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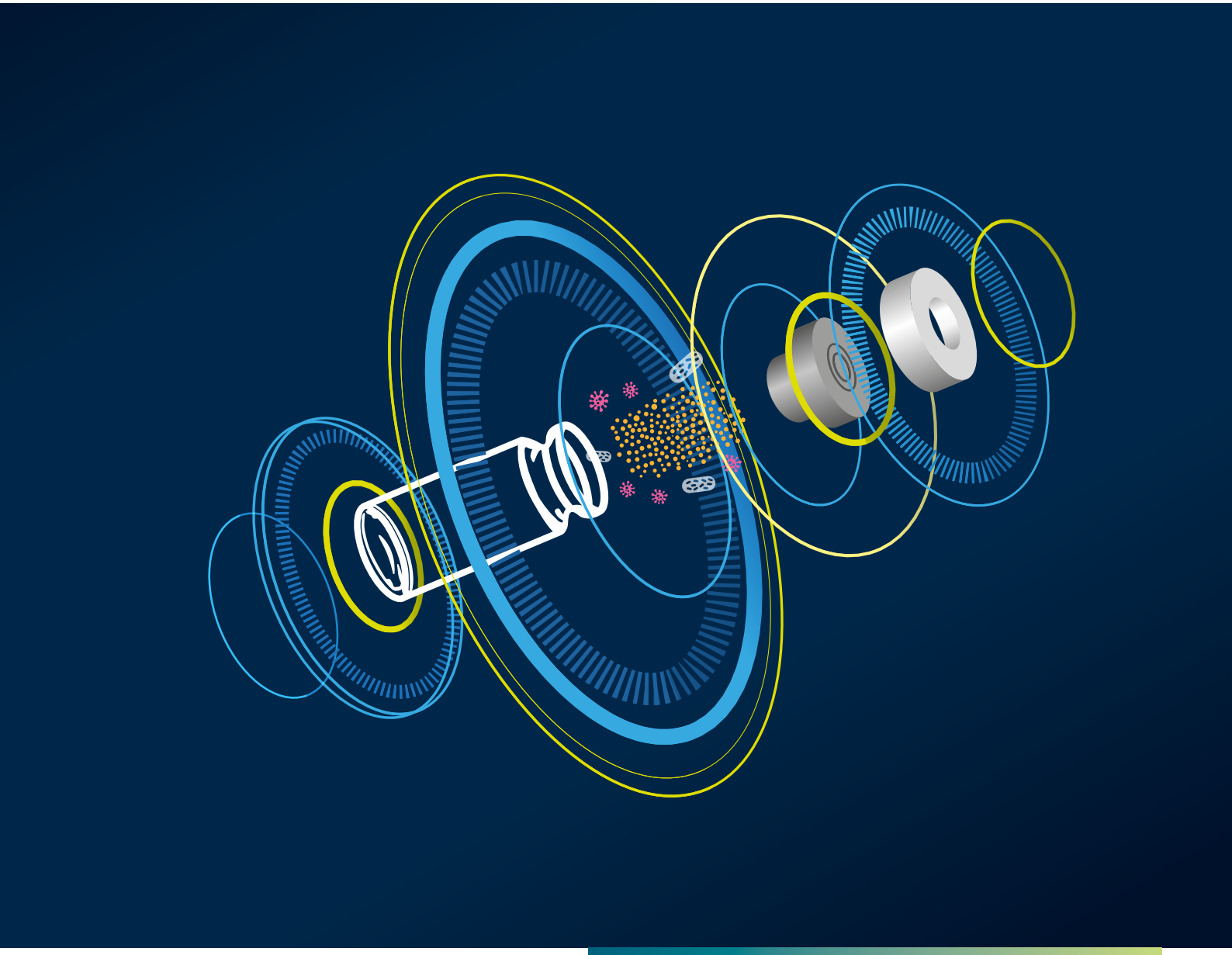
2019 PDA EUROPE

Parenteral Packaging

Interaction of Product, Package, and Process



19-20 MARCH 2019
VENICE, ITALY
EXHIBITION: 19-20 MARCH
EDUCATION & TRAINING: 21-22 MARCH
IG MEETINGS: 18 + 21 MARCH

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WELCOME TO VENICE

SCHEDULE AT A GLANCE

18 March	**10:00 – 16:30**	**Pre-filled Syringes**	**Interest Group Meeting**
18 March	**19:30 – 22:00**	**Welcome Party**	**Supported by** ISG Ompi Stevanato Group
19 March	**9:00 – 18:00**	**Parenteral Packaging**	**Conference, Exhibition**
19 March	**19:00 – 21:30**	**Networking Event**	
20 March	**9:00 – 16:30**	**Parenteral Packaging**	**Conference, Exhibition**
21 March	**10:00 – 17:00**	**Packaging Science**	**Interest Group Meeting**
21 March	**9:00 – 17:00**	**Container Closure Development**	**Training Course**
21 March **22 March**	**9:00 – 17:45** **9:00 – 15:30**	**Test-Methods for Pre-filled Syringe Systems**	**Training Course**
21 March **22 March**	**9:00 – 17:30** **8:30 – 16:30**	**Container Closure Integrity Testing**	**Workshop**
21 March **22 March**	**9:00 – 18:00** **9:00 – 16:30**	**Extractables & Leachables**	**Training Course**

For latest information, please visit: **pda.org/EU/ParPack2019**

Pre-filled Syringes

Focus Topic: Time-to-Market
Novel Approaches to Supporting the Patient by Reducing Pre-Filled Syringe Development Timelines

Dear Colleagues,

Time-to-market is gaining in importance, especially since the industry wants to support patients with new drugs as quickly as possible. Unfortunately, the costs associated with new injectable drug products continue to increase over time. Minimizing development time also presents challenges. In fact, every day added to the development plan actually diminishes the value for licensing or selling of the drug product due to reductions in potential revenue and market exclusivity.

The goal of this meeting is to discuss these challenges with a primary focus on:

- **Approaches and trends in drug development with the potential to rapidly support patients with new drugs.**
- **Time-to-market packaging platforms, new technologies, regulation strategies, clinical and commercial fill & finish, secondary packaging, etc.**
- **Case studies from a pharma/biotech supplier using tools, platforms or methods, supplier solutions, process and technology infrastructure, and development strategies that demonstrate a reduction in time-to-market.**

Take advantage of the open forum design approach offered by this focused Interest Group meeting. Hear presentations from leading experts and interact and discuss your experiences with colleagues in an open atmosphere. Share your opinion and enlarge your knowledge in an interactive format discussion. Receive the latest information about activities of the Interest Group/Pre-filled Syringes.

