Tuesday, 21 October

CEST Daylight Time (UTC +2:00)

07:30 – 17:00	Registration Open Foyer X4
09:00 – 09:20	Welcome and Innovation Award Announcement Hall D Committee Member: Falk Klar PhD, General Manager, Vice President Europe, Parenteral Drug Association
09:20 – 09:25	Welcome From the Co-Chairs Hall D 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
	Opening Session Part I

Part one of the opening session focuses on patients 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 – 10:30	09:25 – 09:45	Patient Perspectives on the Treatment of Obesity with GLP1s Hall D • Keynote Speaker: Sylvine M. Raverdy-Wilson MA, PhD, Clinical and Human Factors Manager, Becton Dickinson
	09:45 – 10:05	Physician Perspectives on the Treatment of Obesity with GLP1s Hall D • Keynote Speaker: Bernhard Ludvik MD, Head, 1st Medical Department, Landstrasse Clinic
	10:05 – 10:30	 Q&A, Disucssion Hall D Moderator: Jakob Lange PhD, VP & Head of Account and Business Development, Ypsomed AG Panelist: Bernhard Ludvik MD, Head, 1st Medical Department, Landstrasse Clinic Panelist: Sylvine M. Raverdy-Wilson MA, PhD, Clinical and Human Factors Manager, Becton

		Dickinson		
10:30 – 11:30	Networking Cof	fee Break, Exhibition, and Guided Poster Walk		
	Guided Poster V	Guided Poster Walk Part I		
	Foyer X3			
	Moderator: Chri	ista Jansen-Otten DI, Director Technical Product Development, West Pharmaceutical Services, Inc.		
		A Strategic Approach to Design Control in Large Volume Ready-to-Use Cartridges		
	10:40 – 11:25	Foyer X3		
	10.40 - 11.23	Poster Presenter: Alessia Mocci , Product Design Developer, Stevanato Group		
		Optimizing Drug Delivery For At-Home Use		
	10:40 – 11:25	Foyer X3		
	10.10 11.20	 Poster Presenter: Robert Lindner PhD, Global Product Manager Bulk and Sterile Cartridges, SCHOTT Pharma 		
		Push-to-Activate vs Button-Activated? A Self-Injection Device Interchangeability Study		
	10:40 _ 11:25	Foyer X3		
	10:40 – 11:25	 Poster Presenter: Nenad Suknovic PhD, Senior Research Lead – Usability Engineering, Global Product Development, SHL Medical 		
		Al in Automated Visual Inspection of Prefilled Cartridges: Success Stories		
	10:40 – 11:25	Foyer X3		
		Poster Presenter: Federico Scattolin , ,		
		Insights of Human Factor Considerations that may Influence User Experience in Drug-Device Combination Products Design		
	10:40 – 11:25	Foyer X3		
		 Poster Presenter: Jeremy Guo PhD, SVP, Head of DPD and Clinical DP Manufacturing network, WuXi Biologics 		
		Impact Of Tolerable Injection Conditions And Interindividual Sample Geometry Variability On Tissue Backpressure, Its Variability, And Formulation Spreading, Resulting From Subcutaneous Injections		
	10:40 – 11:25	Foyer X3		
		Poster Presenter: Aurélien Baquié , PhD candidate, Nemera and INSERM U1059 SAINBIOSE		
		Poster Presenter: Pascal Dugand MSc, Technology Product Manager – Parenteral, Nemera		
		Development and Use of an Innovative Methodology for Analyzing Visible Particulates		
	10:40 – 11:25	Foyer X3		
		 Poster Presenter: Antoine Buonomo MSc, R&D Analytical Development Engineer, Becton Dickinson 		
		Unlock Key Insights for Robust Method Validation in Design Verification and Manufacturing of Medical Devices		

	10:40 – 11:25	Foyer X3
		Poster Presenter: Ying Wang PhD, A.R. Fellow, Head of device development science, Pfizer UK
		Quantification of Silicone oil in Primary Packaging Materials using HPLC
	10:40 – 11:25	Foyer X3
		Poster Presenter: Tabea Koch , Scientist, Boehringer Ingelheim
		Mastering Novel Combination Product Transfer to Commercial Manufacturing
	10:40 – 11:25	Foyer X3
		Poster Presenter: Alexis Dechelette PhD, Director, Design & Innovation, Kymanox
		Mental Models and User Interface Design Considerations for Large-Volume Subcutaneous Infusion Devices
	10:40 – 11:25	Foyer X3
		Poster Presenter: Chris Franzese PharmD, MHS, Principal & Clinical Leader, Matchstick LLC
		Exploring Opportunities for Large Volume Subcutaneous (LVSC) Injections for Acute Illness Treatment from Both Patient and Healthcare Perspectives
	10:40 – 11:25	Foyer X3
		Poster Presenter: Simon Moss BA(Hons) PGCert, Principal Human Factors Engineer, Pfizer
		Mitigating Risk in ANDA Submissions: A Case Study on Leveraging Human Factors Data During Generic GLP-1 Combination Product Development
	10:40 – 11:25	Foyer X3
		 Poster Presenter: Laurie Brunet-Manquat MSc, Clinical & Human factors manager, Becton Dickinson
		Ebeam Technology – Transfer Technology For Pre-Sterilized RTU Components
	10:40 – 11:25	Foyer X3
10.10 11.05		Poster Presenter: Manfred Holzer , Strategic Product Manager E-Beam Technology, SKAN AG
10:40 – 11:25		Preclinical Evaluation on the Functionality and Usability of a High-Volume Auto-Injector (HVAI) as an Off-Body Injector Enabled by Recombinant Human Hyaluronidase PH20 (rHuPH20)
	10:40 – 11:25	Foyer X3
		Poster Presenter: David Kang , Director, Drug Delivery & Innovation, Halozyme Therapeutics
		Sustainable Drug Delivery Devices: A Whole Value Chain Approach
	10:40 – 11:25	Foyer X3
		Poster Presenter: Rich Harrison , ,
		Assessing Plunger Stopper Movement under Low Pressure and Variable Temperature Conditions
	10:40 – 11:25	Foyer X3
		Poster Presenter: Charlotte Utting BSc, Laboratory Supervisor, Smithers Medical Device Testing Division

