

	Agenda
	PDA Universe of Pre-Filled Syringes and Injection Devices Conference 2025

Tuesday, 21 October

09:00 – 09:20

Welcome and and Innovation Award Announcement

Committee Member: Falk Klar, PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

09:20 – 09:25

Welcome From the Co-Chairs

Co-Chair: Theresa E. Bankston, PhD, VP Combination Products & Capabilities, *BD*

Co-Chair: Jakob Lange, PhD, VP & Head of Account and Business Development, *Ypsomed AG*

09:25 – 10:30

Opening Session Part I

The opening plenary focuses on patient and physicians’ perspectives on the treatment of Obesity with GLP1s, providing two contrasting views of how this recent and emerging treatment option fits into the overall management of overweight and obesity. Expect to get fresh perspectives and to learn more about the opportunities and challenges in obesity treatment at present, going forward.

Moderator: Jakob Lange, PhD, VP & Head of Account and Business Development, *Ypsomed AG*

09:25 – 09:45

Patient Perspectives on the Treatment of Obesity with GLP1s

Keynote Speaker: Sylvine Raverdy-Wilson

09:45 – 10:05

Physician Perspectives on the Treatment of Obesity with GLP1s

Keynote Speaker: Bernhard Ludvik

10:05 – 10:30

Q&A, Disucssion

Moderator: Jakob Lange, PhD, VP & Head of Account and Business Development, *Ypsomed AG*

10:30 – 11:30

Networking Coffee Break, Exhibition, and Guided Poster Walk

10:30 – 11:30

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Tech Talks

11:05 – 12:40

Opening Session Part II

Moderator: Jakob Lange, PhD, VP & Head of Account and Business Development, *Ypsomed AG*

11:05 – 11:25
A Holistic Assessment of Drug/Device Deliverability: From Molecule to Patient
Presenter: Galen Shi, PhD , Vice President of Engineering – Delivery Devices, <i>Eli Lilly and Company</i>
11:25 – 11:45
Transforming Traditional Pharma into a Combination Products Company
Presenter: Karthik Vaideeswaran, PhD, MBA , Associate Vice President, Delivery, Device & Connected Solutions, <i>Merck</i>
11:45 – 11:55
Interactive Questionnaire
11:55 – 12:40
Plenary Discussion
Moderator: Jakob Lange, PhD , VP & Head of Account and Business Development, <i>Ypsomed AG</i>

11:30 – 12:40

Opening Session Part II

The opening plenary focuses on patient and physicians’ perspectives on the treatment of Obesity with GLP1s, providing two contrasting views of how this recent and emerging treatment option fits into the overall management of overweight and obesity. Expect to get fresh perspectives and to learn more about the opportunities and challenges in obesity treatment at present, going forward.

Moderator: Jakob Lange, PhD, VP & Head of Account and Business Development, *Ypsomed AG*

11:30 – 11:50
A Holistic Assessment of Drug/Device Deliverability: From Molecule to Patient
Presenter: Galen Shi, PhD , Vice President of Engineering – Delivery Devices, <i>Eli Lilly and Company</i>
11:50 – 12:10
Transforming Traditional Pharma into a Combination Products Company

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Presenter: Karthik Vaideeswaran, PhD, MBA, Associate Vice President, Delivery, Device & Connected Solutions, *Merck*

12:10 – 12:20

Interactive Questionnaire

Moderator: Jakob Lange, PhD, VP & Head of Account and Business Development, *Ypsomed AG*

12:20 – 12:40

Q&A, Discussion

Moderator: Jakob Lange, PhD, VP & Head of Account and Business Development, *Ypsomed AG*

12:40 – 13:10

Tech Talks

12:40 – 14:10

Networking Lunch Break, Poster Session & Exhibition

14:10 – 15:30

Session 1, Track A

Real-world data on device performance informs future device development. This session will provide case studies and strategies leveraging prior art and market product experience to develop new devices with improved safety and functionality efficiently.