Brigitte Reutter-Haerle, *Vetter Pharma International GmbH, Interest Group Leader Europe*
Brigitte Reutter-Haerle is the Vice President of Marketing / Corporate Communications for Vetter, a leading contract development and manufacturing organization that serves the global pharma/biotech industry. She was called to this new position in September 2014 and is responsible for the company's international marketing activities, product and service management as well as HR marketing and internal communication. Between 2004 and 2014, she held the position of Director Corporate Marketing. In 2009, she led the communications program for Vetter's U.S. expansion. Ms. Reutter-Haerle joined Vetter in 1996, serving in the company's sales and marketing function, and transferred to corporate marketing three years later. She began her career in 1983, holding various positions in the sales organizations of firms including Hilton International and TNT Express Worldwide. Ms. Reutter-Haerle earned a B.A. and a degree in Business Administration from Baden-Wuerttemberg Cooperative State University. She has been leading the Pre-filled Syringe Interest Group/Europe of the Parenteral Drug Association since 2007.

18. Jan 2019

Monday, 18 March 2019

10:00	**Welcome and Introduction**	Falk Klar, *PDA Europe* Brigitte Reutter-Haerle, *Vetter*

Innovations to Shorten Time-to-Market

Moderator: **Brigitte Reutter-Haerle,** *Vetter*

Due to reductions in potential revenue and market exclusivity, every day added to the development plan diminishes the value for licensing or selling of the drug product. In this session, leading experts discuss platform technologies as well as new technologies and methods that demonstrate how a reduction in time-to-market can be achieved.

10:10	**Accelerating Time-to-Market of Smart Devices: How to Effectively Upgrade Self-Injection Device Platforms into Integrated Cloud-Connected Systems**	Andreas Schneider, *Ypsomed*
10:35	**Switch from High Speed Line to Flexible Tabletop and/or Manual Assembly in Packaging with the Goal to Shorten Time-to-Market**	Guido Drees, *Roche*
11:00	**Coffee Break, Poster Session & Exhibition**	
11:30	**Root Cause Investigation on a Drug Formulation Interacting with Silicone Oil Resulting in Extended Injection Time Using an Auto-injector Device**	Robert Hormes, *Novartis*
12:00	**Lunch Break, Poster Session & Exhibition**	

Interactive Session - Innovations to Shorten Time-to-Market

Moderator: **Frank Bamberg,** *Roche*

After parting in three groups the participants will enter a structured conversational process regarding Risks and Challenges, Technical Solutions and Partnerships and Cooperation in three rounds. Facilitated by a table moderator, each group is introduced to the topic and will have a set amount of time to discuss and gather key points on each topic. As each group will build on the knowledge already gathered, each round will be shorter than the previous one. Inspired by the method developed by Juanita Brown und David Isaacs this session will result in conclusive take home messages on each topic discussed.

13:00	**Introduction**		Frank Bamberg, *Roche*
13:10	**Transition to 3 Groups**		
	Risks and Challenges Moderator: Michael Betz, *Roche*	**Technical Solutions** Moderator: Gabriele Peron, *Stevanato Group*	**Partnerships and Cooperation** Moderator: Andreas Schneider, *Ypsomed*
13:15	**Round 1**		
13:35	**Round 2**		
13:50	**Round 3**		
14:00	**Summary**		
14:30	**Coffee Break, Poster Session & Exhibition**		

Novel Approaches & Practical Implementations		*Moderator:* **Philippe Lauwers,** *Terumo*
15:00	**Track and Trace of Primary Packaging Containers – A Discussion on the Fill & Finish Operations for Single Containers**	Bernd Zeiss, *Gerresheimer* Riccardo Marcon, *Stevanato Group* Diana Loeber, *Schott* Chi Yuen Liu, *Johnson & Johnson*
15:25	**Modular Robotic Inspection - Fully Automated Inspection with an Autonomous Island Mini-Plant**	Andrea Sardella, *Stevanato Group* Michael Betz, *Roche*
15:50	**Roadmap to Create a Global Presence in Aseptic Injectable Fill & Finish from a Development Capability to Full Scale Commercial Expansion: A Corden Pharma Case History**	Silvia Lissoni, *Corden Pharma*
16:15	**Summary and Q&A**	
16:30	**Conclusion of Interest Group Meeting**	Brigitte Reutter-Haerle, *Vetter*

Admission is included in the Conference Fee. Please make sure you are registered!
Thanks to Stevanato Group for supporting this special event!

Dear Colleagues,

PDA Europe is pleased to present the **9th Parenteral Packaging Conference,** returning to Venice for the second time. This conference has become highly regarded and this year's edition will continue the series of exceptional presentations and discussions. Industry leaders and technical experts from pharma and supplier companies along with regulators will cover many aspects of the drug product-package interface.

Primary packaging of a parenteral pharmaceutical drug product should be designed, processed and manufactured, to ensure efficacy and safety of the patients.

Biopharmaceuticals are a standard therapeutic modality to treat severe diseases; however, they require special considerations for processing and packaging.

Developments in packaging materials such as innovations in glass and their characteristics regarding interactions with the drug product formulation and end-user preferences will be discussed. Case studies of the implementation of new guidelines, for example **Annex 1 of the European GMP Guideline** and **USP 800** along with some of the latest developments in packaging materials & components and the role of **Container Closure Integrity (CCI)** in product-package development, assembly and processing will be presented.

The conference program is intended to initiate and support discussion and professional exchange through a diversity of scientific presentations, workshops, interest group meetings, training courses, joint dinners and networking events.

We look forward to you joining us in amazing Venice!

Sincerely,
The Chairs

Roger Asselta,
Conference Chair,
Genesis Packaging Technologies

Roman Mathaes, *PhD,*
Conference Chair,
Lonza

18. Jan 2019

Tuesday, 19 March 2019

9:00	**Welcome and Introduction**	Kerstin Wilken, *PDA Europe* Roger Asselta, *Genesis Packaging Technologies* Roman Mathaes, *Lonza*
	OPENING PLENARY	
9:15	**Keynote: The Evolution of Parenteral Drug Substance and Drug Product Primary Containers**	Karthik Vaideeswaran, *Eli Lilly*
Session 1:	**Packaging Considerations for Cold Storage** *Moderator:*	**Derek Duncan,** *LIGHTHOUSE*
9:45	**Primary Container Design for Drug Substance at Cryo- and Cold Temperatures**	Ronald Iacocca, *Eli Lilly*
10:15	**Q&A, Discussion**	
10:45	**Coffee Break, Poster Session & Exhibition**	
11:15	**Nonlinear Finite Element Simulation of Frozen Container Closure Systems**	Holger Roehl, *Roche*
11:45	**Case Study: Ensuring Container Closure Integrity of a Gene Therapy Cancer Vaccine in Need of Deep Cold Storage**	Josine Wilmer, *LIGHTHOUSE*
12:15	**Q&A, Discussion**	
12:45	**Lunch Break, Poster Session & Exhibition**	