	Impact of Injection Stress and Collection Methods on Drug Quality of Autoinjector
10:40 – 11:25	Foyer X3
	Poster Presenter: Wei Chen PhD, Executive Director, WuXi Biologics
	Accelerating Autoinjector Clip Design Verification with Digital Twin Technology
10:40 – 11:25	Foyer X3
	Poster Presenter: Jack Dunkley CEng MIMechE, Engineering Director, Haughton Design
	Development of a Portable Indenter Device for Assessing Tissue Stiffness at Injection Sites
10:40 – 11:25	Foyer X3
	Poster Presenter: Alexander Lyness , ,
	Sustainability in Subcutaneous Drug Delivery: Collaborative Opportunities from the SC Consortium Benchmarking Initiative
10:40 – 11:25	Foyer X3
	Poster Presenter: Madeleine Anderson , Insights Manager, Matchstick
	Predicting Creep Performance of Spring-Loaded Parts in Injection Devices
10:40 – 11:25	Foyer X3
	Poster Presenter: Mark Hazel , Application Development Engineer, Delrin uk Ltd
	Navigating Biocompatibility For Combination Products
10:40 – 11:25	Foyer X3
	Poster Presenter: Soroosh Bagheriasl PhD, Director, BioPhorum
	Reducing Product Carbon Footprint – Design Impact
10:40 – 11:25	Foyer X3
	Poster Presenter: David Cook , ,
	The Big Misunderstandard: On the Application of ISO 2859-1 for Drug Delivery Device Lot Inspection
10:40 – 11:25	Foyer X3
	Poster Presenter: Basel Taha PhD, President, Prossima Health Inc
	Identification of Foreign Particulate Matter in Assembled Autoinjectors Through Long-Time Tracking of Individual Particles' Trajectories
10:40 – 11:25	Foyer X3
	Poster Presenter: Matthias Kahl , Head of R&D and Lab Services, WILCO AG
	Advancing RTU Tub Innovations
10:40 – 11:25	Foyer X3
.0.10 11.20	Poster Presenter: Sophie Ruddick , Market Development Manager, Eastman
	Size Matters? Patient Insights from a Wearability Study on Large-Volume OBDS

Foyer X3
 Poster Presenter: Carlo Valbonesi Master Degree, Human Factors Engineer, Stevanato Group

Transforming Sterile Manufacturing For Syringes

Foyer X3
 Poster Presenter: Matous Michalek , ,

Understanding Engagement With Sustainable Injection Devices Through Behavioural Science

Foyer X3
 Poster Presenter: Lara Zaki MSc, Senior FEI Innovation & Strategy Consultant, Team Consulting

Tech Talks

Foyer X3

10:40 - 11:20

10:40 – 10:50	PFAS Control Strategy in Pharmaceutical Rubber Stopper Production Foyer X3 • Tech Talk Presenter: Mike Yang Master's degree, Marketing Manager, Sheng Zou
10:50 – 11:00	VH2O2 Sterilization for Ready to Use (RTU) Containers Foyer X3 • Tech Talk Presenter: Juha P Mattila MEng, Senior Manager, Technical Services, STERIS Life Sciences
11:00 – 11:10	Rethinking Plunger Design for Modern Drug Delivery Needs Foyer X3 • Tech Talk Presenter: Sebastien Cordier MS, Technical Product Manager PFS, Aptar Pharma
11:10 – 11:20	From Layers to Particles: Deep Learning for Silicone & SvP Characterization Foyer X3 • Tech Talk Presenter: Diana Koschel, Senior Manager R&D, BD

Opening Session Part II

Hall D

The second part of the opening session will present pharma company perspectives on going all the way from molecule to the patient, covering the development of combination products and their integration into a pharma company's patient offering. Expect to hear fresh perspectives and to learn more about the opportunities and challenges both in obesity treatment and in taking combination product development to the next level!

