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

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

Agenda

Tuesday, 17 October 2023

09:00	**Welcome: Opening Remarks & Introduction**	Falk Klar, *PDA Europe* Theresa Bankston, *BD* Alessandro Morandotti, *Stevanato Group*
09:15-12:40 I Opening Plenary: The Evolving Landscape of Patient-Centric Care	**Moderator:**	Theresa Bankston, *BD*
Significant advances in injectable drug delivery have been made over the past 20 years, and rapid evolution aimed at improving patient experience, health outcomes, and total cost of care is expected to continue. This session will reflect on drivers and enablers for this evolution, challenges faced, the impact achieved, and expectations for the future. We will learn perspectives from a patient, drug manufacturer, device developer, and service provider on what it takes to develop, commercialize, and manage effective therapies, together. The audience can expect to hear highlights about market and healthcare ecosystem dynamics, the role and future of smart devices, how to incorporate patient insights, shared lessons learned, future opportunities, and more.		
KEYNOTE PRESENTATIONS		
	The Inspiring Evolution of Parenteral Combination Products from 2004 to Today from an Entrepreneurial Perspective – And a Peek at What Is Coming	Stephen Perry, *Kymanox*
	How Understanding Patient Behavior and Experience Can Assist in the Development and Optimization of Treatments – A Patient Perspective	Piet Christiaens, *Nelson Lab*
10:15	**Coffee Break, Poster Session & Exhibition, Tech Talks & Guided Poster Walk (Part I)**	
	How Smart Devices are Impacting Delivery of Care and Improving Patient Experience	Ralph Camardelli, *Sanofi* Eric Dessertenne, *Biocorp*
	Interactive Questionnaire Session	*Via Mentimeter*
	Panel Discussion	
12:40	**Lunch Break, Poster Session & Exhibition & Tech Talks**	
Transition to Parallel Tracks		
Parallel Tracks ABC		

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Session 1	Track A	Track B	Track C
14:10-15:30	**Large Volume**	**Digital Health and Smart Devices**	**Manufacturing**
Moderators:	Frank Bamberg, *CSL Behring*	Jakob Lange, *Ypsomed*	Laurent Jeanmart, *GSK Vaccines*
	Large-volume injections are a challenge primarily for the patient. Device manufacturers and the pharmaceutical industry have taken on this challenge. Devices were adapted to the needs of the patients and the injection volume. Additives were developed so that the human body absorbs larger amounts better. In this event, solutions, and the ways to get there will be shown and discussed.	The digital revolution is making its way into the injection device area. This session will provide examples of recent innovations and approaches to include behavioral science in the development of smart devices, how digital health can enable improved adherence tracking, and obtaining regulatory clearance for digital solutions in the injection space.	Regarding manufacturing processes in constant evolution, this session will describe several case studies about track and trace solutions (RFID) and efficient collaboration for stability improvement for a combination product. Moreover, new Ready to Use (RTU) container aseptic practices in compliance with EU GMP Annex 1 will also be presented.
	Pre-Clinical Assessment of a High-Volume, High-Speed Prototype Auto-Injector to Subcutaneously Deliver a Polyclonal Antibody with Recombinant Human Hyaluronidase PH20 (rHuPH20) David Kang, *Halozyme Therapeutics*	**Next Generation Auto-Injectors: Leveraging the Power of a Digital Platform for Enhanced Adherence Tracking** Teodora Caragea, *Merck KGaA*	**A Case Study in the Implementation of Radio Frequency Identification (RFID) - Enabled Pre-Filled Syringes on an Aseptic Fill and Finish Line** Herve Soukiassian, *BD* Mario Schwab, *Optima*
	Exploring US Payer Perspectives on Large-Volume Subcutaneous OnBody Delivery Systems: A Double-Blinded Preference Study Mehul Desai, *Enable Injections*	**Injecting Behavioral Science into Self-Administration Combination Products, Where Digital Meets Physical: Reflections, Challenges, and Observations** Julian Dixon, *AstraZeneca*	**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** Andreas Kerschbaumer, *Novartis* Manfred Holzer, *SKAN*

