PDA
Parenteral Drug Association

The Parenteral Drug Association presents:

Interest Group Meeting Pre-filled Syringes 11 April

2016 PDA Europe Conference

Parenteral Packaging

Keep up with the ever advancing pharmaceutical packaging market!

11 April	14 April	14-15 April	14-15 April	14-15 April	14-15 April
Molded Glass: From Manufacturing Process to Applications	Container Closure Development	Container Closure Integrity: Regulations, Test Methods, Application	Extractables and Leachables	Good Glass Handling Practices in Parenteral Packaging	Drug Delivery Combination Products

europe.pda.org/ParPack2016

Register by 12 March 2016 and SAVE!

Conference, Exhibition

12-13 April 2016

Hilton Molino Stucky

Venice | Italy

Media Partners

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SCHEDULE AT A GLANCE

11 April	10:00 – 17:00	Interest Group Meeting Pre-filled Syringes	IG Meeting
11 April	14:00 – 18:00	Molded Glass: From Manufacturing Process to Applications	Workshop
11 April	19:30 – 22:30	Welcome Party - Skybar Hilton Molino Stucky	
12 April 12 April 13 April	09:00 – 18:15 18:15 – 21:15 07:00 – 15:45	Conference Networking Event / Hilton Molino Stucky Conference	Conference, Exhibition
14 April	09:00 – 17:00	Container Closure Development	Training Course
14 April 15 April	09:00 – 18:00 09:00 – 16:30	Container Closure Integrity: Regulations, Test Methods, Application	Workshop
14 April 15 April	09:00 – 18:00 09:00 – 16:30	Extractables and Leachables	Training Course
14 April 15 April	09:00 – 18:00 09:00 – 16:30	Good Glass Handling Practices in Parenteral Packaging	Workshop
14 April 15 April	09:00 – 17:30 09:00 – 17:30	Drug Delivery Combination Products	Workshop

For latest information, please visit: **europe.pda.org/ParPack2016**

PDA Europe supports the children's hospice „Sonnenhof"

The Sonnenhof Hospice, located near PDA's office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases.

At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering.

Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy: buy a package of chewing gums at the registration desk.

THANK YOU!

To know more about the Sonnenhof Hospice, please visit
www.bjoern-schulz-stiftung.de

SONNENHOF

Dear Colleagues,

Stay up to date regarding the latest trends in **Parenteral Packaging** by joining **PDA Europe's Conference in Venice, Italy, 12-13 April 2016!**

As proper packaging of pharmaceuticals is crucial to drug stability, this conference and the accompanying exhibition address quality of components and containers as much as aspects of processing, product distribution and storage. Excellent speakers from the industry, regulatory and academia will give detailed information about opportunities and challenges the advancing pharmaceutical packaging market faces.

The conference aims to keep its attendees updated about all regulatory aspects involved in the parenteral packaging process, such as new regulations from European and US agencies, the revision of Annex 1, and PDA Technical Reports.

We are especially proud to be featuring a whole session dedicated to the unique and surprisingly versatile packaging material glass, with the leading manufacturers sharing their latest developments.

Different materials such as polymers & elastomers and their characteristics regarding supplier issues and end-user preferences will also be discussed as well as the design of primary and secondary packaging. The role of Container Closure Integrity (CCI) in product-package development, post-approval product changes and routine manufacturing will be explored, and information on aseptic processing will be given.

Of equal importance to the content is to interact with the speakers and your fellow attendees. Hotel Molino Stucky Venice will offer a comfortable atmosphere for refreshment breaks, on-site lunches and evening receptions with plenty of opportunities for discussion and networking.

Join PDA Europe's Parenteral Packaging Conference in one of the most beautiful cities in the world!

Welcome to Venice!

Jörg Zürcher, *Bayer, Conference Chair*

Scientific Program Planning Committee

Jörg Zürcher, *Bayer, Conference Chair*
Roger Asselta, *Genesis Packaging*
Bettine Boltres, *SCHOTT*
Paolo Golfetto, *OMPI*
Renaud Janssen, *Datwyler*
Stefan Merkle, *Janssen*
Anna Malori, *Bormioli Rocco*
Galen Shi, *Eli Lilly*
Michael Spallek, *rommelag*
Georg Roessling, *PDA Europe*

Interest Group Meeting Pre-filled Syringes

31 Mar 2016

Monday, 11 April 2016		**10:00 – 17:00**
10:00	**Welcome and Introduction**	Georg Roessling, *PDA Europe* Brigitte Reutter-Härle, *Vetter, IG Leader Pre-filled Syringes*
10:10	**News from the Interest Group** **Highlights & Trends from Vienna, Austria** **"The 2015 Universe of Pre-filled Syringes and Injection Devices"** **Outlook: 2016 Universe of Pre-filled Syringes in Huntington Beach, CA, USA**	Brigitte Reutter-Härle, *Vetter*
10:30	**Highlights & Trends Pre-conference Workshop, Vienna, Austria** **"Innovative Combination Products"**	William Dierick, *TERUMO*
11:00	**Discussion and Q&A**	
11:30	**Lunch Break**	