PARALLEL TRACKS

Session 2:	**TRACK A**	**TRACK B**
	Glass Moderator: Claudia Heinl, *SCHOTT*	**Manufacturing in the Digital Age** Moderator: Bettine Boltres, *WEST*
14:00	**Delamination in Glass Containers for Pharmaceutical Application: The International Commission on Glass (ICG) Technical Committee TC12** Massimo Guglielmi, *University of Padova*	**Identification and Quantification: Multisensor Drone Technology** Fabian Thygs, *Janssen J&J*
14:20	**Innovations in Glass Production** Robert Hayes, *Gerresheimer*	**Comprehensive Container Closure System (CCS) Stack-up Simulation and Optimization in the Digital Age** Anthony Bucci, *WEST*
14:40	**A Case Study for Mitigation of Visual Particulate in Glass Ready-to-Use Vials** Anthony Vico, *Stevanato Group* Elizabeth Jane Pavlik, *MSD*	**Testing and Computational Modelling in the Study of Cartridge Failure** Daniela P. Boso, *University of Padova*
15:00	**New Parenteral Glass Packaging Option May Lead to Reduction in Particulates and Ultimately Drug Shortages** Kyle Hoff, *Corning*	**Quantifying the Vial Capping Process Using Micro-Computed Tomography** Robert Ovadia, *Genentech*
15:20	**Q&A, Discussion**	**Q&A, Discussion**
15:40	**Coffee Break, Poster Session & Exhibition**	

PDA IS PROUD TO INVITE YOU TO A VERY SPECIAL NETWORKING EVENT

Join us for a Fabulous Evening and Dinner on a Venetian Galleon

Date & Time:
19 March 2019, 18:50

Meeting Point:
Hotel Lobby, Hilton Molino Stucky

Boat Depature:
19:00

21:30
Return to the Hilton Hotel Molino Stucky

Dress Code: Casual

Please confirm your attendance at the PDA registration desk.

Session 3:	TRACK A	TRACK B
	Considerations on Container Closure Integrity Moderator: Roger Asselta, *Genesis Packaging Technologies*	**Chemical Interactions of Drug Product and Primary Packaging** Moderator: Galen Shi, *Eli Lilly*
16:10	**Balancing Container Closure Integrity and Aesthetics for Robust Primary Packaging** Yusuf Oni, *Bristol-Myers Squibb*	**The Advantages of Considering Primary Container Systems as an Excipient During Formulation Development** Cathy Zhao, *WEST*
16:40	**Container Closure Integrity Testing – Method Development for Freeze- Dried Products Using Laser-based Headspace Oxygen Analysis** Soren Dahl, *Novo Nordisk*	**Comparative Leachable Study for Glass Vials to Demonstrate the Impact of Low Fill Volume** Volker Rupertus, *SCHOTT*
17:10	**Interlaboratory Study of Container Closure Integrity He-leak Test Method - Comparison of Different Types of Artificial Leaks** Klaus Wuchner, *Janssen J&J* Daniel Wagner, *Sanofi*	**Interactions of Leachables with Proteins: Combined In-Silico and Experimental Model to Monitor the Potential Impact on Quality and Safety of Therapeutic Proteins** Piet Christiaens, *Nelson Labs*
17:40	**Q&A, Discussion**	**Q&A, Discussion**
18:00	**End of Day 1 and Networking Event**	