Moderator: Galen Shi, PhD, Vice President of Engineering – Delivery Devices, *Eli Lilly and Company*

14:10 – 14:25

Lessons Learned: A Device Manufacturer's Perspective on the Launch of the First Biosimilar in an On-Body Injector

Presenter: Andrei Yosef, PhD, General Manager and President, *LTS Device Technologies*

14:25 – 14:40

Analysis Framework for Wearable Injector Systems to Improve Functionality, Safety and Reliability

Presenter: Scott Lovald, PhD, Senior Managing Engineer, *Exponent*

14:40 – 14:55

Advancing Platform Technologies for Combination Products

Co-Presenter: Fubin Wu, MS, Co-founder & President, *GessNet*

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Co-Presenter: Nicole M. Bergmann, PhD, MBA, Sr. Director - Device, Design and Connected Solutions, *Eli Lilly and Company*

14:55 – 15:30

Session 1, Track A: Q&A, Discussion

Moderator: Galen Shi, PhD, Vice President of Engineering – Delivery Devices, *Eli Lilly and Company*

14:10 – 15:30

Session 1, Track B

This track explores innovative strategies to enhance home care by addressing stakeholder needs, fostering patient engagement, and strengthening support systems, ranging from oncology nursing perspectives to digital tools that drive adherence and improve outcomes.

Moderator: Frank Bamberg, MA, Head of Primary Packaging and Medical Devices - Product Care, *CSL Behring*

14:10 – 14:25

Exploring At-Home Cancer Treatment Potentials: A Comparative Study of Oncology Nurses' Perspectives and Practices in the EU and US

Presenter: Reza Abedian, PhD, Senior Medical Affairs Manager, *Gerresheimer*

14:25 – 14:40

Driving Adherence and Improving the Patient Experience through At-home Engagement

Co-Presenter: Aude Ouensanga, MPH, Head of Strategy and Patient Engagement, *Noble and Aptar Pharma company*

Co-Presenter: Joseph Reynolds, MS, Director of User Experience Services, *Noble International, LLC*

14:40 – 14:55

B-COMPASS: Improving Patient Support, Treatment Adherence, and Outcomes

Presenter: Claire J Everitt, MEng, BSc (Psych), Design Engineering Lead - Medical Devices, *Pfizer*

14:55 – 15:30

Session 1, Track B: Q&A, Discussion

Moderator: Frank Bamberg, MA, Head of Primary Packaging and Medical Devices - Product Care, *CSL Behring*

14:10 – 15:30

Session 1, Track C

Ensuring the integrity of prefilled syringes (PFS) and autoinjectors is more critical than ever as delivery systems become increasingly complex and demands on storage, performance, and safety grow. This session explores cutting-edge strategies and novel imaging techniques that are redefining how we evaluate the

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robustness of these drug delivery systems.

Moderator: Philippe Lauwers, Technology Development Director, *Terumo Pharmaceutical Solutions*

14:10 – 14:25
Innovative Design and Testing Strategy for an Autoinjector to Precisely Determine Leaks in the Prefilled Syringe
Presenter: Matthias Kahl , Head of R&D and Lab Services, <i>WILCO AG</i>
14:25 – 14:40
Evaluation of Container Closure Integrity and Failure Modes of Prefilled Syringes at Cryogenic Storage Temperatures
Academic Presenter: Oliver Germershaus, PhD , Professor for Pharmaceutical Technology of Macromolecular Drugs, <i>University of Applied Sciences and Arts Northwestern Switzerland</i>
14:40 – 14:55
Unraveling Pre-filled Syringe Needle Clogging by Neutron and Synchrotron X-ray Imaging
Presenter: Vlad Novak, PhD , Group Leader, <i>ANAXAM</i>
14:55 – 15:30
Session 1, Track C: Q&A, Discussion
Moderator: Philippe Lauwers , Technology Development Director, <i>Terumo Pharmaceutical Solutions</i>

15:30 – 16:00

Tech Talks

15:30 – 16:30

Networking Coffee Break, Exhibition and Guided Poster Walk

16:30 – 17:50

Session 2, Track A

Explore how innovative delivery systems are transforming the administration of complex biologics—from dual-liquid co-formulations to automated reconstitution of lyophilized drugs. Learn how smart adaptations to standard platforms and redefined device specs can accelerate development, improve patient outcomes, and sustainability.

Moderator: Christian Helbig, Vice President Glass Syringe Business, *SCHOTT Pharma*

16:30 – 16:45
Dual Liquid Drug Formulation Trends & Challenges: Incremental Innovation to Enable Usage of Standard Platform Components

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and Address Growing Needs

Presenter: **Matthieu CHARVIN**, Senior Project Manager - New Product Development, *BD Medical - Pharmaceutical Systems*

16:45 – 17:00

Addressing Challenging Formulations: A Novel Drug Delivery System Supporting the Automated Reconstitution and Delivery of Lyophilized Solutions