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

		A Holistic Assessment of Drug/Device Deliverability: From Molecule to Patient
11:30 – 11:50	11.20 11.50	Hall D
	11.50 – 11.50	 Presenter: Galen Shi PhD, Vice President of Engineering – Delivery Devices, Eli Lilly and Company
		Transforming Traditional Pharma into a Combination Products Company

11:30 – 12:40	11:50 – 12:10	 Presenter: Karthik Vaideeswaran PhD, MBA, Associate Vice President and Head, Device Delivery and Technology, Merck
	12:10 – 12:30	 Q&A, Discussion Hall D Moderator: Theresa E Bankston PhD, VP Combination Products & Capabilities, BD Panelist: Galen Shi PhD, Vice President of Engineering – Delivery Devices, Eli Lilly and Company Panelist: Karthik Vaideeswaran PhD, MBA, Associate Vice President and Head, Device Delivery and Technology, Merck
	12:30 – 12:40	Interactive Questionnaire Hall D • Moderator: Jakob Lange PhD, VP & Head of Account and Business Development, Ypsomed AG • Moderator: Theresa E Bankston PhD, VP Combination Products & Capabilities, BD
12:40 – 14:10	Networking Lun Foyer X2-X3	ch Break, Poster Session & Exhibition
	Tech Talks Foyer X3	
	12:50 – 13:00	A Journey Towards Cyber-Resilient Drug Delivery Systems Foyer X3 • Tech Talk Presenter: Gea Bianchi MSc, Software Quality Senior Engineer Cybersecurity Authority, Flex
	13:00 – 13:10	Unlocking The Potential of Connected Drug Delivery devices Foyer X3 • Tech Talk Presenter: Paul Draper MEng, Senior Sector Manager, Medical & Scientific, DCA Design International
	13:10 – 13:20	From Market Trends to Production Readiness: Empowering Medical Device Manufacturing Foyer X3 • Tech Talk Presenter: Christian A Scherer DiplIng., Executive Vice President Sales, Körber Pharma
12:50 – 14:00	13:20 – 13:30	Annex 1 Compliant RTU Transfer to Grade A With E-Beam Foyer X3 • Tech Talk Presenter: Manfred Holzer, Strategic Product Manager E-Beam Technology, SKAN AG
	13:30 – 13:40	Innovating Primary Packaging: The New SCHOTT TOPPAC® Cartridge Foyer X3

 Tech Talk Presenter: Christoph Zauner, Head of Product Management Polymer Syringes, SCHOTT Pharma

Vytal®: Innovative RTU Snap-Fit Closure System

13:40 - 13:50

Foyer X3

• Tech Talk Presenter: Ana Isabel Gutierrez . .

Environmental Responsibility and Pioneering Usability

13:50 - 14:00

Foyer X3

• Tech Talk Presenter: Tobias Theiler PhD, Head of Science and Evidence, Ypsomed AG

Session 1, Track C: Precision Testing and Imaging to Advance PFS and Autoinjector Integrity

Hall K

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 robustness of these drug delivery systems.

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

Innovative Design and Testing Strategy for an Autoinjector to Precisely Determine Leaks in the Prefilled Syringe

14:10 - 14:25 Hall K

• Presenter: Matthias Kahl, Head of R&D and Lab Services, WILCO AG

Evaluation of Container Closure Integrity and Failure Modes of Prefilled Syringes at Cryogenic Storage Temperatures

14:25 - 14:40

14:10 - 15:30

Hall K

 Academic Presenter: Oliver Germershaus PhD, Professor for Pharmaceutical Technology of Macromolecular Drugs, University of Applied Sciences and Arts Northwestern Switzerland

Unraveling Pre-filled Syringe Needle Clogging by Neutron and Synchrotron X-ray Imaging

14:40 - 14:55

Hall K

Presenter: Vlad Novak PhD, Group Leader, ANAXAM

Session 1, Track C: Q&A, Discussion

Hall K

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

14:55 - 15:30

- Panelist: Oliver Germershaus PhD, Professor for Pharmaceutical Technology of Macromolecular Drugs, University of Applied Sciences and Arts Northwestern Switzerland
- Panelist: Matthias Kahl, Head of R&D and Lab Services, WILCO AG
- Panelist: Vlad Novak PhD, Group Leader, ANAXAM

Session 1, Track A: Development and Trends

Hall D

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

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

14:10 - 14:25 Hall D

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

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

14:25 – 14:40 Hall D

• Presenter: Scott Lovald PhD, MBA, MEME, Senior Managing Engineer, Exponent

14:10 - 15:30

Advancing Platform Technologies for Combination Products

Hall D

14:40 - 14:55

- Co-Presenter: Fubin Wu MS, Co-founder & President, GessNet
- Co-Presenter: Nicole M Bergmann PhD, MBA, Sr. Director Device, Design and Connected Solutions, *Eli Lilly and Company*

Session 1, Track A: Q&A, Discussion

Hall D

- Moderator: Galen Shi PhD, Vice President of Engineering Delivery Devices, Eli Lilly and Company
- 14:55 15:30
- Panelist: Nicole M Bergmann PhD, MBA, Sr. Director Device, Design and Connected Solutions, *Eli Lilly and Company*
- Panelist: Scott Lovald PhD, MBA, MEME, Senior Managing Engineer, Exponent
- Panelist: Fubin Wu MS, Co-founder & President, GessNet
- Panelist: Andrei Yosef PhD, General Manager and President, LTS Device Technologies

Session 1, Track B: Enhancing Home Care: Stakeholder Needs, Patient Engagement, and Support Systems

Hall G

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

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

14:10 - 14:25

Hall G

• Presenter: Reza Abedian PhD, Head of Business Development & Customer Solutions, Gerresheimer - Advanced Technologies