Draft Agenda subject to change, all speakers pending confirmation

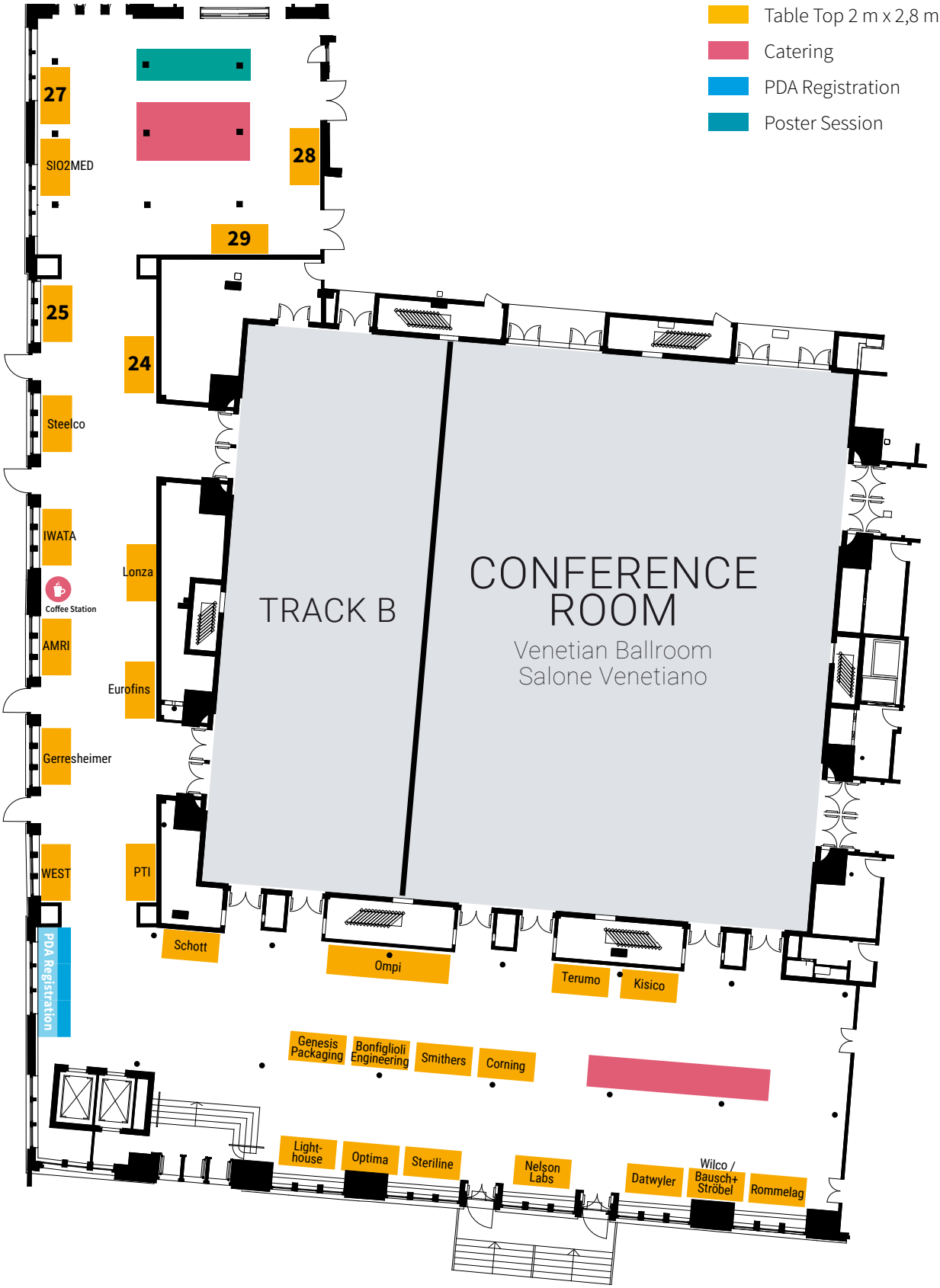
Wednesday, 20 March 2019

9:00	**Keynote: Getting Ready for Annex1 and USP 800**	Roman Mathaes, *Lonza* Hanns-Christian Mahler, *Lonza*
Session 4	**Regulatory Updates**	*Moderator:* **Daniele Zuccato,** *Stevanato Group*
9:30	**Chinese Regulatory Update**	Yonghua Gao, *CNPPA*
10:00	**USP Chapter Changes on Glass and Rubber**	Bettine Boltres, *WEST* Renaud Janssen, *Datwyler*
10:30	**ISO Standard Series ISO 11040 on Pre-filled Syringes, Updates on ISO Technical Committees TC76 and TC84**	Horst Koller, *HK Packaging*
11:00	**Q&A, Discussion**	
11:30	**Coffee Break, Poster Session & Exhibition**	

PARALLEL TRACKS		
Session 5:	**TRACK A**	**TRACK B**
	Challenges in Development & Manufacture Moderator: Renaud Janssen, *Datwyler*	**Sterilization of Packaging** Moderator: Joerg Zuercher, *Bayer*
12:00	**A Quality by Design Approach Toward Manufacturing of Elastomeric Components for Parenteral Packaging Applications** Rahul Thakar, *Datwyler*	**Validation of VH2O2 Sterilization Process per ISO14937** Juha Mattila, *STERIS*
12:25	**Multi-Chamber IV Bag Film Development** William Roberts, *Sealed Air Corporation*	**Alternative Sterilization Techniques for Elastomeric Components for Primary Packaging** Bram Jongen, *Datwyler*
12:50	**Q&A, Discussion**	**Q&A, Discussion**
13:00	**Lunch Break, Poster Session & Exhibition**	

CLOSING PLENARY		
Session 6	**Primary Packaging Choices and Their Technical Impact**	*Moderator: Roman Mathaes, Lonza*
14:00	**Factors Influencing Quality of Biopharmaceuticals in Pre-filled Syringes**	Susumu Uchiyama, *Osaka University*
14:30	**Lyophilization in Pre-filled Syringes: Evaluating the Influence of Primary Container Material and Loading Device**	Timothy Dutill, *Lyophilization Technologies* Kevin Constable, *Terumo*
15:00	**Coffee Break, Poster Session & Exhibition**	
15:30	**Quality of Components & Containers – Design, Materials, New Technologies**	Robert Hormes, *Novartis*
16:00	**Q&A, Discussion**	
16:30	**End of Conference & Farewell**	Roger Asselta, *Genesis Packaging Technologies* Roman Mathaes, *Lonza* Kerstin Wilken, *PDA Europe*

Draft Agenda subject to change, all speakers pending confirmation



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pda.org/EU/UPS2019

2019 PDA EUROPE

The Universe of Pre-filled Syringes and Injection Devices

Advancing Drug Delivery Systems to Improve Patients' Lives

22-23 OCTOBER 2019
GOTHENBURG, SWEDEN
PRE-CONFERENCE WORKSHOPS: 21 OCTOBER
CONFERENCE & EXHIBITION: 22-23 OCTOBER
EDUCATION & TRAINING: 24-25 OCTOBER

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PDA Scientific Poster Presentation

Exhibit your Work

Deadline:
1 February 2019

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Canvas size to work on:
85 cm x 120 cm (33,465 x 47,244 in) – portrait format
Slug / Bleed: 2 mm (0,079 in)

Images:
120dpi (low) - 150dpi (high) depending on size.All Images Color Profile ISO Coated v2 (ECI)

Document size of the PDF:
85 cm x 206 cm (33,465 x 81,102 in) – portrait format
Slug / Bleed: 2 mm (0,079 in)

All posters will be printed by PDA and displayed as part of the exhibition.

Poster Display is included in the regular conference registration fee. Please send your file and poster title to Nadjeschda Gomez-Stahl **gomez@pda.org.**

Packaging Science

Focus Topic: CCI at Deep Cold Temperatures

Dear Colleagues,

Based on feedback from industry and the many open questions, our focus topic for 2019 will be **CCI at Deep Cold Temperatures**.

Please be invited to contribute to this open forum and discuss latest approaches, exchange experience, and share technology updates on primary packaging challenges related to:

- Cell and Gene Therapy Market
- CAR-T Therapy
- Regulatory challenges for CCI at cold temperatures
- Challenges for different materials at cold temperatures
- Measurement techniques

We will have experts to the mentioned topics and would like to highlight this topic from many different angles.

Take advantage of the open forum design offered by the small Interest Group meeting approach. Hear presentations from renowned international experts, interact and discuss your experiences with colleagues in round table discussions and forums during the meeting.

Roger Asselta, *Genesis Packaging Technologies*
Roger Asselta is Vice President of Technical Affairs at Genesis Packaging Technologies. He has over 25 years of experience in pharmaceutical packaging, working for firms producing glass containers, plastic containers and closures, elastomeric closures and seals, and sealing technology equipment. This year, he is co-chair of the PDA Parenteral Packaging conference.

Bettine Boltres, *PhD, WEST*
Bettine Boltres has 8 years' experience in the primary packaging industry. As Technical Account Manager, Europe, for WEST Pharmaceutical Systems she is supporting pharmaceutical companies in assessing the scientific challenges of elastomers as primary packaging components, complementing her 7 years' work as Product Manager for Schott Pharmaceutical Tubing, where she provided scientific consulting for glass primary packaging. This year, she is member of the Program Planning Committee of the PDA Parenteral Packaging conference.

Derek Duncan, *PhD, LIGHTHOUSE*
Derek Duncan, PhD, began his career as a Research Scientist at the Dutch Institute for Atomic & Molecular Physics in Amsterdam. He then moved into industry holding various Product & Application Development positions. is responsible for developing applications for pharmaceutical process monitoring and finished product inspection for Lighthouse Instruments. He is based in Amsterdam. This year, he is member of the Program Planning Committee of the PDA Parenteral Packaging conference.

