

## Tuesday, 22 October 2019

<b>9:00</b>	<b>Welcome: Opening Remarks &amp; Introduction</b>	Falk Klar, <i>PDA Europe</i>
	<b>PDA Awards</b>	Conference Chairs Thomas Schoenknecht, <i>LONZA</i> Mathias Romacker, <i>Pfizer</i>

**Opening Plenary** *Moderators:* **Thomas Schoenknecht, LONZA**  
**Mathias Romacker, Pfizer**

### KEYNOTE PRESENTATIONS - Regulatory & Technology Highlights

<b>9:30</b>	<b>Digital Health: Design for the Behaviour You Would Like to See</b>	Julia Häring, <i>Novo Nordisk</i>
<b>9:55</b>	<b>European Combination Devices Guideline</b>	Pascal Venneugues, <i>European Medicines Agency</i>
<b>10:20</b>	<b>Challenges and Opportunities of Developing a Self-Injectable Platform for Global Health Applications</b>	Dennis Lee, <i>Gates Foundation</i> & Robin Hwang, <i>ICP Consulting</i>
<b>10:45</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	
<b>11:30</b>	<b>Delivery Device Development in Midst of an Evolving Landscape of Novel Drug Modalities, Patient Centered Design and Digital Health</b>	Andrew Ratz, <i>Eli Lilly</i>
<b>11:55</b>	<b>Life-Cycle Management of Combination Products</b>	Juan C. Kuang, <i>Amgen</i>

**Panel Discussion, Q&A**

**13:00 Lunch Break, Poster Session & Exhibition**  
**Demo Booths in the Exhibition Space**

### TRANSITION TO PARALLEL TRACKS

#### PARALLEL TRACKS ABC

Session 1	TRACK A	TRACK B	TRACK C
	<b>Human Factors</b>	<b>Polymer Containers</b>	<b>Regulatory Perspectives</b>
	<i>Moderator:</i> Sherri Biondi, <i>AstraZeneca</i>	<i>Moderator:</i> William Dierick, <i>Terumo</i>	<i>Moderator:</i> Olivia Henderson, <i>Amgen</i>
<b>14:30</b>	<b>Larger Injection Volumes, Longer Injection Times – Where are the Users’ Limits with Handheld Devices?</b>  <i>Jakob Lange, Ypsomed</i>	<b>Business Case and Journey of Launching a Biosimilar in a Polymer Prefilled Syringe in the International Market</b>  <i>Yoshifumi Torii, Fujifilm Kyowa Kirin Biologics Co.</i>	<b>An Opportunity to Leverage the Medical Devices Regulation (MDR) Whilst Supporting a Broad Innovative Portfolio in Pharma</b>  <i>Daniel Latham, Novartis &amp; Mark Chipperfield, Corvus Device</i>
<b>14:50</b>	<b>Practical Pathways for Human Factors Regulatory Compliance for Parenteral Products</b>  <i>Bjorg Hunter, GSK</i>	<b>Polymer Prefilled Syringes and Cartridges - Process Technology Development and Handling Aspects for Successful Fill-And-Finish</b>  <i>Philipp Hoerner, Bausch + Stroebel</i>	<b>Impact of MDR Article 117 on Marketing Authorization Applications for Pre-filled Syringes</b>  <i>Stephanie Horn, F. Hoffmann-La Roche</i>

<b>15:10</b>	<b>Human Factors Perspectives on Leveraging a Platform Technology</b>  Nicholas Stones, <i>Novartis</i>	<b>Excipients Effects on Functionality of Glass and Polymer Based Pre-filled Syringes</b>  Liang Fang, <i>WEST</i>	<b>MDR Article 117: Notified Body Opinion Interpretation and Implementation</b>  Blake Green, <i>Amgen</i>
<b>15:30</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>

**16:00 Coffee Break, Poster Session & Exhibition**

**TRANSITION TO PARALLEL TRACKS**

**PARALLEL TRACKS ABC**

<b>Session 2</b>	<b>TRACK A</b>	<b>TRACK B</b>	<b>TRACK C</b>
	<b>Large Volume Injection</b>	<b>Manufacturing and Processing Technologies</b>	<b>Novel Therapeutics</b>
	<i>Moderator:</i> Ian Thompson, <i>Ypsomed</i>	<i>Moderators:</i> Laurent Jeanmart, <i>GSK</i> Hanns-Christian Mahler, <i>LONZA</i>	<i>Moderator:</i> Manfred Maeder, <i>Novartis</i>
<b>16:45</b>	<b>MRI Clinical Imaging of Human Subcutaneous Injections Up to 10ml in the Abdomen, Thigh and Arm</b>  Wendy D Woodley, <i>Becton Dickinson</i>	<b>Innovations in Manufacturing of Elastomeric Components for Parenteral Packaging Applications</b>  Rahul Thakar, <i>Datwyler Sealing Solutions</i>	<b>Design Considerations Pertaining to Primary Container Used for Cell Therapy Products</b>  Min Wei, <i>AstraZeneca</i>
<b>17:05</b>	<b>Evaluating Formulation and Device Factors on Subcutaneous Administration</b>  Rhea Sirkar, <i>Eli Lilly</i>	<b>Augmented Reality for Preventive Maintenance</b>  Michael Pratz, <i>Bausch &amp; Stroebel</i>	<b>A Science-Based Recommendation of Elastomer Components for Biologic Drugs</b>  Cathy Zhao, <i>WEST</i>
<b>17:25</b>	<b>Evolving Component Technologies to Meet the Needs of Cartridge Delivery Applications</b>  Simon Cote & Royce C. Brockett, <i>WEST</i>	<b>Vision Robot Unit (VRU)</b>  Michael Betz, <i>F. Hoffmann-La Roche</i> Andrea Sardella, <i>Stevanato Group</i>	<b>Challenges &amp; Device Opportunities with Microliter Dose Delivery Using Standard Pre-fillable Syringes: A Case Study</b>  Gautam Shetty, <i>Congruence Medical Solutions &amp; Kedar Datar, Boehringer Ingelheim</i>
<b>17:45</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>