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

14:25 – 14:40

Hall G

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

14:10 - 15:30

	44.40 44.55	Hall G
	14:40 – 14:55	 Presenter: Claire J. Everitt MEng, BSc (Psych), Design Engineering Lead - Medical Devices, Pfizer
		Session 1, Track B: Q&A, Discussion
		 Hall G Moderator: Frank Bamberg MA, Head of Primary Packaging and Medical Devices - Product
	14:55 – 15:30	Care, CSL Behring • Panelist: Reza Abedian PhD, Head of Business Development & Customer Solutions,
		Gerresheimer - Advanced Technologies • Panelist: Claire J. Everitt MEng, BSc (Psych), Design Engineering Lead - Medical Devices,
		Pfizer • Panelist: Joseph Reynolds MS, Director of User Experience Services, Noble International, LLC
5:30 – 16:30	Networking Coff Foyer X2-X3	fee Break, Exhibition and Guided Poster Walk
	Tech Talks	
	Foyer X3	
		From Stress to Success: A Shot at Zero Defects
	15:35 – 15:45	Foyer X3
		Tech Talk Presenter: Daryl Wells , Principal Product Manager, SmartSkin Technologies
		Addressing Large-Volume Subcutaneous Delivery Challenges with enFuse: A Patient- and Provider-Centric Solution
	15:45 – 15:55	Foyer X3
		 Tech Talk Presenter: Mehul Desai PharmD, MBA, Vice President, Medical Affairs, Enable Injections
15:35 – 16:25		Ensuring Excellence in Manufacturing
	15:55 – 16:05	Foyer X3
		Tech Talk Presenter: Michael Wecker , ,
		Novartis Contract Manufacturing - Fill and Finish Capabilities
	16:05 – 16:15	Foyer X3
		 Tech Talk Presenter: Hassan Khairat, Associate Director Business Development CDMO, Novartis
		Devices for Combination Products: A Partnership Worth More Than the Sum of Its Parts
	16:15 – 16:25	Foyer X3
	10.10 - 10.20	 Tech Talk Presenter: Bernd Zeiss DiplBiol., Head of Scientific Affairs and Application Technologies, Gerresheimer

Moderator: Andrea Allmendinger Prof Dr, Chief Scientific Officer, ten23 health

	Beyond App Fatigue: Alternative Ways of Adherence Monitoring in Home Injections
45.4040.05	Foyer X3
15:40 – 16:25	Poster Presenter: David Christen , ,
	Statistical Method for Classifying Abdominal Stiffness Behavior in a Human Factor Dataset
45.4040.05	Foyer X3
15:40 – 16:25	Poster Presenter: Alexander Lyness , ,
	Development of Plungers for Pre-filled Syringe Systems
	Foyer X3
15:40 – 16:25	 Poster Presenter: Christa Jansen-Otten DI, Director Technical Product Development, West Pharmaceutical Services, Inc.
	Improved Design Robustness by Combining Injection Molding Software With Measuring Software
15:40 – 16:25	Foyer X3
	 Poster Presenter: Glenn Svedberg M.Sc, Group Sustainability & Technology Director, Nolato AB
	VH2O2 Sterilization Under Deep Vacuum conditions for PFS Containing a Thermosensitive Drug Product
15:40 – 16:25	Foyer X3
	Poster Presenter: Serena Carella , Learning Campus Experience Director, Fedegari Autoclavi SpA
	Capitalizing on ASME V&V40: Regulatory-Grade Modeling and Simulation as an Alternative to Testing
15:40 – 16:25	Foyer X3
	 Poster Presenter: Peter Harley MEng, PhD, FIMechE, Head of Technology, Crux Product Design
	Determining the Oxygen Permeation Rate through Different Syringes
15:40 – 16:25	Foyer X3
10.40 - 10.23	 Poster Presenter: Marnix Wieffer PhD, MBA, Analytical services consultant, Lighthouse instruments
	Faster and Safer Single-Use Technologies From Thaw to Final Fill
15:40 – 16:25	Foyer X3
	Poster Presenter: Lucie Clavel Master Degree, Product Manager Fill & Finish, Sartorius
	Device Attributes that Matter: Patient Preferences and Drivers of Treatment Migration in Immunoglobulin Therapy
15:40 – 16:25	Foyer X3

	15:40 – 16:25	CCI Testing of High Viscosity Product in Pre-Filled Syringe Foyer X3 • Poster Presenter: Guerney D.H Hunt MS, Research Engineer 1, Packaging Technologies and Inspection
	15:40 – 16:25	Needle-Free Auto Injector Demonstration of Intramuscular Injection by MRI and Example of a PBPK Modeling to Show No Impact of Subcutaneous Fraction on Drug Exposure Foyer X3 • Poster Presenter: Don Zinn , ,
	15:40 – 16:25	Risk Reduction in Suspension-Based Formulations through Simulation-Driven Design Foyer X3 • Poster Presenter: Tim Quigg , Development Director, Crux Product Design
15:40 – 16:25	15:40 – 16:25	Preclinical Investigation of Subcutaneous Delivery of an Antibody-Drug Conjugate (ADC) with Recombinant Human Hyaluronidase PH20 (rHuPH20) and a High-Volume Auto-Injector Foyer X3 • Poster Presenter: David Kang, Director, Drug Delivery & Innovation, Halozyme Therapeutics
	15:40 – 16:25	Impact of Incomplete Plunger Rod Engagement on the Functionality of Prefilled Syringes Foyer X3 • Poster Presenter: Wei Chen PhD, Executive Director, WuXi Biologics
	15:40 – 16:25	Mechanical Disturbances and Sterility Integrity in Pre-Filled Syringe Assembly: Evaluating Risks of Stopper Displacement and Rotation During Plunger Rod Installation Foyer X3 Poster Presenter: Jeremy Guo PhD, SVP, Head of DPD and Clinical DP Manufacturing network, WuXi Biologics
	15:40 – 16:25	Evaluation of PLAJEX™ 1mL Long Luer Lock Pre-Fillable Syringe with NeoFlex™ Plunger Stopper after Deep Cold Storage Foyer X3 • Poster Presenter: Jianxiu Zhao PhD, Senior Technology Development Manager, Terumo
	15:40 – 16:25	Enabling Conversion of IV Formulation Into SC Formulations Foyer X3 • Poster Presenter: Byung Ha Lee PhD, Chief Business Officer, Huonslab Co., Ltd.
	15:40 – 16:25	Al-Driven Injection Molding & Assembly Optimization in MedTech Foyer X3 • Poster Presenter: Felix Müller, CEO and Co-Founder, plus10
	15:40 – 16:25	Development of High-Concentration PFS Combination Products: A Strategic Approach to Life-Cycle Management for a Biological Drug Foyer X3