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	A Case Study: How Stakeholder Needs Guided the Collaborative Development of a Pre-Filled Syringe and an Autoinjector for Large-Volume Subcutaneous Drug Delivery Sven Pohle, *SCHOTT Pharma* Reto Jost, *Ypsomed*	**Regulatory Clearance for Implementation of a Digital Solution Supporting Use of an Autoinjector** Christoph Joosten, *F. Hoffmann-La-Roche*	**Synergistic Collaboration with Glass Syringe Manufacturer during Drug Product Lifecycle: A Case Study on Improved Stability for a Combination Product** Stefano Pilati, St*evanato Group* Andy Han, *Bayer (remote presentation)*
	Q&A, Discussion	**Q&A, Discussion**	**Q&A, Discussion**
15:30	**Coffee Break, Poster Session & Exhibition + Guided Poster Walk (Part II) & Tech Talks**		
Transition to Parallel Tracks			
Parallel Tracks ABC			
Session 2	**Track A**	**Track B**	**Track C**
16:30-17:50	**Patient Interface**	**Development**	**Regulatory**
Moderators:	Christin Helbig, *SCHOTT Pharma*	Shirish Ingawale, *Takeda*	Manfred Maeder, *Novartis*
	The pharma industry has increasingly adopted the mantra of "patient-centricity" which aims to put the patient at the heart of the consideration of the drug and device development process. In this session, we will present and discuss aspects of Human Factor practices in the context of Low-to-Middle-Income healthcare settings, early inclusive design approaches as well as patient insights on their sustainability expectations of drug delivery devices.	Persistent innovation continues to drive evolution of treatment modalities and injection systems that strive to fulfil growing trends such as novel formulations, self-administration, less frequent dosing, etc. This session will focus on developing robust, reliable, and high-quality drug delivery devices and drug/device combination products. The speakers will discuss approaches to achieve highly desired and equally challenging traits – speed, optimal quality, and enhanced user experience – during the development of combination products through risk-based approach and control strategies.	During our regulatory session, we will hear about the most recent changes and expectations on the Medical Device Regulation (MDR) including the expectations on the GSPRs (General Safety and Performance Requirements) for medical devices and drug-device combinations. And we will learn more about the notified body opinion process and some case studies associated with that new requirement. Furthermore, there will be some evaluation and comparison of new HFE (Human Factors Engineering) requirements around the globe.

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	Inclusive Design in Medicine and Device Development Dave Pearce and Chiko Ncube, *GSK*	**Combination Products Control Strategy– A Holistic Approach and Statistical Considerations** Ying Wang, *Pfizer*	**Update on Technical Report 73-2: Application of Medical Device Regulations, EU GMP Annex I Requirements (GSPRs) for Staked Needle Syringes** Bettine Boltres, *West*
	Patient Voices in Sustainable Drug Delivery: Insights on Self-Injection Devices Jakob Lange, *Ypsomed*	**The Strategy of Accelerating Injectable Combination Product Development for Faster Clinical Entry and Market Access** Peng Li, *Merck Group*	**Article 117 Medical Device Regulation (MDR) - Notified Body Opinion: State of the Play and Lessons Learned** Christiana Hofmann, *Anteris Medical*
	Global Health: Deploying Human Factors Research Within Low-to-Middle-Income Countries Alejandra Anderson & Timothy Quigg, *Crux Product Design*	**Current Trends and Future Innovations in Autoinjectors for Large-Volume Subcutaneous Delivery: A Systematic Literature Review** Andreas Schneider, *Ypsomed*	**Are we Two of a Kind? Recent Regulatory Developments across the Globe, and how those might Impact Future European Human Factors Engineering Submissions** Petra Boeree, *Emergo by UL*
17:50	**End of Day 1 & Networking Event**		

Wednesday, 18 October 2023

09:00-10:20 I Morning Plenary: Industry Partnerships for Sustainable Product Design and Recycling	**Moderator:** Akshay R. Kamdar, *Eli Lilly and Company*

This plenary session focuses on the importance of sustainability in the pharma/biotech industry. Key topics such as designing products with a patient and planet-centric mindset, addressing recycling challenges for medical devices with design guidance for end-of-life recycling, and exploring industry partnerships and collaborations for recycling will be highlighted.

KEYNOTE PRESENTATIONS

	Designing for Patients and the Planet: Circular Solutions for Pharmaceutical Products	Cedric Gysel, *Johnson & Johnson*
	Industry Collaboration for Device Sustainability	Paolo Mangiagalli, *Sanofi*
	HPRC Design Guidance: Enabling Recycling at End-of-Life	Bas Coolsma, *Healthcare Plastics Recycling Council (HPRC)*

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	Addressing Recycling: One of the Bottlenecks of Circularity	Naresh Budhavaram, *Eli Lilly and Company*
	Panel Discussion	
10:20	**Coffee Break, Poster Session & Exhibition & Tech Talks**	

