



**2023 PDA Universe of Pre-Filled Syringes and Injection Devices Conference**  
 17-18 October 2023 | Gothenburg | Sweden  
**20<sup>th</sup> Edition**

*20 Years of Innovation in Drug Delivery – What’s Next?*

Agenda			
Tuesday, 17 October 2023			
9:00	<b>Welcome: Opening Remarks &amp; Introduction</b>		Falk Klar, <i>PDA Europe</i>  Theresa Bankston, <i>BD</i> Alessandro Morandotti, <i>Stevanato Group</i>
<b>Opening Plenary: The Evolving Landscape of Patient-Centric Care</b>		<b>Moderator:</b>	Theresa Bankston, <i>BD</i>
<b>KEYNOTE PRESENTATIONS</b>			
	<b>The Inspiring Evolution of Parenteral Combination Products from 2004 to Today from an Entrepreneurial Perspective – And a Peek at What Is Coming</b>		<i>Kymanox</i>
	<b>How Understanding Patient Behavior and Experience can assist in the Development and Optimization of Treatments – A Patient Perspective</b>		<i>Nelson Lab</i>
<b>10:05</b>	<b>Coffee Break, Poster Session &amp; Exhibition &amp; Guided Poster Walk (Part I)</b>		
	<b>How Smart Devices are Impacting Delivery of Care and Improving Patient Experience</b>		<i>Sanofi &amp; Biocorp</i>
	<b>Interactive Questionnaire Session</b>		<i>Via Mentimeter</i>
	<b>Panel Discussion</b>		
<b>12:40</b>	<b>Lunch Break, Poster Session &amp; Exhibition &amp; Tech Talks</b>		
<b>Transition to Parallel Tracks</b>			
<b>Parallel Tracks ABC</b>			
<b>Session 1</b>	<b>Track A</b>	<b>Track B</b>	<b>Track C</b>
	<b>Large Volume</b>	<b>Digital Health and Smart Devices</b>	<b>Manufacturing</b>
<b>Moderators:</b>	Frank Bamberg, <i>CSL Behring</i>	Jakob Lange, <i>Ypsomed</i>	Laurent Jeanmart, <i>GSK Vaccines</i>



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	<p><b>Pre-Clinical Assessment of a High-Volume, High-Speed Prototype Auto-Injector to Subcutaneously Deliver a Polyclonal Antibody with Recombinant Human Hyaluronidase PH20 (rHuPH20)</b></p> <p><i>Halozyme Therapeutics</i></p>	<p><b>Next Generation Auto-Injectors: Leveraging the Power of a Digital Platform for Enhanced Adherence Tracking</b></p> <p><i>Merck KGaA</i></p>	<p><b>A Case Study in the Implementation of Radio Frequency Identification (RFID) - enabled Pre-Filled Syringes on an Aseptic Fill and Finish Line</b></p> <p><i>BD &amp; Optima</i></p>
	<p><b>Exploring US Payer Perspectives on Large-Volume Subcutaneous OnBody Delivery Systems: A Double-Blinded Preference Study</b></p> <p><i>Enable Injections, Inc</i></p>	<p><b>Injecting Behavioral Science into Self-Administration Combination Products, Where Digital Meets Physical: Reflections, Challenges, and Observations</b></p> <p><i>AstraZeneca</i></p>	<p><b>Validatable Transfer Method for Ready to Use (RTU) Syringes and Vials into Grade A in Compliance with EU GMP Annex 1 including a Case Study</b></p> <p><i>Novartis &amp; SKAN</i></p>
	<p><b>A Case Study: How Stakeholder Needs to Guide the Collaborative Development of a Pre-Filled Syringe and an Autoinjector for Large-Volume Subcutaneous Drug Delivery</b></p> <p><i>SCHOTT Pharma &amp; Ypsomed</i></p>	<p><b>Regulatory Clearance for Implementation of a Digital Solution Supporting Use of an Autoinjector</b></p> <p><i>F. Hoffmann-La-Roche</i></p>	<p><b>Synergistic Collaboration with Glass Syringe Manufacturer during Drug Product Lifecycle: A Case Study on Improved Stability for a Combination Product</b></p> <p><i>Nuova Ompi &amp; Bayer</i></p>
	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>
<b>15:30</b>	<b>Coffee Break, Poster Session &amp; Exhibition + Guided Poster Walk (Part II) &amp; Tech Talks</b>		
<b>Transition to Parallel Tracks</b>			
<b>Parallel Tracks ABC</b>			
<b>Session 2</b>	<b>Track A</b>	<b>Track B</b>	<b>Track C</b>
	<b>Patient Interface</b>	<b>Development</b>	<b>Regulatory</b>
<b>Moderators:</b>	Christin Helbig, <i>SCHOTT Pharma</i>	Shirish Ingawale, <i>Takeda</i>	Manfred Maeder, <i>Novartis</i>
	<p><b>Inclusive Design in Medicine and Device Development</b></p> <p><i>GSK</i></p>	<p><b>Combination Products Control Strategy– A Holistic Approach and Statistical Considerations</b></p> <p><i>Pfizer</i></p>	<p><b>Update on Technical Report 73-2: Application of Medical Device Regulations, EU GMP Annex I Requirements (GSPRs) for Staked Needle Syringes</b></p> <p><i>West</i></p>



