

Tuesday, 22 October 2019

9:00	Welcome: Opening Remarks & Introduction	Falk Klar, <i>PDA Europe</i>
	PDA Awards	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

9:30	Digital Health: Design for the Behaviour You Would Like to See	Julia Häring, <i>Novo Nordisk</i>
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9:55	Drug-Device Combinations in the EU: An Update	Pascal Venneugues, <i>European Medicines Agency</i>
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10:20	Challenges and Opportunities of Developing a Self-Injectable Platform for Global Health Applications	Dennis Lee, <i>Gates Foundation</i> & Robin Hwang, <i>ICP Consulting</i>
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10:45 Coffee Break, Poster Session & Exhibition

11:30	Delivery Device Development in Midst of an Evolving Landscape of Novel Drug Modalities, Patient Centered Design and Digital Health	Andrew Ratz, <i>Eli Lilly</i>
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11:55	Life-Cycle Management of Combination Products	Juan C. Kuang, <i>Amgen</i>
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12:20 Panel Discussion, Q&A

13:00 Lunch Break, Poster Session & Exhibition

TRANSITION TO PARALLEL TRACKS

PARALLEL TRACKS ABC

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

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

16:00 Coffee Break, Poster Session & Exhibition

TRANSITION TO PARALLEL TRACKS

PARALLEL TRACKS ABC

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

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

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 · 19:30h - 22:00h
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.

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

10:45 Coffee Break, Poster Session & Exhibition

PARALLEL TRACKS ABC

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

13:00 Lunch Break, Poster Session & Exhibition

Closing Plenary - Keynotes

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

14:20	Formulation and Device Lifecycle Management – The Role of Drug Delivery Devices in Improving Access to Medicines	Beate Bittner, <i>F. Hoffmann-La Roche</i>
14:45	A Novel Approach to Characterizing Drug Delivery System Flow Performance	Roman Mathaes, <i>LONZA</i>
15:10	Coffee Break, Poster Session & Exhibition	
15:40	Closing Panel Discussion, Q&A	
16:10	Conference Summary by the 2019 Co-Chairs	Thomas Schoenknecht, <i>LONZA</i> Mathias Romacker, <i>Pfizer</i>
16:30	Closing Comments & Farewell	Falk Klar, <i>PDA Europe</i>

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