18. Jan 2019

Thursday, 21 March 2019

10:00	**Welcome and Introduction**	Bettine Boltres, *WEST* Derek Duncan, *LIGHTHOUSE* Roger Asselta, *Genesis Packaging Technologies*
Keynote	**Chemical and Physical Properties of Different Packaging Materials**	Bettine Boltres, *WEST* Otto Schubert, *Rommelag*

Cell & Gene Therapeutics

Moderator: **Derek Duncan,** *LIGHTHOUSE*

One of the areas in which there is a push for new packaging options is in the area of cell and gene therapies. These products require deep cold storage ranging from -80 ˚C to cryogenic temperatures. Initial studies have shown that these low temperatures pose challenges to the traditional package for injectables—the rubber-stoppered glass vial. This can introduce some risk to container closure integrity. Current solutions and the future outlook will be discussed in this session.

	Polymer Container System for Storage of Cell Therapy Products at Cryogenic Temperature	Nicolas Brandes, *WEST*
	Introduction on Cell & Gene Therapeutics - Challenges in Packaging • **What requirements need to be met when packaging and storing cell and gene therapeutics?** • **What solutions are currently available and how do different container react in deep cold temperatures?** • **Which challenges still need to be overcome?**	
11:30	**Coffee Break, Poster Session & Exhibition**	

Materials and their Requirements for Deep Cold Storage

Moderator: **Bettine Boltres,** *WEST*

In order to understand why and how different materials behave differently under different temperature conditions, the session will start with an in-depth dive into the relevant physical and chemical properties of glass, rubber and plastics. Further on, we will get inside information from industry into the challenges that they are facing. We will discuss different approaches and especially identify those areas that still need to be addressed.

12:00	**Vial Solutions:** **Challenges for Glass and Stoppers in Deep Cold Temperatures**	Chris Folta, *Janssen J&J*
	Container Closure Systems at Deep Cold Storage	Holger Roehl, *Roche*
	Discussion: Current Materials Used in Deep Cold Temperatures, the Challenges and a Future Outlook	
13:30	**Lunch Break, Poster Session & Exhibition**	

Roundtable Discussions – Current Packaging Options and Challenges

Moderator: **Roger Asselta,** *Genesis Packaging Technologies*

14:30	**Cell & Gene Therapies**	**Requirements for Different Materials**
	Requirements for Different Materials	**Cell & Gene Therapies**
15:00	**Coffee Break, Poster Session & Exhibition**	
	Discussion on Hot Topics from the Conference	
17:00	**Conclusion and Farewell**	

Container Closure Development

Overview

The course will give an overview on how to develop a container closure system for parenteral products. Starting with setting up a product profile of the final product container, all aspects will be covered, like selection of materials, assessment of container closure systems, specification and documentation of components and entire systems. In addition, current hot topics such as glass delamination and container closure integrity testing will be discussed.

For all topics of the agenda presentations will be given. The participants are invited to add own experience, ask questions and offer issues to be discussed within the group and/or with the trainer. The intention is to work in an open workshop-like atmosphere.

Who Should Attend

- Scientists in Drug Product Development
- Scientists/ Engineers in Packaging Development
- Regulatory Affairs Experts

Learning Objectives

- Set-up of a target product profile of a container closure system
- Select appropriate container closure materials, components, and systems
- Apply the appropriate regulations and standards to container closure systems for parenteral formulations
- Prepare a development plan of a container closure systems from the early development until market phase
- Specify container closure systems regarding technical aspects and regulatory requirements
- Understand compendial requirements and quality as well as technical standards regarding
- container closure components and systems

Jörg Zürcher, *Senior Scientist, Bayer*
Jörg Zürcher is a pharmacist by education. After his studies and PhD thesis at the Free University in Berlin, he started his career in the pharmaceutical industry 1990 with the former Schering AG. He is responsible for the development of container closure systems and application devices at Bayer HealthCare and has more than 25 years' experience in that field. His current focus is the development of systems/devices for liquid and parenteral as well as ophthalmic dosage forms.

Thursday, 21 March 2019	9:00 – 17:00
09:00	**Welcome and Introduction**
09:30	**Definitions** • Compendial definition • Functional definition • Components vs CCS • Description of options • Materials
09:45	• **Regulatory Background** • Ph.Eur. • USP • JP • FDA Guideline • EU Directive • Relevant eCTD sections
10:45	**Coffee Break**
11:15	• **Development of Container Closure Systems** • Set-up of target profile • Packaging materials • Modification of materials • Extractables & Leachables (E&L) testing • Permeability • Light transmission • Processability • Functional testing • Container closure integrity (CCI) • Shipping assessment • Combination products
12:30	**Lunch Break**
13:30	**Workshop: Develop Your CCS**
15:00	**Coffee Break**
15:30	**Presentation of Workshop Results**
16:00	• **Setting of Specifications / Submission Documentation** • Technical/ Quality specification • Regulatory specification • Technical drawing • Regulatory drawing • DMF for US submission
16:30	**Wrap-up and Final Q&A**
17:00	**End of Course**

Test-Methods for Pre-filled Syringe Systems

Overview

The course will be an interactive lecture around Pre-filled Syringe Systems including ISO compliance testing. The participants will benefit from first hand information of both lecture leaders based on practical experience. The lecture includes the life cycle of a PFS from the idea to finished marketed product.

Who Should Attend

- The course is designed specifically for those who are involved or interested in the development, manufacturing and QC-testing of a Pre-filled Syringe System
- Engineers and Managers in Device Development and all other technical functions surrounding syringe systems
- Quality Personal / Regulatory Personal
- Clinical and commercial Drug Product Manufacturing

Learning Objectives

- Materials used for PFS Systems
- Luer Cone and Luer Lock Compliance Testing
- Requirements for the empty sterile sub-assembled syringe ready for filling
- Test Methods for Drug Product Filled Syringes
- PFS used in Delivery Systems

Faculty

Horst Koller, *CEO, HK Packaging Consulting*
Prior to becoming a consultant, Horst worked for Abbott Diagnostic and SCHOTT Pharmaceutical Packaging with a total of more than 20 years industry experience. His consulting company is focusing on Technical, Regulatory and QM-Support around Primary and Secondary Packaging Systems including Medical Devices. He is an active member within the technical ISO Committees TC76 and TC84 as well as an active speaker on international conferences. He holds an Engineering degree in Biotechnology from the University of Applied Sciences in Mannheim / Germany.