	Poster Presenter: Jing Liu , ,
	Dual-Chamber Device Holding Carrier Design Considerations
45.4040.05	Foyer X3
15:40 – 16:25	 Poster Presenter: Michael S Thomas M.S. Pharmaceutics, Research Fellow, Lyophilizatio Technology Inc.
	A Holistic Approach to De-Risking and Accelerating Subcutaneous Formulations Developm
15:40 – 16:25	Foyer X3
	Poster Presenter: Sigrid Saaler-Reinhardt , ,
	Patient Characterisation For Setting Design Constraints – A Case Study on Gathering Anthropometric Data
15:40 – 16:25	Foyer X3
	Poster Presenter: Kyle Berman , Principal Mechanical Engineer, Pfizer
	From Flow to Blockage: The Dynamics of Needle Clogging in PFS
15:40 – 16:25	Foyer X3
15:40 - 16:25	• Poster Presenter: Fabiano Bonaventura MSc, Expert Science & Technology, Novartis Pharmaceutical Manufacturing GmbH
	Double-Sided 1.5 mL Fluoropolymer-Laminated Plunger for Low-Volume Cartridge Solutions
15:40 – 16:25	Foyer X3
10.10	 Poster Presenter: Amy Gindhart, Manager Scientific Communications, West Pharmaceutic Services
	Mitigating CCI Risks in PFS Under Deep Cold Storage: A Case Study Using Headspace Analysis
15:40 – 16:25	Foyer X3
10.40 - 10.23	 Poster Presenter: Marnix Wieffer PhD, MBA, Analytical services consultant, Lighthouse instruments
	A New Form of Protein Aggregates: An Early Warning Sign for Polysorbate Degradation
15:40 – 16:25	Foyer X3
	Poster Presenter: Laura Philips , ,
	Impact of VH2O2 Sterilization as Established Category A Modality
15:40 – 16:25	Foyer X3
10.40 - 10.23	 Poster Presenter: Juha P Mattila MEng, Senior Manager, Technical Services, STERIS Life Sciences
	Exploring Platform Synergies: Enabling High-Viscosity Biologic Delivery with SHL Medical's Molly® 2.25 mL Autoinjector and Stevanato Group's Syringes
	Foyer X3
15:40 – 16:25	Poster Presenter: Nina Fetz Phd, Senior Manager Customer Solutions, SHL Medical
	• Poster Presenter: Enrico Barichello , Global Product Manager Syringe Platform, Stevanato

Group Plunger Movement in Prefilled Syringes: An Altitude Simulation Study Foyer X3 15:40 - 16:25• Poster Presenter: Steven Malbon BSc, Combination & Physical Devices Manager, Medical Engineering Technologies Ltd **Redefining The Sustainability Benchmark** Foyer X3 15:40 - 16:25 • Poster Presenter: Alex Fong MBA, Head of Insight, Owen Mumford Ltd Risk Management For Sterilized Delivery System Components in Their Packaging: How to **Define and Control The Risk of Post-Sterilization Contamination?** 15:40 - 16:25 Foyer X3 Poster Presenter: Maxime Haure , , Session 2, Track A: Innovative Components for Complex Drug Delivery: Challenges, Platforms, and Sustainability Hall D Explore how innovative delivery systems are transforming the administration of complex biologics—from dual-liquid coformulations 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 Dual Liquid Drug Formulation Trends & Challenges: Incremental Innovation to Enable Usage of Standard Platform Components and Address Growing Needs

16:30 - 16:45

Hall D

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

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

Hall D

16:45 - 17:00

16:30 - 17:50

- Co-Presenter: Seda Aksel PhD, Product Manager, SHL Medical AG
- Co-Presenter: Michael S Thomas M.S. Pharmaceutics, Research Fellow, Lyophilization Technology Inc.

Challenging Design Requirements to Unlock Innovation and Improve Sustainability

17:00 – 17:15

Hall D

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

Session 2, Track A: Q&A, Discussion

Hall D

- Moderator: Christian Helbig, Vice President Glass Syringe Business, SCHOTT Pharma
- Panelist: Seda Aksel PhD, Product Manager, SHL Medical AG

17:15 – 17:50

 Panelist: Matthieu Charvin, Senior Project Manager - New Product Development, BD Medical -Pharmaceutical Systems

- Panelist: Will Marsh, Senior Sector Manager Medical & Scientific, DCA Design International
- Panelist: Michael S Thomas M.S. Pharmaceutics, Research Fellow, Lyophilization Technology Inc.