Focus Topic: Assembly of Pre-filled Syringes into Devices

12:30	**Device Assembly using Pre-filled Syringes**	Markus Rothen, *INSYS Industrial Systems*
12:55	**Best Practice in Glass Handling During Device Development and Commercialization**	Thomas Schoenknecht, *SHL*
13:20	**Assembly of Pre-filled Syringes into Devices**	Bruno Reuter, *SHL*
	Pre-filled Syringe Silicone Treatment and Auto-Injector Performance: From Laboratory to Industrial Production	Alessandro Morandotti, *OMPI*
13:50	**Silicone-oil-free COP Pre-filled Syringes integrated in 2-step Auto-Injectors: Solving Challenges of Modern Biotech Drugs and Patients' Needs**	William Dierick, *TERUMO,* Orfeo Niedermann, *YPSOMED*
14:15	**Discussion and Q&A**	
14:45	**Coffee Break**	
15:10	**SiOPlas Parenteral Containers:** **A new packaging material for sensitive biological drugs**	Holger Krenz, *SiO_2 Medical*
15:40	**Turbid Biological Drug Product Solution - Getting The Mystery Solved**	Marina Becker, *Roche*
16:05	**IV Compatible Pre-filled Syringe Solutions for Fast Track Registration**	Dragana Cvijanovic, *Becton Dickinson*
16:30	**Discussion and Q&A**	
17:00	**Conclusion of Interest Group Meeting**	

JOIN OUR WELCOME PARTY AT SKYLINE ROOFTOP BAR

Date & Time:
11 April 2016, 19:30–22:30

Location:
Hilton Molino Stucky

Dress Code: Casual

Admission rules: If you are not registered yet, get your ticket now.
A limited number of tickets is still available on a first-come, first-served basis.

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HEALTH INSIDE

HEALTH is the inestimable value to which Pharmaceutical Industry is committed. BORMIOLI ROCCO contributes to this mission with its PHARMA BU, an entity entirely and exclusively dedicated to the production of pharmaceutical packaging, driven by the same demanding requirements that guide this industry: quality, precision, safety, innovation.

Our products are developed to guarantee absolute integrity of the contained drugs, to allow them to express their full healing potential and ensure patients a secure treatment. Our packaging solutions are innovatively designed to satisfy patients' functional needs and improve the quality of their life.

We are conscious and proud to carry HEALTH INSIDE.

Workshop
Moulded Glass: From Manufacturing Process to Applications
11 April from 2:00 PM to 6:00 PM
Hilton Molino Stucky hotel

Cocktail Party
11 April from 7:30 PM to 10:30 PM
Skyline Rooftop Bar of the
Hilton Molino Stucky hotel

Conference
12 - 13 April Bormioli Rocco,
booth 21 - Hilton Molino Stucky hotel

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Bormioli Rocco
PHARMA

Molded Glass:
From Manufacturing Process to Applications

31 Mar 2016

Monday, 11 April 2016		**14:00 – 18:00**
14:00	**Introduction and Welcome**	Georg Roessling, *PDA Europe* Maurizio Silvestri, *Bormioli Rocco*
14:05	**The Global Pharmaceutical Market: Innovation, Specialty and Technology Shifts to 2020**	Sarah Rickwood, *IMS Health*
14:35	**Inhalation as Alternative Delivery Option to Increase Patient Adherence**	Francesca Buttini, *University of Parma , King's College London, and RCPE*
15:05	**The Manufacturing Process of Glass Containers: An Industry Perspective**	Corrado Ferrozzi, *Bormioli Rocco*
15:35	**Discussion and Q&A**	
16:00	**Coffee Break**	
16:20	**Regulatory Perspective on Glass Containers (Based on PDA Technical Report 43)**	Georg Roessling, *PDA Europe*
16:50	**Chemical and Physical Characterization Properties of Molded Glass Containers**	Nicola Favaro, *Stazione Sperimentale Vetro*
17:30	**Round Table Discussion**	All Workshop Speakers
18:00	**End of Workshop**	

