



9th American

# DDF Summit

Drug Delivery & Formulation

## Agenda ○ Day 1 ○ Monday September 9th, 2019

07:40–08:40 AM Registration & Refreshments

08:40–08:50 AM **Chair's Opening Remarks**

Rosario LoBrutto, Head of Scientific Affairs, **Sandoz**

08:50–09:25 AM **Understanding Developability Assessment of Small Molecules**

Room 1 Keynote • **Small Molecules**

**Sudhakar Garad**, Global Head of Chemical and Pharmaceutical Profiling, **Novartis Institutes for BioMedical Research**

09:30–10:05 AM

**Current Trends in Technology and Regulatory Landscapes for Developing and Bringing Generics and Innovative Medicines to Market**

Room 1 Case Study • **Small Molecules**

Rosario LoBrutto, Head of Scientific Affairs, **Sandoz**

**Ultrasmall Targeted Nanoparticles with Engineered Antibody Fragments for Imaging of HER2-overexpressing Breast Cancer**

Room 2 Case Study • **Biologics**

**Marcello Marelli**, Senior Scientist Antibody Discovery and Protein Engineering, **AstraZeneca**

**Biopharm Combination Product Development: Container Closure selections/criteria and Injection force modelling**

Room 3 Case Study • **Device Development**

**Aarti Gidh**, Technology Development Team Lead, **GSK**

10:10–10:45 AM

**Unlocking Full Formulation Performance through Advanced Excipients**

Room 1 Solution Spotlight • **Small Molecules**

**Dr. Kathryn Hewlett**, Application Development & Innovation Scientist, **DuPont Nutrition & Biosciences**

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

Room 2 Solution Spotlight • **Biologics**

**Eleonora Cerasoli, Ph.D.**, Science Manager, Technology Group, **Albumedix**

**A QbD Approach Towards Manufacturing of Parenteral Packaging Components with First Line USA**

Room 3 Solution Spotlight • **Device Development**

**Rahul Thakar**, Technical Key Account Manager, **Datwyler Pharma Packaging, Inc.**

10:45–11:35 AM **iSolve & Networking Break**



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## Agenda Day 1 Monday September 9th, 2019

11:35–12:10 PM

### **Solubility Strategies at the Interface of Drug Discovery and Development**

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

Dr. Philippe Lienard, CMC Pre-Development Science Leader, **Sanofi**

### **Machine Learning Models for Predicting P-gp and BCRP Mediated Efflux**

Room 2 Case Study • [Biologics](#)

Istvan Enyedy, Principal Scientist, **Biogen**

### **Incorporating Behaviour Design into Digital Health Tools**

Room 3 Case Study • [Device Development](#)

Paul Upham, Head, Smart Devices, **Genentech**

12:15–12:50 PM

### **Continuous Melt Granulation of Thermally Labile Drug**

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

Tony Listro, Vice President of Technical and Quality, **Foster Delivery Science**

### **Bridging the Drug Substance to Drug Product Continuum for Poorly Soluble Molecules**

Room 2 Solution Spotlight • [Technology & Innovation](#)

David Lyon, Senior Fellow, Research, **Lonza Pharma & Biotech**

### **The Sorrel Wearable Drug Delivery Platform for Your Primary Container**

Room 3 Solution Spotlight • [Device Development](#)

Dr. Andrei Yosef, CEO, **Sorrel Medical**

12:50–1:50 PM

### **Lunch & Learn Round Table with W.L. Gore & Associates**

Silicone-Free Option for Delivery of Sensitive Biologics in Bare Glass Pre-Filled Syringes  
Moderated by Russ Hornung, Business Development- Drug Delivery and Packaging, W.L. Gore & Associates



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1:50–2:25 PM

#### **Building a Chemical Space Map for in- silico Prediction of Supersaturation by Mesoporous Silica**

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

Suman Luthra, Senior Principal Scientist, Pfizer

#### **Quest for Quality Drugs – Use of First Principle Based Biophysical Assays to select Manufacturable Molecule**

Room 2 Case Study • [Biologics](#)

Sathya Venkataramani, Associate Director, Janssen Biotherapeutics

#### **Harnessing the Power of the Digital Exhaust to Improve Patient Outcomes**

Room 3 Case Study • [Device Development](#)

Graham Jones, Director of Innovation, Novartis

2:30–3:05 PM

#### **How do I Quickly Develop First-in-Human (FIH) Dosage Forms and Avoid CMC Delays while Achieving Proof-of Concept (POC)?**

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

Kieran Crowley, Executive Director and Head of Drug Development Solutions North America, Quotient Sciences