Session 2, Track B: Autoinjectors: The Fascinating World of User-Centered Innovation

Hall G

16:30 - 17:50

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.

ish Ingawale PhD, Director, Device & Combination Product Development, <i>Takeda</i>
A Study of Factors Impacting User Perceptions of Reusable and Disposable Autoinjectors
Hall G
Co-Presenter: Gemma Wood MBA, CMgr, Director, Platform Management, Phillips Medisize
Co-Presenter: Amanda Tilles MS, Human Factors Engineering Manager, Phillips Medisize
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
Hall G
• Presenter: Chloé Stoll PhD, Clinical and Human Factors Senior Specialist, BD
Epinephrine Autoinjector Re-imagined: An Introduction to Design Thinking and User-centered Innovation
Hall G
• Presenter: James Best , Design Manager, Studio lead, Flex
Session 2, Track B: Q&A, Discussion
Hall G
 Moderator: Shirish Ingawale PhD, Director, Device & Combination Product Development, Takeda
Panelist: James Best , Design Manager, Studio lead, Flex
Panelist: Chloé Stoll PhD, Clinical and Human Factors Senior Specialist, BD
Panelist: Amanda Tilles MS, Human Factors Engineering Manager, Phillips Medisize

Session 2, Track C: Advancing Manufacturing & Quality Control

Hall K

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

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

16:30 – 17:50	16:30 – 16:45	 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 Hall K • 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 Hall K • Co-Presenter: Fitore Kasumaj PhD, MSAT Biotherapeutics DP Primary Container Sr. 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 Hall K Moderator: Alessandro Morandotti , Director Product Development - Drug Containment Solutions, Stevanato Group Panelist: Massimo Frasson , CEO & General Manager, Brevetti CEA Panelist: Fitore Kasumaj PhD, MSAT Biotherapeutics DP Primary Container Sr. Principal Engineer, Johnson & Johnson Innovative Medicine Panelist: Roman Mathaes Dr., Chief Executive Officer, Clear Solutions Laboratories AG Panelist: Jessica Rocco MD, Technical Leader - Product Development DCS, Stevanato Group
	Conference End	I of Day 1

Hall K

17:50 - 17:50

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.

19:30 - 22:00

Networking Event

Wednesday, 22 October

CEST Daylight Time (UTC +2:00)

07:30 - 17:00

Registration Open

Foyer X4

Morning Session PDA Interest Group on Pre-Filled Syringes

Hall G

Discover how RFID-enabled prefillable syringes (PFS) can help overcome bottlenecks in pharmaceutical fill/finish. Based on a GMP pilot study, this session highlights improvements in inspection efficiency, documentation accuracy, and operator experience—plus future use cases like automated reconciliation and anti-counterfeiting.

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

Revolutionizing Traceability with RFID - A Pilot Study

Hall G 08:00 - 08:4508:05 - 08:25 Co-Presenter: Herve Soukiassian , Assoc. Director – Product Development, BD • Co-Presenter: Emilien Folzer PhD, Principal scientist, ten23 health **Q&A**, Discussion Hall G 08:25 - 08:45• Moderator: Brigitte Reutter-Haerle, Vice President Product Management & Marketing, Vetter Opening Session Day 2: Medical Device Regulation (MDR) 2020-2025 – Success, Pitfalls and Learnings Hall D With the implementation of MDR, new opportunities but also challenges emerged. Learn firsthand from Notified Body and Pharma experts what worked, what did not, and what to expect next. Get perspectives and learn how to better collaborate to obtain a successful notified body opinion for drug-device-combination products with a minimum of unnecessary pain. Moderator: Dominik Ziegler MSc, Executive Director Device Technology Solution Center, Novartis Pharma Five Years of Providing NBOps - A Notified Body Perspective of Lessons Learnt, Opportunities for Improvement, and a Look to the Future 09:00 - 09:25Hall D Presenter: Theresa Jeary MSc, Global Head - Medicinal & Biologics Team, BSI Reflections on the (EU) 2017/745 Art. 117 'Notified Body Opinion' - a Pharma Company 09:00 - 10:20**Experience** Hall D 09:25 - 09:50• Presenter: Stephanie Göbel Dipl-Ing FH, Senior Regulatory Program Director PTR Device and Combination Products, Roche / Genentech Q&A, Discussion Hall D Moderator: Dominik Ziegler MSc, Executive Director Device Technology Solution Center, Novartis Pharma 09:50 - 10:20• Panelist: Stephanie Göbel Dipl-Ing FH, Senior Regulatory Program Director PTR Device and Combination Products, Roche / Genentech • Panelist: Theresa Jeary MSc, Global Head - Medicinal & Biologics Team, BSI **Networking Coffee Break, Exhibition and Poster Session** 10:20 - 11:10Foyer X2-X3 **Tech Talks** Fover X3 Resuspension, Multichamber & Large Volume Autoinjectors Foyer X3 10:25 - 10:35 Tech Talk Presenter: David DeSalvo MS, MBA, Vice President, Combination Product Development, Kindeva Drug Delivery Simplifying Reconstitution: Addressing Lyophilized Formulations with a Dual-Chamber **Cartridge Autoinjector**

