2023 PDA Parenteral Packaging Conference
Are you ready? Incorporating Safety, User Centricities, and Sustainability into Packaging Innovation
Lido di Venezia, Italy

18-19 April 2023

Tuesday, 18 April 2023		**09:00-17:15**
9:00	Welcome and Introduction	Falk Klar, *PDA Europe*
9:05	Welcome from the Chairs	Bettine Boltres, *WEST* Derek Duncan, *LIGHTHOUSE Instruments*
Opening Plenary: Where are we with Sustainability and how can we include it in Regulatory Developments?		**Moderator:** Bettine Boltres, *WEST*
We will start this conference with highlights from our conference theme and the regulatory world. We will discuss how we can even recycle glass containers that have already been contaminated, a challenge that has not yet been tackled. This is being complemented with updates and news from the U.S. FDA and the European Pharmacopeia.		
9:15	**Opening Keynote:** The Global Problem of Pharmaceutical Glass Waste	Stephen Whettingsteel, *Krysteline Technologies*
9:40	Having your Cake and Eating it too: Developmental Considerations for Preservative-Free Multidose Drug Products	Erika Pfeiler, *U.S. FDA* *-remote presentation-*
10:10	Recent Developments in Ph. Eur. Packaging Chapters	Valentina Petrusevska, *EDQM*
10:40	**Coffee Break, Poster Session & Exhibition**	
11:10	Towards Circular Packaging and Devices	Arne Kloke, *SCHOTT Pharma on behalf of Alliance to Zero* Kurt Kugler, *Schreiner Group on behalf of Alliance to Zero*

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11:35	Updates on Technical Reports 73-2 (MDR GSPR Requirements for PFS)		Bettine Boltres, *WEST*	
11:50	Interactive Questionnaire Session		**Moderator:** Bettine Boltres, *WEST*	
12:05	Q&A, Panel Discussion		**Moderator:** Bettine Boltres, *WEST*	
12:50	**Lunch Break, Poster Session & Exhibition**			
13:35	**LIVE Guided Poster Walk** Engage with our Poster Presenters in our Exhibition Hall			
Session 1	**Track A** **Insights from Container Closure System Development**	**Moderator:** Philippe Lauwers, *Terumo*	**Track B** **Container Closure Integrity Testing (CCIT) Part I**	**Moderator:** Miho Soma, *Gilead*
In this session, we will present a case study detailing the development strategy of a cartridge packaging system for a micro-suspension, as well as a case study presenting advanced testing technologies and how they help to better estimate the risk of excessive injection forces during formulation refinement.			In this session, we will explore the application of new technologies and innovative approaches to ensure CCI for next-generation products, such as frozen-stored mRNA-based vaccines filled in vials or pre-filled syringes.	
14:05	Impact of Terminal Sterilization on Cartridge Packaging System Development for Suspensions	Dominick DeGrazio, *GSK*	Unlocking New Paths to Container Closure Integrity Assurance Realization	Mihaela Simianu, *SmartSkin Technologies* Michael Edey, *Pfizer*
14:30	Leveraging the Relationship between Viscosity and Injection Force to Optimize Development Cost and Timeline	Jean-Sebastien Steffen, *Lonza*	Container Integrity in the Time of Covid-19	Satish Singh, *Moderna* *-remote presentation-*

14:55	Q&A, Discussion	**Moderator:** Philippe Lauwers, *Terumo*	Q&A, Discussion	**Moderator:** Miho Soma, *Gilead*
15:25	**Coffee Break, Poster Session & Exhibition**			
Session 2	**Track A** **Closed System Transfer Devices (CSTD)**	**Moderator:** Derek Duncan, *LIGHTHOUSE Instruments*	**Track B** **Packaging Material Interactions and Defect Evaluation**	**Moderator:** Sinue Gomez, *Corning*
This session will highlight the risks associated with the interconnection of CSTDs and propose design specifications and practical strategies to reduce these risks when developing new container closure systems and drug products.			Join us for an exciting discussion on extractable interactions of packaging with alternative sterilization techniques and challenges to determine equivalency. In this session, you will also hear about the creation of a comprehensive defect library for Blow-Fill-Seal (BFS) containers.	
15:55	Comprehensive Risk Assessment and Development of Design Specifications for the Interconnection of Closed System Drug Transfer Devices and Vial Container Closure Systems	Pete Sargent, *PQRI Group*	Extractables Evaluation X-Ray or Gamma Irradiated SU Devices and Materials	Ina Pahl, *Sartorius*
16:20	Strategies for De-risking of Clinical CSTD use during Chemistry, Manufacturing, Control (CMC) Development	Matthias Winzer, *Merck KGaA*	Defect Library of Blow-Fill-Seal Containers	Heino Prinz, *Rommelag*
16:45	Q&A, Discussion	**Moderator:** Derek Duncan,	Q&A, Discussion	**Moderator:** Sinue Gomez, *Corning*