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	<b>Patient Voices in Sustainable Drug Delivery: Insights on Self-Injection Devices</b>  <i>Ypsomed</i>	<b>The Strategy of Accelerating Injectable Combination Product Development for Faster Clinical Entry and Market Access</b>  <i>Merck Group</i>	<b>Article 117 Medical Device Regulation (MDR) - Notified Body Opinion: State of the Play and Lessons Learned</b>  <i>Anteris Medical</i>
	<b>Global Health: Deploying Human Factors Research Within Low-to-Middle-Income Countries</b>  <i>Crux Product Design</i>	<b>Current Trends and Future Innovations in Autoinjectors for Large-Volume Subcutaneous Delivery: A Systematic Literature Review</b>  <i>Ypsomed</i>	<b>Are we Two of a Kind? Recent Regulatory Developments across the Globe, and how those might Impact Future European Human Factors Engineering Submissions</b>  <i>Emergo by UL</i>
<b>17:50</b>	<b>End of Day 1 &amp; Networking Event</b>		

<b>Wednesday, 18 October 2023</b>			
<b>9:00 Morning Plenary</b>		<b>Moderator:</b> Akshay R. Kamdar, <i>Eli Lilly and Company</i>	
<b>KEYNOTE PRESENTATIONS</b>			
	<b>HPRC Design Guidance: Enabling Recycling at End-of-Life</b>	<i>Healthcare Plastics Recycling Council (HPRC)</i>	
	<b>Addressing Recycling: One of the Bottlenecks of Circularity</b>	<i>Eli Lilly and Company</i>	
	<b>Industry Collaboration for Device Sustainability</b>	<i>Sanofi</i>	
	<b>Designing for Patients and the Planet: Circular Solutions for Pharmaceutical Products</b>	<i>Johnson &amp; Johnson</i>	
	<b>Panel Discussion</b>		
<b>10:20</b>	<b>Coffee Break, Poster Session &amp; Exhibition &amp; Tech Talks</b>		
<b>Parallel Tracks ABC</b>			
<b>Session 3</b>	<b>Track A</b>	<b>Track B</b>	<b>Track C</b>
	<b>Sustainability</b>	<b>Innovation and Collaboration</b>	<b>Drug Container Interaction</b>



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<b>Moderators:</b>	Maggie Reiff, <i>Genixus</i>	Philippe Lauwers, <i>Terumo</i>	Roman Mathaes, <i>Clear Solutions</i>
	<b>Carbon Footprint of Capital Good Gains Attention</b>  <i>Harro Höfliger &amp; Körber Pharma</i>	<b>From Drug Development to Final-Packaged Product: The Role of Strategic Partnerships in Streamlining On-Body Delivery Systems Manufacturing</b>  <i>Stevanato Group &amp; ThermoFisher</i>	<b>Silicone Depletion in Combination Products Induced by Biologics</b>  <i>Ludwig-Maximilians-Universität München</i>
	<b>EcoDesign Considerations and CO<sup>2</sup> Reduction for Medical Devices</b>  <i>Nolato AB</i>	<b>Importance of Selection and Management of Appropriate Partnerships for Combination Product Development and Lifecycle Management – Perspectives from a Pharmaceutical Company and A Device Manufacturer</b>  <i>Biogen &amp; BD</i>	<b>Comprehensive Countermeasures to Reduce Proteinaceous Visible Particles in Liquid Monoclonal Antibody Products</b>  <i>Chugai Pharmaceutical</i>
	<b>A Parametric Model Developed from Activity-Based Footprinting to Simplify the Complexity of Lifecycle Assessment Towards Sustainable Autoinjector Devices</b>  <i>SHL Medical</i>	<b>The Secret of Successful Partnerships between the Pharmaceutical Companies and Their Device Suppliers</b>  <i>Merck &amp; Co, Inc</i>	<b>Delivering a Superior Ophthalmic Pre-Filled Syringe (PFS) with Low Particles and Exceptional Human Factors</b>  <i>SIO2 &amp; Cytiva</i>
	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>
<b>12:25</b>	<b>Lunch Break, Poster Session &amp; Exhibition &amp; Tech Talks</b>		
<b>Closing Plenary - Keynotes</b>		<b>Moderator:</b>	Alessandro Morandotti, <i>Stevanato Group</i>
	<b>Manufacturing of Pre-Filled Syringes – The Impact of New EU GMP Annex 1</b>		<i>Local Inspectorate Tübingen</i>
	<b>Title to be Announced</b>		<i>U.S. FDA</i>
<b>15:15</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>		



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16:00	Passport Raffle	
	Closing Panel Discussion	
	Chair Conference Summary	Theresa Bankston, <i>BD</i> Alessandro Morandotti, <i>Stevanato Group</i>
	Closing Comments & Farewell	Falk Klar, <i>PDA Europe</i>
17:15	End of Conference	