Thursday, 21 March 2019 9:00 – 17:45

9:00	**Welcome**
9:15	**Introduction to Syringe Systems and Components**
10.30	**Coffee Break**
11:00	**Regulatory Requirements of Finished Pre-filled Syringes – Part 1** • System Characterization / Physical Characterization
12:30	**Lunch Break**
13:30	**Regulatory Requirements of Finished Pre-filled Syringes – Part 2** • Pharmaceutical Characterization
15:30	**Coffee Break**
16:00	**Luer cone and Luer lock Compliance Testing for Glass and Polymer Syringes**
17:30	**Wrap-up of Day 1**
17:45	**End of Day 1**

Friday, 22 March 2019 9:00 – 15:30

9:00	**Requirements for the Empty Sterile Sub-assembled Syringes Ready for Filling- Part 1** • Cone Breakage / Flange Breakage / Leakage
10:15	**Coffee Break**
10:45	**Requirements for the Empty Sterile Sub-assembled Syringes Ready for Filling- Part 1 (cont.)** • Cone Breakage / Flange Breakage / Closure Testing
11:45	**Requirements for the Empty Sterile Sub-assembled Syringes Ready for Filling- Part 2** • Break Loose and Gliding Force / Needle Testing / Particulate Matter
13:15	**Lunch Break**
14:15	**Additional Testing for Use in Delivery Devices**
15:15	**Wrap-up of Day 2**
15:30	**End of Training Course**

Container Closure Integrity Testing

Overview

This workshop focuses on theoretical and practical fundamentals of various CCI testing technologies and provides a systematic approach to apply these testing methods for CCI verification throughout drug product lifecycle. The Workshop will enable the participants to implement CCI testing strategies to ensure adequate drug product protection and be compliant with relevant regulatory and compendia requirements. In this Workshop, participants gain critical problem solving skills through:

- interactive discussions with a panel of cross-functional technical experts consisting of CCI testing laboratory experts, testing instrument suppliers/manufacturers, and pharmaceutical packaging development engineers
- hands-on testing training on the newest innovations and state-of-the-art instruments
- real-world case studies

Who Should Attend

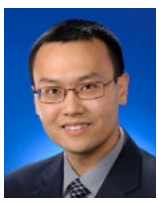
- Parenteral drug packaging engineers and formulation scientists
- Laboratory scientific staff and managers
- Parenteral manufacturing staff
- Sterility Quality Assurance
- Regulatory affair scientists
- Pharmaceutical packaging component manufacturing staff

Presentation of Technology, Instruments Demo and Hands-on Training kindly supported by several suppliers of Container Closure Integrity testing systems and services (detailed supplier update coming soon).

Learning Objectives

This workshop utilizes lectures, case studies, and interactive hands-on training on testing instruments to provide insight into the latest developments of Container Closure Integrity (CCI) Testing, with focus on achieving the following key objectives:

- Understanding up-to-date regulatory and pharmacopeia requirements on CCI.
- Defining CCI requirements for various container and drug product types using a risk-based approach.
- Explaining working principles of various CCI testing techniques and their practical applications, with focus on deterministic methods such as tracer gas detection (e.g. helium leak detection), electrical conductivity and capacitance (HVLD), vacuum decay leak detection, laser-based gas headspace analysis, mass extraction leak test.
- Selecting and applying appropriate testing methods for both laboratory and in-process testing to formulate comprehensive package integrity verification profiles.
- Defining CCI testing method development and validation approach and best practices.
- Avoiding common issues and pitfalls in CCI testing applications.



Lei Li, *Ph.D, Associate Engineer Advisor Delivery and Device R&D, Eli Lilly*

Lei Li currently serves as an engineer advisor at Delivery and Device R&D, Eli Lilly and Company. Lei has 9 years of experience in pharmaceutical and medical device industry, with focus on developing API and drug product packaging in support of clinical development and product commercialization, and establishing cold-chain distribution for biologic products. His current responsibilities include developing package integrity verification profiles for Lilly's diverse pipeline portfolio, developing and validating CCI testing methods, and supporting commercial control strategy development for CCI verification throughout drug product and device life cycle. He is a frequent speaker at PDA conferences and author of peer-reviewed articles and book chapters on CCI test methods. Lei Li received his Ph. D. in Analytical Chemistry from West Virginia University; prior to joining Eli Lilly, he worked at GE Plastics as an analytical and material scientist.

Thursday, 21 March 2019 9:00 – 17:30

9:00 **Welcome and Introduction**

9:15 **Regulatory Requirements:**
CCI Introduction, Regulatory Requirements, and Industry Trends

9:45 **CCI Assurance throughout Product Lifecycle**
- Testing requirement definition – risk based approach
- CCI Profile & Testing strategy development

10:30 **Coffee Break**

11:00 **Introduction to Group Exercise #1:**
Product life cycle testing and method selection

11:15 **CCI Test Methods: Fundamentals and Overview**
- CCI defects and commonly used positive controls
- "Sizing" CCI defects using gas flow dynamics
- Evolution of CCI testing technology: liquid flow, gas flow, electron flow (electric current)

12:00 **Lunch Break**

13:00 **CCI Test Methods: Fundamentals and Overview** (continued)
- Deterministic vs probabilistic definitions
- Physicochemical methods vs microbiological methods: differences and correlations
- Microbial and Dye Ingress Testing Basics
- Seal Quality Testing
- Introduction **group exercise #2: Method Characteristics**

14:00 **Advanced CCI Testing Technologies**
- Vacuum and pressure decay
- Mass Extraction
- Headspace analysis
- HVLD

15:00 **Coffee Break**

15:30 **CCI Testing Technologies** (continued)
- Tracer gas (helium leak detection)
- Seal Integrity method example (residual seal force)

16:00 **Current Topics: Industry Best-Practices and Novel Technologies**
1. AMI Optical emission spectroscopy for CCI testing
2. API Container Testing using HeLD; Review Helium leak detection video

17:00 **Group Exercise #2: Method Characteristics**
- review, discussion

Day 1 Review, Q&A

17:30 **End of Day 1**

Friday, 22 March 2019 8:30 – 16:30

8:30 **Application Case Studies – Section 1**
- Vacuum and pressure decay
- Mass Extraction

9:10 **Hands-on Training**

9:50 **Application Case Studies – Section 2**
- Headspace analysis
- HVLD

10:30 **Coffee Break**

11:00 **Application Case Studies – Section 3**
- Tracer gas (helium leak detection)
- SQT (Residual Seal Force)

11:40 **Instrument Demo and Hands-on Training**

12:40 **Lunch Break**

13:40 **Development and Validation of Integrity Test Methods**
- Method development best practices
- Method validation strategy
- Pitfalls and solutions

14:30 **Approaches to CCI Testing Method Selection**
- Method selection considerations
- Class discussion - examples

15:00 **Coffee Break**

15:30 **Group Exercise #1: Method Selection Review, Discussion, Q&A**

16:00 **Class Discussion, Recognition, Certification**

16:30 **End of Workshop**

Allison L. Dill, *PhD, Eli Lilly and Company*

Allison Dill, Ph.D. is a Senior Research Scientist in Delivery and Device Connected Solutions at Eli Lilly and Company, Indianapolis, IN. She received a BS in Chemistry and Biology from Indiana University, and worked for 4 years as an analytical chemist in Product Research and Development before attending graduate school. She received her Ph.D. in Analytical Chemistry from Purdue University, studying imaging mass spectrometry for disease state characterization. While at Lilly, she has been responsible for the analytical control strategy of many solid oral and parenteral dosage forms and has contributed to several regulatory submissions. Her recent contributions have focused on enabling the delivery of the early phase portfolio within a complex global network with responsibility for the analytical control strategy of both the active pharmaceutical ingredient and the drug product. She is now focusing on the CCI strategy for multiple molecules with a concentration in on-line high voltage leak detection for 100% inspection.