	10:35 – 10:45 Foyer X3 • Tech Talk Presenter: Gene Rhode Fensalida Pantig,
10:25 – 11:05	Next Generation of Syringe Closure Technology Foyer X3 10:45 – 10:55 • Tech Talk Presenter: Tobias Nemeth, Director DS Primary Packaging Service & Projects / Product & Service Manager, Vetter
	Terumo CDMO: Reducing Complexity From Drug Development to Delivery to the Patients Foyer X3 10:55 – 11:05 Tech Talk Presenter: Anil Busimi Msc, MBA, VP Strategy & Marketing, Terumo Pharmaceutical Solutions
	Session 3, Track A: Exploring the Space of Large Volume Injections Hall D 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 Simulation of Large Volume, High-Viscosity Subcutaneous Injections with Transport and
11:10 – 12:30	Absorption 11:10 – 11:25 Foyer X3 • Presenter: Scott Lovald PhD, MBA, MEME, Senior Managing Engineer, Exponent
	Injection Rate Impact on Depot Morphology of a High Viscosity Long Acting Injectable in Physiologically Relevant Ex Vivo Porcine Tissue Hall D 11:25 – 11:40 • Co-Presenter: Robert CH Gresham PhD, Senior Device Engineer, Gilead Sciences • Co-Presenter: Tyler A Novak PhD, Director of Drug Delivery Innovation, Gilead Sciences
	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 11:40 – 11:55 Hall D Co-Presenter: Reto Jost MSc, Director, Category Lead Large Volume Injectors, Ypsomed AG Co-Presenter: Sven Pohle PhD, Product Manager, SCHOTT Pharma
	Session 3, Track A: Q&A, Discussion Hall D • Moderator: Flora Felsovalyi PhD, Associate Director, Lonza • Panelist: Robert CH Gresham PhD, Senior Device Engineer, Gilead Sciences • Panelist: Reto Jost MSc, Director, Category Lead Large Volume Injectors, Ypsomed AG • Panelist: Scott Lovald PhD, MBA, MEME, Senior Managing Engineer, Exponent

Panelist: Tyler A Novak PhD, Director of Drug Delivery Innovation, Gilead Sciences

Session 3, Track B: Connected Devices and Digital Patient Engagement

Hall G

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

Empowering Patients: The Benefits of Connected Injection Devices on Health Outcomes – A
Focus on Autoinjectors

11:10 - 11:25 Hall G

• Presenter: Marco Rigamonti , General Manager, European Health Solutions Design, Flex

Supporting Patients to Self-Inject: The Journey to Develop Digital Instructions

Hall G

11:25 - 11:40

- Co-Presenter: Katie Cornish PhD, Senior Human Factors Engineer, AstraZeneca
- Co-Presenter: Thomas Grant PhD, Senior Consultant Digital Health, Team Consulting

RFID-Enabled Prefilled Syringe System: Minimizing Drug Waste While Enhancing User Convenience and Sustainability

Hall G

11:40 - 11:55

- Co-Presenter: Christoph Zauner , Head of Product Management Polymer Syringes, SCHOTT Pharma
- Co-Presenter: Nick Petersen BA, Growth Product Manager, RFID, Bluesight, Inc.

Session 3, Track B: Q&A, Discussion

Hall G

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

11:55 - 12:30

- Panelist: Katie Cornish PhD, Senior Human Factors Engineer, AstraZeneca
- Panelist: Thomas Grant PhD, Senior Consultant Digital Health, Team Consulting
- Panelist: Nick Petersen BA, Growth Product Manager, RFID, Bluesight, Inc.
- Panelist: Marco Rigamonti , General Manager, European Health Solutions Design, Flex

Session 3, Track C: Advanced Analysis of Drug Delivery Systems

Hall K

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

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

11:10 – 12:30

		Hall K
	11:10 – 11:25	Co-Presenter: Stefan Scheler , Associate Director Science & Technology, Novartis Pharmaceutical Manufacturing GmbH
		 Co-Presenter: Fabiano Bonaventura MSc, Expert Science & Technology, Novartis Pharmaceutical Manufacturing GmbH
		Proof of Significant Oxygen Ingress Reduction for COC Syringes Through Highly Effective Barrier Labels
	11:25 – 11:40	Hall K
11:10 – 12:30		Presenter: Corinna Endres MSc, Product Manager, Schreiner MediPharm
		Advantages of Intradermal Injection: From Infection Diseases Vaccine Delivery Toward Lymphatic Vessel Application for Cancer Therapy
		Hall K
	11:40 – 11:55	 Co-Presenter: Sakiko Shimizu MA, Chief Scientist, Pharmaceutical Solution Devision, Terumo Corporation
		Co-Presenter: Michele Guasti , Global Product Manager, Terumo Europe
		Session 3, Track C: Q&A, Discussion
		Hall K
		Moderator: Jeffrey Givand PhD, Executive Director, Device and Combination Product
		Development, <i>Merck</i>
	11:55 – 12:30	 Panelist: Fabiano Bonaventura MSc, Expert Science & Technology, Novartis Pharmaceutical Manufacturing GmbH
		Panelist: Corinna Endres MSc, Product Manager, Schreiner MediPharm
		Panelist: Michele Guasti , Global Product Manager, Terumo Europe
		 Panelist: Stefan Scheler , Associate Director Science & Technology, Novartis Pharmaceutical Manufacturing GmbH
12:30 – 14:30	Networking Lun	nch Break, Poster Session & Exhibition
	Foyer X2-X3	
	Tech Talks	
	Foyer X3	
		De-Risking Autoinjector Integration with Pre-Fillable Syringes
	12:50 – 13:00	Foyer X3
	1	Tech Talk Presenter: Adam Stops , ,
		The Role of the Container Closure Manufacturer in the LVSCDD Solutions
	13:00 – 13:10	Foyer X3
	12.55	 Tech Talk Presenter: Paolo Ferrigno, Product Manager, Prefilled Syringes & Cartridges, Datwyler
		Systems Approach to Navigate USP <382>
	13:10 – 13:20	Foyer X3