Co-Presenter: **Seda Aksel, PhD**, Product Manager, *SHL Medical AG*

Co-Presenter: **Michael S. Thomas, Masters in Pharmaceutics**, Research Fellow, *Lyophilization Technology Inc.*

17:00 – 17:15

Challenging Design Requirements to Unlock Innovation and Improve Sustainability

Presenter: **Will Marsh**, Senior Sector Manager Medical & Scientific, *DCA Design International*

17:15 – 17:50

Session 2, Track A: Q&A, Discussion

Moderator: **Christian Helbig**, Vice President Glass Syringe Business, *SCHOTT Pharma*

16:30 – 17:50

Session 2, Track B

Immerse yourself in the revolutionary world of autoinjectors, where patient centricity, intuitive design, and sustainability are transforming drug delivery. This session explores breakthrough research on reusable devices, usability in GLP-1 therapies for high-BMI patients, and the art of crafting epinephrine autoinjectors. Discover how cutting-edge insights are driving adoption and improving outcomes. Don't miss this exciting look into the future of user-centered innovation.

Moderator: **Shirish Ingawale, PhD**, Director, Device Development, *Takeda*

16:30 – 16:45

A Study of Factors Impacting User Perceptions of Reusable and Disposable Autoinjectors

Co-Presenter: **Gemma Wood, MBA, CMgr**, Director, Platform Management, *Phillips Medisize*

Co-Presenter: **Amanda Tilles, MS**, Human Factors Engineering Manager, *Phillips Medisize*

16:45 – 17:00

Autoinjector considerations for generic GLP-1 drug-device development: Utilizing comparative human factors studies to assess the usability impact and preference of differing activation mechanisms

Presenter: **Chloé Stoll, PhD**, Clinical and Human Factors Senior Specialist, *BD*

17:00 – 17:15

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Epinephrine Autoinjector Re-imagined: An Introduction to Design Thinking and User-centered Innovation

Presenter: James Best, Design Manager, Studio lead, *Flex*

17:15 – 17:50

Session 2, Track B: Q&A, Discussion

Moderator: Shirish Ingawale, PhD, Director, Device Development, *Takeda*

16:30 – 17:50

Session 2, Track C

Join us to review some examples of cross-industry collaboration and continuous improvement processes applied during the lifecycle of primary packaging materials and how predictive analysis and artificial intelligence can reduce complexity and increase flexibility during the automatic visual inspection in large-scale manufacturing.

Moderator: Alessandro Morandotti, Director Product Development - Drug Containment Solutions, *Stevanato Group*

16:30 – 16:45

AI-Driven Automated Visual Inspection for Combination Products: Challenges and Solutions in Large-Scale such as GLP-1 Manufacturing

Co-Presenter: Roman Mathaes, Dr., Chief Executive Officer, *Clear Solutions Laboratories AG*

Co-Presenter: Massimo Frasson, CEO & General Manager, *Brevetti CEA*

16:45 – 17:00

Minimizing Particulate Matter in Intravitreal PFS by Improving Syringe Manufacturing Process

Presenter: Yuki Takeuchi, MS, Global Product Manager, PLAJEX, *Terumo Pharmaceutical Solutions*

17:00 – 17:15

Cross-Industry Collaboration: A Fast and Effective Approach to face Market Challenges for Drug Product

Co-Presenter: Fitore Kasumaj, PhD, MSAT Biotherapeutics DP Primary Packaging Principal Engineer, *Johnson & Johnson Innovative Medicine*

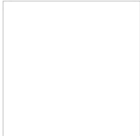
Co-Presenter: Jessica Rocco, MD, Technical Leader - Product Development DCS, *Stevanato Group*

17:15 – 17:50

Session 2, Track C: Q&A, Discussion

Moderator: Alessandro Morandotti, Director Product Development - Drug Containment Solutions, *Stevanato Group*

17:50 – 22:00

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End of Day 1 and Networking Event

PDA Goes Rockabilly VS. Viennese Opera Ball Opposites attract, let the contrast shine Experience a night where classic elegance meets rock ,n' roll rebellion. Dress to impress in your best vintage rockabilly attire or come as a vision of Viennese sophistication. Dance to the beat of rockabilly band and waltz under the chandeliers.