**18:00 End of Day 1 & Networking Event**

Program subject to change without prior notice - for most current updates, go to [pda.org/EU/UPS2019](http://pda.org/EU/UPS2019)

# TUESDAY NIGHT FEVER

The Parenteral Drug Association warmly invites you to an evening of  
Networking, Dinner & Dance.

Relax, Chat, and Dance the Night Away With PDA!



**22 October 2019 · 19:00h - 21:30h**  
**Teatergatan at Valand**  
**Vasagatan 41**  
**411 36 Gothenburg**

Location Within a Short Walking Distance from the Conference Venue

DRESS CODE: 1970s Disco Attire  
Admission is included in the Conference Registration.  
To reserve your ticket, please register online.

**disco**

**Wednesday, 23 October 2019**

Morning Plenary

Moderator: **Mathias Romacker**, Pfizer

**KEYNOTE PRESENTATIONS - Patient & Payers Perspectives**

- 9:00 **Patient Perspective of Managing Type 1 Diabetes in the Digital Age** Johan Ahstrom, *Patient Speaker*
- 9:25 **The Evolving Payer Perspective on Injection Treatment Devices: Balancing Costs, Convenience, Outcomes and More** Robert S. Epstein, *Epstein Health*
- 9:50 **Unsolved Mystery: How to Get Payers to Reward Injection Device Innovation Every Time** John Alter, *Pfizer*,

10:15 **Panel Discussion** Moderator: Max Cambras, *LEK*  
**Partnering with Payers and Health Systems to Support Digital Innovation in Drug Delivery Devices**

10:45 **Coffee Break, Poster Session & Exhibition**

**PARALLEL TRACKS ABC**

Session 3	TRACK A	TRACK B	TRACK C
	<b>Connectivity - Smart Devices in Clinical Trials</b>	<b>Manufacturing and Processing Technologies</b>	<b>Development Strategies</b>
	Moderator: Markus Bauss, <i>SHL Connect</i>	Moderators: Theresa Bankston, <i>BD</i> Philippe Lauwers, <i>Terumo</i>	Moderator: Brigitte Reutter-Haerle, <i>Vetter</i>
11:30	<b>Digital Health Application Development Within a Pharmaceutical Culture</b>  Gareth Hilton, <i>AstraZeneca</i>	<b>Case Study: Modular Scalability &amp; Flexibility in Device Assembly - From Early Stage to Full Scale Production</b>  Jens Schou Christensen, <i>Stevanato Group</i>	<b>Collaboration to Enable a Simple, Reliable Device Suitable for Self-Administration in Early Clinical Studies Through to Commercialization</b>  Nicolas Bralet, <i>Becton Dickinson</i> & Peter Krulevitch, <i>Janssen</i>
11:50	<b>A Behavioural Design Approach to Digital Health Solutions</b>  Geraint Davies, <i>F. Hoffmann-La Roche</i>	<b>Modularizing Assembly and Testing Equipment for Auto and Pen Injectors</b>  Gilbert Fluetsch & Lucy Chung, <i>SHL Group</i>	<b>Creating a Parenteral Drug Delivery Device for Developing Markets</b>  Rob Veasey, <i>DCA Design International</i> & Stefan Bohling, <i>Sanofi Aventis</i>
12:10	<b>To Connect or Not to Connect: When Should A Parenteral Device Go Connected?</b>  Paul Greenhalgh, <i>TeamConsulting</i>	<b>Seeing the Hidden: Detection of Leakage in Pre-filled Syringe During Storage by Neutron Radiography</b>  Jonas Fransson, <i>Swedish Orphan Biovitrum</i>	<b>Software and Services to Transform Drugs into Disease Management Solutions</b>  Alexander Dahmani, <i>QuiO Technologies</i>
12:30	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>

13:00 **Lunch Break, Poster Session & Exhibition**  
**Live Demonstrations in the Exhibition Space**

## Closing Plenary - Keynotes

Moderators: **Mathias Romacker**, Pfizer  
**Thomas Schoenknecht**, LONZA

**14:30**     **Formulation and Device Lifecycle Management –  
The Role of Drug Delivery Devices in  
Improving Access to Medicines**

Beate Bittner,  
*F. Hoffmann-La Roche*

**15:00**     **A Novel Approach to Characterizing  
Drug Delivery System Flow Performance**

Roman Mathaes, *LONZA*

**15:30**     **Closing Panel Discussion, Q&A**

**16:00**     **Conference Summary by the 2019 Co-Chairs**

Thomas Schoenknecht, *LONZA*  
Mathias Romacker, *Pfizer*

**16:30**     **Closing Comments & Farewell**

Falk Klar, *PDA Europe*

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