysphagia

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

Dr Joshua Boateng, Reader (Associate Professor), School of Science, University of Greenwich

Agenda Day 3 Wednesday 13th March 2019

4:20 PM - 4:55 PM

Nanoparticle Based Formulations: Special Emphasis on Bioavailability Improvement and Delayed Release upon Parenteral Administration

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

Dr Yogeshwar Bachhav, Associate Director Pharmaceutical Development, AiCuris Anti-infective Cures

Enhancing the Oral Bioavailability of Peptide and Protein by use of Functionalised Self-Emulsifying Drug Delivery Systems (f-SEDDS)

Room 2 • Case Study • **Biologics**

Anette Müllertz, Professor, Head of Center, University of Copenhagen

Miniaturised Capacitive Devices for the Detection of Circulating Biomarkers, Enabling Real-Time Kinetic Measurements, Integrable with Microfluidic Systems

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

Dr Federica Mantovani, Industrial Liaison, Elettra

5:00 PM - 5:45 PM

Are We Prepared for the Regulations on Patient-Focused/Patient-Centric Drug Development?

Room 1 • Panel Discussion • **Technology & Innovation**

Sven Stegemann, Director, Pharmaceutical Business Development, Lonza

Leonie Wagner-Hattler, Formulation Scientist, F. Hoffmann-La Roche

Louise Place, Head Of Regulatory Affairs and Senior Quality Assurance Consultant, Cambridge Design Partnership

5:45 PM - 5:50 PM

Chair's Closing Remarks

Room 1

Mostafa Nakach, Head of Pharmaceutical Engineering, Sanofi