Wednesday, 22 October

08:00 – 08:45

Morning Session Interest Group on Pre-Filled Syringes

Moderator: Brigitte Reutter-Haerle, Vice President Product Management & Marketing, *Vetter*

08:05 – 08:25

Revolutionizing Traceability with RFID – A Pilot Study

Co-Presenter: Herve Soukiassian, Assoc. Director – Product Development, *BD*

Co-Presenter: Emilien Folzer

08:25 – 08:45

Q&A, Discussion

Moderator: Brigitte Reutter-Haerle, Vice President Product Management & Marketing, *Vetter*

09:00 – 10:20

Opening Session Day 2

Moderator: Dominik Ziegler, MSc, Executive Director Device Technology Solution Center, *Novartis Pharma*

09:00 – 09:25

Reflections on the (EU) 2017/745 Art. 117 'Notified Body Opinion' – a Pharma Company experience

Presenter: Stephanie Göbel, Dipl-Ing FH, Senior Regulatory Program Director PTR Device and Combination Products, *Roche / Genentech*

09:25 – 09:50

To Be Announced

09:50 – 10:20

Q&A, Discussion

Moderator: Dominik Ziegler, MSc, Executive Director Device Technology Solution Center, *Novartis Pharma*

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10:20 – 11:10

Networking Coffee Break, Exhibition and Poster Session

10:20 – 11:10

Tech Talks

11:10 – 12:30

Session 3, Track A

As the demand for patient-centric, subcutaneous delivery of biologics and long-acting injectables continues to grow, the development of large volume injection systems has become a key area of innovation and scientific inquiry. This session brings together three experts exploring the complex interplay between formulation science, delivery mechanics, and patient experience in the context of high-viscosity, large-volume subcutaneous administration.

Moderator: Flora Felsovalyi, PhD, Associate Director, *Lonza*

11:10 – 11:25

Simulation of Large Volume, High-Viscosity Subcutaneous Injections with Transport and Absorption

Presenter: Scott Lovald, PhD, Senior Managing Engineer, *Exponent*

11:25 – 11:40

Injection Rate Impact on Depot Morphology of a High Viscosity Long Acting Injectable in Physiologically Relevant Ex Vivo Porcine Tissue

Co-Presenter: Robert CH Gresham, PhD, Post Doctoral Scientist, *Gilead Sciences*

Co-Presenter: Tyler A. Novak, PhD, Director of Drug Delivery Innovation, *Gilead Sciences*

11:40 – 11:55

Large Volume Subcutaneous Injections and the Patient’s Perspective: How Usability and Tolerability Data Help Define the Performance Characteristics of a 5.5 ml Drug Delivery System – a Case Study

Co-Presenter: Reto Jost, MSc, Director, Category Lead Large Volume Injectors, *Ypsomed AG*

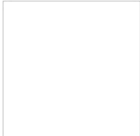
Co-Presenter: Sven Pohle, PhD, Product Manager, *SCHOTT Pharma*

11:55 – 12:30

Session 3, Track A: Q&A, Discussion

Moderator: Flora Felsovalyi, PhD, Associate Director, *Lonza*

11:10 – 12:30

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Session 3, Track B

Digital health has the potential to support and empower patients as they self-inject and manage their condition; in addition, it can inform the decision-making of healthcare providers and reduce the risk of medication errors. This session focuses on three case studies exploring different approaches (Fully-Connected / Digital Only / Enhanced Traceability) used to support patients during onboarding and their self-injection journey, or to enhance the traceability and management of medications within a hospital setting.

Moderator: John Burke, Managing Consultant – Drug Delivery, *Team Consulting*

11:10 – 11:25
Empowering Patients: The Benefits of Connected Injection Devices on Health Outcomes – A Focus on Autoinjectors
Co-Presenter: Marco Rigamonti , General Manager, European Health Solutions Design, <i>Flex</i>
Co-Presenter: Matthew Keiser , Director, Core Team Leader, Device and Connected Solution Engineering Global Healthcare Operations, <i>Merck KGaA, Darmstadt, Germany - EMD Serono, Inc.</i>
11:20 – 11:35
Supporting Patients to Self-Inject: The Journey to Develop Digital Instructions
Co-Presenter: Katie Cornish, PhD , Senior Human Factors Engineer, <i>AstraZeneca</i>
Co-Presenter: Thomas Grant, PhD , Senior Consultant – Digital Health, <i>Team Consulting</i>
11:40 – 11:55
RFID-Enabled Prefilled Syringe System: Minimizing Drug Waste While Enhancing User Convenience and Sustainability
Co-Presenter: Christoph Zauner , Head of product managment polymer solutions, <i>Schott Pharma</i>
Co-Presenter: Nick Petersen , VP, Corporate Development, <i>bluesight</i>
11:55 – 12:30
Session 3, Track B: Q&A, Discussion
Moderator: John Burke , Managing Consultant – Drug Delivery, <i>Team Consulting</i>

11:10 – 12:30

Session 3, Track C

Deeper analysis of drug delivery system performance is enabling the continued advancement of delivery system design to accommodate the complexity of molecular entities and formulations being developed. This session will highlight innovative technologies and characterization techniques that are permitting a deeper understanding of system performance and the promise of novel technologies.