Extractables & Leachables

Including: Important Regulatory Updates – Case Study Section: Selection of the most interesting Case Studies, presented over the last 10 years!

Overview

When making Parenteral Drug Products, pharmaceutical companies are faced with the need to further investigate the materials that will be in contact with the drug product, either during manufacturing, intermediate storage, storage in its final packaging, or during the delivery of the drug to the patient. While historically, the potential safety issues were the main driver in these kinds of investigations, recently, also quality issues – i.e. for biopharmaceuticals – have become an additional concern.

This workshop will look at "Extractables & Leachables" from many different angles: Definitions, Regulatory, Material & Polymer Science, Analytical E/L Methodologies, Safety Assessments, Study Design for different parenteral primary packaging systems, as well as for injection devices.

Learning Objectives

Upon completion of this workshop, you will be able to:

- Explain in detail the current regulatory requirements for container/closure qualification from an E/L perspective.
- Explain the upcoming changes in regulations, standards and recommendations from PQRI, USP and BPOG and how these changes could impact a future evaluation of a pharmaceutical C/C-system.
- Understand the materials of construction – and their composition – of container closure systems, and how they could impact the safety and quality of a parenteral drug product.
- Put together an evaluation program (review of provided documentation, analytical testing) of different types of parenteral drug product container/closure systems.
- Perform a safety/risk assessment of analytical results, obtained after completion of an E/L study.

Who Should Attend

- Pharmaceutical Packaging and Device Engineers
- Production Engineers, using SU systems
- Regulatory Affairs Officers
- Pharmaceutical R & D Managers
- Analytical Chemists, working on E/L
- Quality Assurance Officers

Dennis Jenke, *PhD, Chief Executive Scientist, Triad Scientific Solutions*

Dennis Jenke is the Chief Executive Scientist for Triad Scientific Solutions, a provider of science-based solutions to plastic/product compatibility challenges associated with packaging, manufacturing equipment and delivery devices in the pharmaceutical, cosmetic, food and related industries. He was a Distinguished Scientist at Baxter Healthcare Corporation where for more than three decades he lead a team whose primary responsibility includes the assessment of material/product compatibility, specifically with respect to establishing the suitability for use of packaging systems, manufacturing systems and administration devices for pharmaceutical products (for example, extractables/leachables and product ingredient binding). He has published extensively in the areas of analytical chemistry, environmental science and material/solution compatibility and serves as an expert reviewer for numerous pharmaceutical and analytical journals. He is the author of the book Compatibility of Pharmaceutical Solutions and Contact Materials; Safety Considerations Associated with Extractables and Leachables and a contributing author to the Leachables and Extractables Handbook. Dennis Jenke is a member of numerous industry groups whose charter is to establish best demonstrated practices in the area of material/solution compatibility.

Thursday, 21 March 2019 9:00 – 18:00

Introduction on Extractables & Leachables (E/L)

- What is the importance of a good E/L-qualification
- Historical cases of leachables, impacting the quality or the safety of a drug product
- Regulatory requirements (FDA, EMA…) for primary packaging

Understanding the Materials, Used in the Manufacture of Pharmaceutical Containers & Closures

- Types of polymers – examples in medical/pharmaceutical use
- Understanding the composition of polymers
- The issues with glass in parenteral applications

FULL Session on Updates of E/L- Regulations, Standards and Recommendations

- Pharma Packaging:
- Preview of the final PQRI Parenteral Drug Product (DPD) & ODP Chemistry group
- Update on the most recent developments on the USP <661> chapters
- Devices
- Chemical characterization of devices according to ISO 10993-18: What changes are coming up?
- Upcoming Revisions of the USP <87> and USP <88>: Where could it go to?
- (Bio)Pharmaceutical Manufacturing
- Where is USP with the update on the USP <661.3> Plastic Manufacturing Components standard

How to Perform a Safety Evaluation – Risk Assessment on Extractables & Leachables

- Toxicology 101
- EMA Guideline on Genotoxic Impurities
- ICH M7 (DNA reactive Impurities) and its suggested staged approach
- The Threshold Concept of PQRI (OINDP and PDP/ODP)
- Examples

How to Look at Injection Devices from an E/L Perspective

- Medical device regulations versus pharma packaging
- Test selection process for devices: What to do?
- USP and ISO 10993 series for biocompatibility testing
- Case: Injection device

Piet Christiaens, *PhD, Scientific Director, Nelson Labs*

Piet Christiaens received his Ph.D. from the Analytical Chemistry Department of the University of Leuven (Belgium) in 1991. From 1992 to 1997, he was Lab Manager in two Analytical Contract Laboratories. From 1997 to 2000, he worked as an independent consultant with Shell Chemical Company in Houston, Texas where he conducted research on a new hydrogenation catalyst system for Hydrogenated Triblock Co-Polymers (Kraton Polymers). Since 2001, Mr. Christiaens has been Scientific Director at Nelson Labs Europe (formerly Toxikon Europe) where he develops analytical methods and protocols for both extractables and leachables studies for the Medical and Pharmaceutical Industries. Mr. Christiaens oversees all laboratory operations at Nelson Labs Europe and supports the European business development team.

Friday, 22 March 2019 9:00 – 16:30

E/L Testing for Small Volume Parenteral Applications

- Glass Syringes: the issues with tungsten, glue residues and silicone oil and glass metals leaching
- The Issue with rubbers: the plunger, the needle shield or the tip cap: different approaches needed?
- The impact of secondary packaging – option or necessity?
- Setting up extractable & leachable studies for a pre-filled Syringe or a vial system

E/L Testing for Lyophilized Drug Products

- Primary packaging for the lyophilized drug product – modus of interaction with the DP
- Impact of the "21CFR Part 4" on combination products, used in the administration of a lyo DP
- Critical aspects when designing leachable studies for lyophilized DP
- Integration of the administration procedure (e.g. IV-set, pump system) in leachables evaluation

Large Volume Parenterals

- The challenge in E/L testing for LVP's
- Primary packaging for LVP's – critical materials and components
- Secondary packaging for LVP: critical points to consider

E/L Testing for Disposable and Single-Use Systems in Bioproduction

- How to classify the risk of different single-use systems in the bioproduction process
- Understanding BPSA & BPOG recommendations, and how they can be implemented in the study design
- Performing E/L studies on filters: potential approaches