#### **Freeze Drying Proteins Formulation: A Journey from Challenge to Opportunity**

Room 2 Solution Spotlight • [Biologics](#)

Clara Ip, International Sales Executive, Biopharma Group

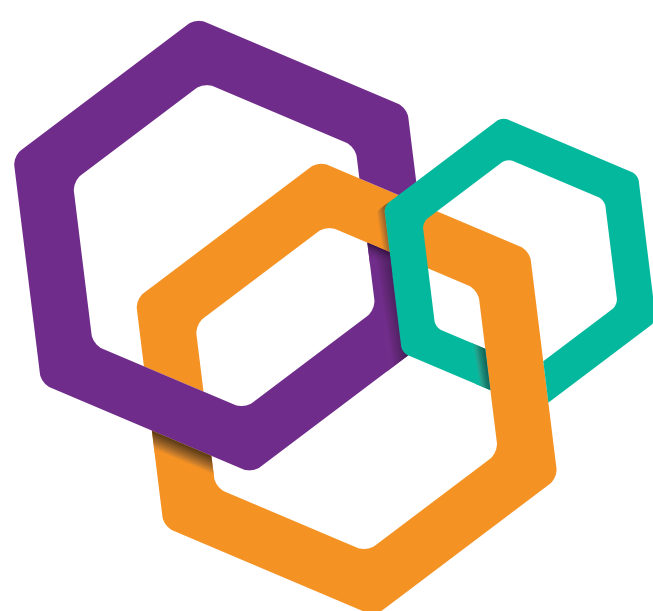
#### **How Platform are you? The Family of Injection Devices that Work from Clinical Trials to Lifecycle Management**

Room 3 Solution Spotlight • [Device Development](#)

Tom Mayer, Business Development Manager, Sonceboz SA

3:05–3:55 PM

iSolve & Networking Break



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## Drug Delivery & Formulation

### Agenda Day 1 Monday September 9th, 2019

3:55–4:30 PM

#### **Flexibility in Pharmaceutical Manufacturing**

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

**Yash Kapoor**, Principal Scientist, **Merck**

#### **Nanoemulsion-Based Therapies: Antimicrobial, Anti-inflammatory and Drug Delivery Properties**

[Room 2](#) Case Study • [Biologics](#)

**Susan M. Ciotti**, Director of Formulation Development, Ann Arbor MI, Adjunct Professor, Pharmaceutical Sciences, University of Michigan, Ann Arbor MI, **BlueWillow Biologics**

#### **Intracutaneous Microneedle Patch Delivery System for the Treatment of Acute Migraine**

[Room 3](#) Case Study • [Device Development](#)

**Yi Ao**, Associate Director, **Zosano Pharma**

4:30–5:05 PM

#### **RNA Nanotechnology for Drug Delivery and Formulation**

[Room 1](#) Keynote • [Biologics](#)

**Peixuan Guo**, Sylvan G. Frank Endowed Chair in Pharmaceutics and Drug Delivery Systems, **The Ohio State University**

5:05–5:50 PM

#### **Panel Discussion: Preparing for Patient-Centric Drug Development Regulations**

[Room 1](#) Moderated by: **Rosario LoBrutto**, Head of Scientific Affairs, **Sandoz**

**Diane Harper**, Director Regulatory Affairs-CMC, **Merck**

**Galen Shi**, Senior Engineering Advisor, **Eli Lilly**

**Graham Jones**, Director of Innovation, **Novartis**

**Paul Upham**, Head, Smart Devices, **Genentech**

5:50–6:00 PM

#### **Chair's Closing Remarks**

**Rosario LoBrutto**, Head of Scientific Affairs, **Sandoz**

6:00–6:10 PM

#### **Poster Presentation Award**

6:10–7:10 PM

#### **Evening Drinks Reception**





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## Agenda Day 2 Tuesday September 10th, 2019

08:00–08:45 AM

Registration & Refreshments

08:45–08:50 AM

### Chair's Opening Remarks

Rosario LoBrutto, Head of Scientific Affairs, **Sandoz**

08:50–09:25 AM

### Formulation Development Gap Assessment for An In-licensed Program: A Case Study

Room 1 Keynote • **Biologics**

Nazila Miller, Director, Drug Product Development, **Takeda**

09:30–10:05 AM

### Formulation Challenges and Strategies for Supporting Toxicology and First in Human Studies

Room 1 Case Study • **Small Molecules**

Chris Ho, Senior Director, Head of Early Formulation Development, PDS, U.S., **Sanofi Genzyme**