Moderator: Jeffrey Givand, PhD, Executive Director, Device and Combination Product Development, *Merck*

11:10 – 11:25
Does Needle Clogging Change the Spatial Distribution of Injected Drugs in Tissue? New Insights by X-Ray Computed Tomography

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Co-Presenter: Fabiano Bonaventura, MSc, Expert Science & Technology, *Novartis Pharmaceutical Manufacturing GmbH*

Co-Presenter: Fabiano Bonaventura, MSc, Expert Science & Technology, *Novartis Pharmaceutical Manufacturing GmbH*

11:25 – 11:40

Proof of Significant Oxygen Ingress Reduction for COC Syringes Through Highly Effective Barrier Labels

Presenter: Corinna Endres, MSc, Product Manager, *Schreiner MediPharm*

11:40 – 11:55

Advantages of Intradermal Injection: From Infection Diseases Vaccine Delivery Toward Lymphatic Vessel Application for Cancer Therapy

Co-Presenter: Sakiko Shimizu, MA, Chief Scientist, Pharmaceutical Solution Devision, *Terumo Corporation*

Co-Presenter: Michele Guasti, Global Product Manager, *Terumo Europe*

11:55 – 12:30

Session 3, Track C: Q&A, Discussion

Moderator: Jeffrey Givand, PhD, Executive Director, Device and Combination Product Development, *Merck*

12:30 – 14:30

Networking Lunch Break, Poster Session & Exhibition

12:30 – 14:30

Tech Talks

14:30 – 15:00

Closing Session Part I

In our closing plenary on Sustainability, we will examine some of the challenges and successes related to decarbonization and circular solutions for devices, including thinking beyond the current paradigm. We will also hear how our industry is collaborating in the face of a shifting regulatory landscape to effect meaningful change and what opportunities exist for us to become more involved to drive greater impact.

Moderator: Theresa E. Bankston, PhD, VP Combination Products & Capabilities, *BD*

Moderator: Marion Briggs, MBA, Sustainability Manager, *HealthBeacon*

15:00 – 15:45

Networking Coffee Break, Exhibition and Poster Session

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	PDA Universe of Pre-Filled Syringes and Injection Devices Conference 2025

15:45 – 16:50

Closing Session Part II

Moderator: Theresa E. Bankston, PhD, VP Combination Products & Capabilities, *BD*

Moderator: Marion Briggs, MBA, Sustainability Manager, *HealthBeacon*

15:45 – 15:55
The Sustainability Interest Group: Aligning PDA Efforts With the Global Sustainability Journey
Co-Presenter: Massine Yanat , Technical Support Service and Sustainability, North America, <i>SGD Pharma</i>
Co-Presenter: Durga Prasad Madhavapeddi, MTech, PMP , Sr. Material Scientist, <i>FUJIFILM Diosynth Biotechnologies</i>
15:55 – 16:10
Title To Be Announced
16:10 – 16:50
Closing Plenary Discussion
Moderator: Theresa E. Bankston, PhD , VP Combination Products & Capabilities, <i>BD</i>
Moderator: Marion Briggs, MBA , Sustainability Manager, <i>HealthBeacon</i>
Panelist: Hanns-Christian Mahler, PhD , CEO, <i>ten23 health</i>
Panelist: Andreas Schneider , Head Innovation Delivery Systems, <i>Ypsomed AG</i>
Panelist: Karthik Vaideeswaran, PhD, MBA , Associate Vice President, Delivery, Device & Connected Solutions, <i>Merck</i>
Panelist: Andrea Redd , Associate Vice President, Global Regulatory Affairs, Drug Device Delivery, <i>Eli Lilly and Company</i>

16:50 – 17:05

Conference Co-Chair Summary

Co-Chair: Theresa E. Bankston, PhD, VP Combination Products & Capabilities, *BD*

Co-Chair: Jakob Lange, PhD, VP & Head of Account and Business Development, *Ypsomed AG*

17:05 – 17:10

Closing Comments & Farewell

Committee Member: Falk Klar, PhD, General Manager, Vice President Europe, *Parenteral Drug Association*