Analytical Techniques and Methodologies in E/L Research

- Discussion of the Analytical Instrumentation used
- The Analytical Chromatographic Screening Process to Discover, Identify and Quantify Organic Extractables
- The Risk of Omissions with the Screening Process
- The Risk of Inexact Identifications in the Screening Process
- The Risk of Inaccurate Quantification when Sscreening
- A Risk Mitigation Strategy when Implementing a Screening Methodology

How to Set-up Extractables & Leachables Studies

- Selecting the right conditions for extraction
- How to select the right compounds to monitor in a leachable study
- Designing a leachable study

John Iannone, *Principal Consultant, iCG Solutions*

John Iannone has a background in Biomedical Engineering from Boston University. Since joining the Biotech/Medtech Industry 15 years ago, John has assisted multiple pharmaceutical & medical device companies with the development of their product safety evaluation strategies. Currently he is a Principal Consultant for iCG, LLC. His areas of expertise include Material Qualification & Biocompatibility, Extractables & Leachables, Chemical Characterization, and attainment of Biological or Toxicological risk assessments for medical devices, pharmaceutical container systems, bioprocessing systems, and combination products. John has given numerous technical presentations and has led many workshops on Extractable & Leachable Considerations, Biocompatibility, Microbiology, and Regulatory Testing Requirements. He also participates in the development of both industry groups' recommendations and regulatory guidelines through Expert Panel membership, global Technical Committees, and industry collaborations.

VENUE

Hilton Molino Stucky Venice
Giudecca, 810
30133 Venice, Italy
Tel: +39 041 272 3311
https://goo.gl/r1dN9L

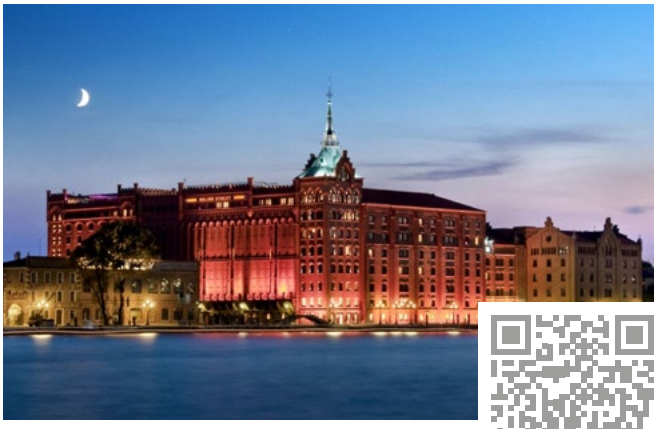
Special Rates

PDA Europe has reserved a limited number of bedrooms. Book your group rate for PDA.

Single Room € 209 per night*
Double Room € 239 per night*

*Rates are per room and night, including the following services and benefits free of charge: Buffet Breakfast in the restaurant, Wireless Internet Connection (WI-FI), VAT, Taxes and Service Charge will apply.
Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

DIRECTIONS



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CONFERENCE REGISTRATION HOURS

Monday, 18 March: 9:00 – 12:00
Tuesday, 19 March: 8:00 – 17:30
Wednesday, 20 March: 8:00 – 17:30

COURSE REGISTRATION HOURS

Monday, 18 March: 9:00 – 12:00
Thursday, 21 March: 8:00 – 16:30
Friday, 22 March: 8:00 – 12:00

TO EXHIBIT:

Exhibition and Sponsorship Opportunities are available. PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees.

SPECIAL REQUIREMENTS

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration-europe@pda.org.

19-20 March 2019 | Venice | Italy

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

Your registration is only complete upon filling in and submitting both pages of this form.

1 Registration

EARLY BIRD DISCOUNT ☐ Book by 3 Feb 2019 to receive € 200 off the conference fee only

All fees given in Euro, excluding VAT (22 %)

19-20 March	Conference only		Conference Fee	
Parenteral Packaging			PDA Member	☐ 1695
			Nonmember	☐ 1995
		Early Bird 750 €	Regulatory/Academic	☐ 850

☐ **Poster Presenter please mark here** (written approval required, conference fee applies)

18 March	Interest Group Meeting	Meeting Fee	
Pre-filled Syringes		All Participants	☐ 350
21 March	Interest Group Meeting	Meeting Fee	
Packaging Science		All Participants	☐ 350
21 March	One-Day Training Course	Training Course Fee	
Container Closure Development		All Participants	☐ 895
21-22 March	Two-Day Workshop	Training Course Fee	
Test-Methods for Pre-filled Syringe Systems		All Participants	☐ 1595
21-22 March	Two-Day Training Course	Training Course Fee	
Extractables & Leachables		All Participants	☐ 1595
21-22 March	Two-Day Workshop	Workshop Fee	
Container Closure Integrity Testing		All Participants	☐ 1595

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☐ My contact information (name, company, job title, city, state, country) being printed on the attendee list distributed at the event.

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The fee includes event documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

Registration fee includes a one-year PDA membership if no further special discount is granted. If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies). ☐

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Parenteral Packaging

19-20 March 2019 | Venice | Italy

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3 WAYS TO REGISTER

1. **online: pda.org/EU/ParPack2019**
2. **FAX: +49 30 4365508-66**
3. **Email: registration-europe@pda.org**

2 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

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3 Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

4 Payment Options

☐ **By Bank Transfer**

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D-13465 Berlin, Germany

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Purchase Order Number

Billing Address: ☐ Same as contact information address above.
If not, please send your billing address to: petzholdt@pda.org

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Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **29 January 2019** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **registration-europe@pda.org or fax to +49 30 4365508-66.**

PDA EUROPE EVENTS

2019

18 March **19-20 March** 21 March	Interest Group Meeting Pre-filled Syringes **Parenteral Packaging** Interest Group Meeting Packaging Science	*	**Venice, Italy**
16-17 May	**Pharmacopoeia**	*	**Geneva, Switzerland**
22-24 May 24 May	**Visual Inspection Week** Interest Group Meeting Visual Inspection	*	**Berlin, Germany**
4-5 June	**Advanced Therapy Medicinal Products**	*	**Vilnius, Lithuania**
24 June **25-26 June**	Interest Group Meeting Quality Systems **4th PDA Europe Annual Meeting**		**Amsterdam, The Netherlands**
3-4 September	**BioManufacturing**	*	**Munich, Germany**
5 September	**Project Management in the Pharmaceutical Industry**	*	**Munich, Germany**
24-25 September	**Pharmaceutical Freeze Drying Technology**	*	**Berlin, Germany**
24-25 September	**Particles in Injectables**	*	**Berlin, Germany**
22-23 October	**The Universe of Pre-filled Syringes and Injection Devices**	*	**Gothenburg, Sweden**
12-13 November	**Outsourcing & Supply Chain**	*	**Lisbon, Portugal**

Subject to change | For latest info: **europe.pda.org** | Shortlist 18 Jan 2019

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