		• Tech Talk Presenter: Richard Kieran MSc, Director, Business Development, West Pharmaceutical Services Inc.
12:50 – 14:20	13:20 – 13:30	Trends, Challenges & Solutions in Drug Delivery Foyer X3 • Tech Talk Presenter: John A. Merhige MEM, Chief Commercial Officer, Credence MedSystems, Inc.
	13:30 – 13:40	Large Volume Drug Delivery Devices: Considerations For HCP and Patient Experience Foyer X3 • Tech Talk Presenter: Brent Rutland , ,
	13:40 – 13:50	How to Ask Better Questions: Cracking the Code of Preference Through Study Design Foyer X3 • Tech Talk Presenter: Kaylene Kau MA, Sr. UX Designer, Phillips Medisize • Tech Talk Presenter: Amanda Tilles MS, Human Factors Engineering Manager, Phillips Medisize
	13:50 – 14:00	From Low to High Viscosity – One Autoinjector To Rule Them All Foyer X3 • Tech Talk Presenter: Thomas Thueer PhD, Program Lead, Haselmeier
	14:00 – 14:10	Development of a High-Volume Auto-Injector (HVAI) Foyer X3 • Tech Talk Presenter: David Kang, Director, Drug Delivery & Innovation, Halozyme Therapeutics
	14:10 – 14:20	Discover How Innovative AI Technology Enhances the Performance of Automated Visual Inspection Machine Within the Parenteral Pharmaceutical Sector Foyer X3 • Tech Talk Presenter: Stefano Selvatici,,

Closing Session Part I

Hall D

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

14:30 - 15:00

From Waste to Circularity: Opportunities and Challenges in Decarbonizing Self-Injection Devices

14:30 – 14:45 Hall D

• Presenter: Andreas Schneider PhD, Head Innovation Delivery Systems, Ypsomed AG

From Carbon Footprint to Carbon Handprint: Transforming the Pharmaceutical Industry's Role

	in Sustainability
	14:45 – 15:00 Hall D • Presenter: Hanns-Christian Mahler PhD, CEO, ten23 health
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15:00 – 15:45	Networking Coffee Break, Exhibition and Poster Session
	Foyer X2-X3
	Tech Talks
	Foyer X3
	Nitrogen Dioxide Sterilization, the Leading Alternative to EO
	15:10 – 15:20 Foyer X3 • Tech Talk Presenter: Michael Maust , Laboratory Manager for Customer Projects, Noxilizer, Inc.
	Designing Next Gen GLP 1 Devices – What Users Want
15:10 – 15:40	Foyer X3 15:20 – 15:30
	 Tech Talk Presenter: Tom Osman MEng (Hons) CEng, Honorary Assistant Professor, University of Birmingham, UK
	What Is Driving the Growth in Dual Drug Delivery Systems?
	Foyer X3 15:30 – 15:40 • Tech Talk Presenter: Alastair Willoughby MEng, Head of Mechanical Engineering, Team Consulting
	Passport Raffle
15:45 – 15:50	Hall D
	Moderator: Melanie Decker , , Parenteral Drug Association
	Closing Session Part II
	Hall D
	Moderator: Theresa E Bankston PhD, VP Combination Products & Capabilities, BD
	Moderator: Jakob Lange PhD VP & Head of Account and Business Development Ypsomed AG
	The Fundamentals of Sustainability
	Hall D
	• Co-Presenter: Massine Yanat , Technical Support Service and Sustainability, North America, SGD Pharma
	 Co-Presenter: Durga Prasad Madhavapeddi MTech, PMP, Sr. Material Scientist, FUJIFILM Diosynth Biotechnologies
15:50 – 16:55	Decarbonisation in Pharma and Healthcare: State of the Sector 2025 Report
10.00 - 10.00	16:00 – 16:15 Hall D • Presenter: Marion Briggs MBA, Associate Director, SLR
	Closing Plenary Discussion
	and the second s

Moderator: Theresa E Bankston PhD, VP Combination Products & Capabilities, BD
 Moderator: Jakob Lange PhD, VP & Head of Account and Business Development, Ypsomed AG
 Panelist: Marion Briggs MBA, Associate Director, SLR
 Panelist: Hanns-Christian Mahler PhD, CEO, ten23 health
 Panelist: Andreas Schneider PhD, Head Innovation Delivery Systems, Ypsomed AG

Conference Co-Chair Summary
Hall D
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

Closing Comments & Farewell

17:05 - 17:10

Hall D

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

PDA Extractables and Leachables Training Course Fall Edition

23 Oct - 24 Oct

PDA Container Closure Integrity Testing - Basic Training Course Fall Edition

23 Oct - 24 Oct

PDA All About Pre-Filled Syringe Systems - Basic Training Course Fall Edition

23 Oct - 24 Oct

PDA Basics of an Environmental Monitoring Program Training Course

19 Nov - 20 Nov

PDA Fundamentals of Aseptic Processing Training Course

23 Oct - 24 Oct