### Evaluating the Impact of Polysorbate 20 Hydrolysis During the Life-time of Protein Formulation: A De-risking Case Study

Room 2 Case Study • **Biologics**

Keethkumar Jain, Senior Scientist Drug Product Development, **Takeda**

### Applying ICH Q12 to Combination Products

Room 3 Case Study • **Device Development**

Diane Harper, Director Regulatory Affairs-CMC, **Merck**

10:10–10:45 AM

### Furosemide- How to Make a Leading Drug Better and its Use Wider

Room 1 Solution Spotlight • **Small Molecules**

Pieter Muntendam, President and CEO, **SQ Innovation AG**

### Oral Thin Films – Tailoring Therapy Needs

Room 2 Solution Spotlight • **Technology & Innovation**

Dr. Marco Emgenbroich, Corporate Vice President Head of Pharmaceutica Development I R&D, **LTS Lohmann**

### A New Micro-Pump for Parkinson's Disease from Sensile Medical

Room 3 Solution Spotlight • **Device Development**

Dr. Gerhard Mayer, Vice President, Business Development, **Sensile Medical AG**

10:45–11:35 AM

iSolve & Networking Break



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11:35–12:10 PM

#### **Oral Controlled-Release Liquid for a Low Potency Drug**

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

Alfred Liang, Senior Director, Pharmaceutical Sciences, **Ferring**

#### **mRNA delivery: Lipid Nanoparticles and Beyond**

Room 2 Case Study • [Biologics](#)

Puneet Tyagi, Senior Scientist Dosage Form Design & Development, **AstraZeneca**

#### **Modelling Autoinjector Injection Time Distribution**

Room 3 Case Study • [Device Development](#)

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

12:15–12:50 PM

#### **Unleashing the Potential of Poorly Water Soluble Drugs with the Next Generation Nano Technology**

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

Andrea Cusack, Managing Director & Chief Business Officer, **Leon-nanodrugs GmbH**

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

Room 2 Solution Spotlight • [Biologics](#)

Dr. Ahmad Ghoniem, Pharmacist – Business Development Manager, **tesa Labtec North America**

#### **enFuse™, a true Wearable Technology Changing the way Drugs are Delivered**

Room 3 Solution Spotlight • [Device Development](#)

Michael Hooven, President and CEO, **Enable Injections, Inc.**

12:50–1:50 PM

Networking Lunch



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1:50–2:25 PM

### **Inner Ear Drug Delivery: a case study on the Inner Ear Delivery of Neurotrophin-3**

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

Qi-Ying Hu, Director of Formulation and Drug Delivery, Decibel Therapeutics

### **Challenges and Impact of Formulation on Exposure to Drive PKPD in CNS Drug Discovery**

Room 2 Case Study • [Biologics](#)

Patrick Trapa, Principal Investigator, DMPK, Biogen

### **Compatibility between Drug Formulation and Syringe / Autoinjector Performance**

Room 3 Case Study • [Device Development](#)

Galen Shi, Senior Engineering Advisor, Eli Lilly

2:30–3:05 PM

### **Functional Polyamino acids: a Versatile & Biocompatible Drug Delivery Toolbox**

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

Vicent J. Nebot, Chief Technical Officer, Polypeptide Therapeutic Solutions S.L.

### **What's in your formulation?**

Room 2 Solution Spotlight • [Biologics](#)

Renee Tobias, M.S., Director of Marketing, Halo Labs

3:05–3:55 PM

Networking Break



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## Agenda Day 2 Tuesday September 10th, 2019

3:55–4:10 PM

### **Quantifying the Value of Flexibility from Continuous Manufacturing of Drug Products**

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

**Robert Meyer**, Head of Innovation Technology Group, Pharmaceutical Commercialization, **Merck**

### **Application of Dynamic Mechanical Analyzer (DMA) to Determine the Glass Transition Temperature of Frozen Protein Formulations**

Room 2 Case Study • [Biologics](#)

**Younghoon Kim**, Scientist- Biologics Drug Product Development and Manufacturing Group, **Sanofi**

### **Lyospheres: Enabling Flexibility for Lyophilized Products**

Room 3 Case Study • [Small Molecules](#)

**Brian K. Meyer**, Principal Scientist New Technologies, Vaccine Drug Product Development, Bioprocess Research and Development, **Merck**

4:15–4:50 PM

### **CMC Strategies to Accelerate Proof-of-Concept for Oral Drugs in the Biotech Industry**

Room 1 Keynote • [Small Molecules](#)

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

4:50–5:00 PM

### **Chair's Closing Remarks**

**Rosario LoBrutto**, Head of Scientific Affairs, **Sandoz**