		LIGHTHOUSE Instruments		
17:15	**End of Conference Day 1 & Networking Event**			

Wednesday, 19 April 2023 08:00-16:35

08:00	**Track A** **Packaging Science Workshop** **Moderator:** Derek Duncan, *LIGHTHOUSE* This Interest Group will be meeting for discussion and current hot topics include among other things: • Implementation of EU GMP Annex 1 requirements for container closure • Primary packaging solutions for therapies needing ultracold storage & transport • Packaging and sustainability • Closed system transfer devices **Please join us for interaction and discussion!**		**Track B** **Pre-Filled Syringes Workshop** **Moderator:** Brigitte Reutter-Härle, *Vetter* Take advantage of the open forum offered by this focused Interest Group workshop. • Listen to Mario Schwab, Optima presenting about **'Fill & Finish and the Challenges of New Packaging Technologies'** • Discuss the latest market trends & industry topics with colleagues • Receive the latest information about activities of this Interest Group • Review and discuss the latest results from the previous polling • Share your opinion and enlarge your knowledge **Looking forward to a great session and discussion!**	
Session 3	**Track A** **Deep Cold Storage**	**Moderator:** Patricia Hughes, *U.S. FDA*	**Track B** **Tackling Challenges in Large-Volume Containers**	**Moderator:** Bram Jongen, *Datwyler*
This session will present case studies relating to container closure integrity failures due to deep cold storage conditions and will discuss the underlining causes of failures. Case studies will cover both vial and pre-filled syringe presentations.			Large-volume containers will be more prominent in the future parenteral packaging landscape. Let's tackle together with key experts' specific challenges and smart solutions.	

9:00	Container Closure Integrity Phenomenology and Failure Mechanisms during Deep Cold Storage	Eloïse Perrin, *BD*	Flexible Container Closure Systems: Unique Opportunities and Challenges	Sharath Gopal and David Pehlman, *Eli Lilly and Company*
9:25	Vials for Deep Cold Storage	Diana Löber, *SCHOTT Pharma*	Container Closure Integrity Testing of Large Volume Containers	Jean-Sebastien Steffen and Federico Sabini, L*ONZA*
09:50	Q&A, Discussion	**Moderator:** Patricia Hughes, *U.S. FDA*	Q&A, Discussion	**Moderator:** Bram Jongen, *Datwyler*
10:20	**Coffee Break, Poster Session & Exhibition**			
Session 4	**Track A** **Container Closure Integrity Testing (CCIT) Part II**	**Moderator:** Coralie Richard, *Eli Lilly and Company*	**Track B** **Insights from Process Experts**	**Moderator:** Folker Steden, *SCHOTT Pharma*
When asked "What is the best strategy to build a CCI program", the typical answer is always "it depends!". Please join this session to get insights on container closure integrity techniques, their comparison, and their applicability through case studies that will help inform your container closure integrity strategy journey.			Are you interested in deep knowledge about aspects of modern process management of remote terminal units injection moldings during sterilization, or how to handle characterizations of container closure integrity and maximum allowable leakage limit limits during large-scale freezing/thawing techniques? Listen to inspiring speeches about best practices and get exclusive insights. Looking forward to a good discussion afterward.	
10:50	Correlating CCI Leak Rates as Determined by Helium Leak Testing and Laser-Based Headspace Carbon Dioxide Analysis Using	Christian Proff, *F. Hoffmann - La Roche*	Exploring the Impact of Injection Molding and Steam Sterilization on Pre-Fillable Cartridge Packaging System Tolerances	Marco Longhin, *Stevanato Group* Peter Harley, *Crux Product Design*

	Modular Positive Controls			
11:15	Strategies to Evaluate Container Closure Integrity (CCI) of Vial and Syringe Systems over Time and Temperature	Amy Gindhart, *WEST*	Large-Scale Freezing and thawing of Biologics in Drug Substance Bottles	Sarah Peláez, *ten23 health*
11:40	Q&A, Discussion	**Moderator:** Coralie Richard, *Eli Lilly and Company*	Q&A, Discussion	**Moderator:** Folker Steden, *SCHOTT Pharma*
12:10	**Lunch Break, Poster Session & Exhibition**			
Closing Plenary: Sustainable Packaging Now and in the Future			**Moderator:** Arne Kloke, *SCHOTT Pharma on behalf of Alliance to Zero*	
We all want to have sustainable operations and products. But HOW? is the question we can insufficiently answer for our industry today. We'll close the conference with a forum exchange on related challenges and solutions approaches that might fuel this transformation. We'll bring together different perspectives – from component suppliers to pharmaceutical companies and from primary packaging and sterile barrier materials to packaging of the final product.				
13:10	Interactive Questionnaire Session		**Moderator:** Arne Kloke, *SCHOTT Pharma on behalf of Alliance to Zero*	
13:25	Decarbonizing Supply Chains in the Pharma Industry		Bridget Ferrari, *Takeda*	
13:40	Sustainable Secondary Packaging in Pharma		Claudia Langjahr and Volker Grouls, *Körber Pharma*	
14:05	**Coffee Break, Poster Session & Exhibition**			
14:35	**Passport Raffle**			

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14:40	The Correlation Between Continuity, Supply Chain Resiliency, and Sustainability in Healthcare Packaging	Kiley Djupstrom, *Kilmer Innovations* Jenn Goff, *Oliver Healthcare Packaging*
15:05	Product Design and Life Cycle Analysis of Sustainable Pharmaceutical Containers	Shivani Polasani, *Corning*
15:30	**Closing Panel Discussion** Join our Discussion with Experts from the Industry • Kiley Djupstrom, *Kilmer Innovations* • Bridget Ferrari, *Takeda* • Jennifer Goff, *Oliver Healthcare Packaging* • Volker Grouls, *Körber Pharma* • Claudia Langjahr, *Körber Pharma* • Shivani Polasani, *Corning*	**Moderator:** Arne Kloke, *SCHOTT Pharma on behalf of Alliance to Zero*
16:10	Chairs Conference Summary	Bettine Boltres, *WEST* Derek Duncan, *LIGHTHOUSE Instruments*
16:30	Closing Remarks & Farewell	Falk Klar, *PDA Europe*
16:35	**End of Conference**	