Parallel Tracks ABC			
Session 3	**Track A**	**Track B**	**Track C**
11:05-12:25	**Sustainability**	**Innovation and Collaboration**	**Drug Container Interaction**
Moderators:	Marion Briggs, *HealthBeacon on behalf of Alliance to Zero*	Philippe Lauwers, *Terumo*	Roman Mathaes, *Clear Solutions*
	This session will focus on the primary drivers and challenges when considering sustainable models within the industry. Our speakers will cover the critical factors influencing lifecycle assessments, digital solutions within sustainability, and how to leverage these processes to increase operational efficiency. Key highlights include real-world examples, strategies for implementation, and how to leverage lifecycle assessment data for a more sustainable future.	Speed to market has become a differentiating factor for success in the pharma industry nowadays. To bring products to market quickly, pharma companies, device suppliers, and contract manufacturers must build strong and efficient partnerships and establish robust supply chain channels. In this session, we will provide valuable insights from all stakeholders and offer recommendations on how to accelerate development, foster seamless collaboration, and better meet customer needs.	Join us for an insightful session on drug-device interaction. Our expert speakers will shed light on key topics such as visible particles in combination products, exploring their impact on drug stability and patient safety. We will also delve into new findings of silicone oil interaction with drug products, addressing potential risks and mitigation strategies. Additionally, our session will focus on the unique challenges encountered in developing pre-filled syringes for intravitreal injections.
	Carbon Footprint of Capital Good Gains Attention Markus Winter, *Harro Höfliger* Bernhard Gerl, *Körber Pharma*	**From Drug Development to Final-Packaged Product: The Role of Strategic Partnerships in Streamlining On-Body Delivery Systems Manufacturing** Christian Riva, *Stevanato Group* Chris Howell, *ThermoFisher*	**Silicone Depletion in Combination Products Induced by Biologics** Wolfgang Friess, *Ludwig-Maximilians-Universität München*

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	EcoDesign Considerations and CO^2 Reduction for Medical Devices Glenn Svedberg, *Nolato AB*	**Importance of Selection and Management of Appropriate Partnerships for Combination Product Development and Lifecycle Management – Perspectives from a Pharmaceutical Company and A Device Manufacturer** Tushar Patki, *Biogen* (*remote presentation)* Nathan Kast, *BD*	**Comprehensive Countermeasures to Reduce Proteinaceous Visible Particles in Liquid Monoclonal Antibody Products** Keijiro Hatade, *Chugai Pharmaceutical*
	A Parametric Model Developed from Activity-Based Footprinting to Simplify the Complexity of Lifecycle Assessment Towards Sustainable Autoinjector Devices Veluska Bruce, *SHL Medical*	**The Secret of Successful Partnerships between Pharmaceutical Companies and Their Device Suppliers** Jiaying Shen, *Merck & Co, Inc*	**Delivering a Superior Ophthalmic Pre-Filled Syringe (PFS) with Low Particles and Exceptional Human Factors** Chris Weikart, *SIO2* Simon Lay, *Cytiva*
	Q&A, Discussion	**Q&A, Discussion**	**Q&A, Discussion**
12:25	**Lunch Break, Poster Session & Exhibition & Tech Talks**		
14:25-17:15 I Closing Plenary - Keynotes		**Moderator:**	Alessandro Morandotti, *Stevanato Group*
Regulatory Compliance is key for the successful development of combination products. Fulfilling these requisites imply continues updated of the regulatory strategy. In this session, we will review and discuss the implication of the New EU GMP Annex 1 on the pre-filled syringes manufacturing and processing, and we will conclude with an overview of the emerging global policies to have a look at what is coming next.			
	Manufacturing of Pre-Filled Syringes – The Impact of New EU GMP Annex 1		Daniel Müller, *Local Inspectorate Tübingen*
	Global Regulatory Policies Impacting Prefilled Syringes and Injection Devices		Rumi Young, BD (*Former FDA-Regulator)*
15:15	**Coffee Break, Poster Session & Exhibition & Tech Talks**		
16:00	**Passport Raffle**		

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	Closing Panel Discussion Join our Discussion with Experts from the Industry and Regulatory • Bart Burgess, *SHL Medical* • Stephen Fournier, *CSL Behring* • Manfred Maeder, *Novartis* • Daniel Müller, *Local Inspectorate Tübingen* • Karthik Vaideeswaran, *Eli Lilly and Company* • Rumi Young, *BD (Former FDA-Regulator)*	
	Co-Chairs Conference Summary	Theresa Bankston, *BD* Alessandro Morandotti, *Stevanato Group*
	Closing Comments & Farewell	Falk Klar, *PDA Europe*
17:15	**End of Conference**	