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<th>Time</th>
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<tr>
<td>07:40–08:40 AM</td>
<td>Registration &amp; Refreshments</td>
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| 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 |
| 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 |
| 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 |
| 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 |
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| 11:45–12:35 PM | iSolve & Networking Break                                                   |
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
Agenda  •  Day 1  • Monday September 9th, 2019

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**
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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<td>Rosario LoBrutto, Head of Scientific Affairs, Sandoz</td>
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<td>08:50–09:25 AM</td>
<td>Formulation Development Gap Assessment for An In-licensed Program: A Case Study</td>
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<td>Room 1 Keynote • Biologics</td>
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<td>Nazila Miller, Director, Drug Product Development, Takeda</td>
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<td>09:30–10:05 AM</td>
<td>Formulation Challenges and Strategies for Supporting Toxicology and First in Human Studies</td>
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<td>Chris Ho, Senior Director, Head of Early Formulation Development, PDS, U.S., Sanofi Genzyme</td>
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<td>Evaluating the Impact of Polysorbate 20 Hydrolysis During the Life-time of Protein Formulation: A De-risking Case Study</td>
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<td>Keethkumar Jain, Senior Scientist Drug Product Development, Takeda</td>
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<td>10:10–10:45 AM</td>
<td>Applying ICH Q12 to Combination Products</td>
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<td>Diane Harper, Director Regulatory Affairs-CMC, Merck</td>
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<td>Furosemide- How to Make a Leading Drug Better and its Use Wider</td>
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<td>Pieter Muntendam, President and CEO, SQ Innovation AG</td>
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<td>Oral Thin Films – Tailoring Therapy Needs</td>
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<td>Room 2 Solution Spotlight • Technology &amp; Innovation</td>
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<td>Dr. Marco Emgenbroich, Corporate Vice President Head of Pharmaceutica Development I R&amp;D, LTS Lohmann</td>
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<td>A New Micro-Pump for Parkinson's Disease from Sensile Medical</td>
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<td>Room 3 Solution Spotlight • Device Development</td>
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<td>Dr. Gerhard Mayer, Vice President, Business Development, Sensile Medical AG</td>
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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 Mucofil® Technology to Bypass the First Pass Effect**
Room 2 Solution Spotlight • Biologics
Dr. Ahmad Ghoniem, Pharmacist – Business Development Manager, tesa Labtec North America

**enFuseTM, 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
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**
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

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