31 Mar 2016

Tuesday, 12 April 2016

9:00	**Welcome and Introduction**	Georg Roessling, *PDA Europe* Jörg Zürcher, *Bayer, Conference Chair*
Keynote Presentations		*Moderator:* **Jörg Zürcher,** *Bayer*
9:10	**Parenterals and other Delivery Options for Biopharmaceuticals**	Marc Rohrschneider, *Boehringer-Ingelheim*
9:40	**Parenteral Delivery Enabling Packaging Solutions: An Industry Overview**	Galen Shi & Ross Allen, *Eli Lilly*
10:10	**Considerations for Pre-fillable Syringes for Parenteral & Intravitreal Use related to Particulates: The Formulation and Human Interface**	Hanns-Christian Mahler, *Lonza*
10:40	**Q&A, Discussion**	
11:00	**Coffee Break & Exhibition**	
Session 1	**Regulatory Update**	Moderator: **Renaud Janssen,** *Datwyler*
11:30	**Critical Parenteral Packaging Issues 2014 - 2015**	Don Klein, *US FDA*
12:00	**Current Regulatory Challenges**	Regulatory Speaker invited
12:25	**Q&A, Discussion**	
12:45	**Lunch Break & Exhibition**	
Session 2	**Materials: Glass**	Moderators: **Jörg Zürcher,** *Bayer* **Paolo Golfetto,** *OMPI*
13:45	**Mechanical Modeling of Parenteral Packaging**	Ronald G. Iacocca, *Eli Lilly*
14:10	**Borosilicate Glass - Putting a New Twist on a Long-Standing Tradition**	Bettine Boltres, *SCHOTT, Pharmaceutical Tubing*
14:35	**The New Glass Tubing Materials for Pharmaceutical Packaging**	Shinsaku Nishida, *Nippon Electric Glass*
15:00	**Coating Technology for the Treatment of Primary Glass Containers for Parenteral Use: A Shortcut Solution to Reducing Time to Market for Biotech Drugs**	Francesco Mestriner, *OMPI*
15:25	**Coffee Break & Exhibition**	
16:00	**Internal Glass Surface Metallic Inclusions: A New Method for the Chemical Characterization and Quality Control of the Container Glass Manufacturing Process**	Nicola Favaro, *Stazione Sperimentale Vetro*
16:25	**Innovative Glass Container Improves Filling Process Quality and Performance**	Christopher Timmons, *Corning* Chi Liu, *Janssen*
16:50	**How to Reduce the Delamination Risk: A Converter Perspective**	Daniele Zuccato, *OMPI*
17:15	**Qualifying Delamination Propensity of Glass Vials**	Volker Rupertus, *SCHOTT, Pharmaceutical Systems*
17:40	**Q&A, Discussion**	
18:15	**End of Conference Day 1 & Networking Reception**	

Please confirm your attendance at the PDA registration desk.

Wednesday, 13 April 2016

PARALLEL MORNING SESSIONS

	Room C Modern Device Development		Rooms D & E Modern Manufacturing	
	Moderator: **Bettine Boltres,** *SCHOTT Pharmaceutical Tubing*		*Moderator:* **Georg Roessling,** *PDA Europe*	
7:00	**Modeling of Auto-Injectors**	Jean-Rene Authelin, *Sanofi*	**Changing Production Strategies: New Challenges in Sterile Filling**	Matthias Poslovski, *Optima Pharma*
7:30	**Q&A, Discussion**		**Roundtable Discussion with Glass Manufacturers**	
8:00	**Welcome Coffee**			

PARALLEL TRACKS

Session 3

	Track A Manufacturing		Track B Materials: Polymers, Elastomers and BFS	
	Moderators: **Renaud Janssen,** *Datwyler;* **Timo Simmen**, *Janssen*		*Moderator:* **Michael Spallek,** *rommelag*	
8:30	**Quality and Reliability: Inline Inspection Solution for BFS Containers**	Dietmar Karepin, *Vitronic*	**Good Reasons to Consider Cyclo Olefin Polymers (COP) for Parenteral Packaging**	Reinhard Scheller, *ZEON*
8:55	**A Comparison of Bio-Decontamination using Hydrogen Peroxide Vapor with Nitrogen Dioxide Gas**	David Opie, *Noxilizer*	**Cyclic Olefin Copolymer (COC): An Innovative, Transparent Plastic Material for Applications in Primary Pharmaceutical Packaging**	Michael Grimm, *TOPAS Advanced Polymers*
9:20	**In-process Testing vs 100% CCIT during Routine Manufacturing – A Biopharmaceutical Industry Perspective**	Brian Vanness, *AbbVie*	**Development of an EP and USP Compliant Soft Polypropylene for Blow-Fill-Seal Applications**	Martina Sandholzer, *Borealis*
9:45	**Polyolefins and Their Influence on Single-Use Technology for Bioprocessing**	Amy Plançon, *Sabic*	**BFS Infusion-Bottles: Correlation of Visual Appearance Survey Data to Optical Measurements**	Christoph Kaschta, *rommelag*
10:10	**Q&A, Discussion**		**Q&A, Discussion**	
10:30	**Coffee Break & Exhibition**			

"PDA's events always present high level, in-depth information

Session 4				
	Track A **Quality & Methods: CCI**		**Track B** **Materials: Polymers, Elastomers and E&L**	
	Moderator: **Roger Asselta,** *Genesis Packaging*		*Moderator:* **Michael Spallek,** *rommelag*	
11:00	**How Tight is a Syringe – Understanding Permeation and CCI Defects in a Syringe**	Derek Duncan, *LIGHTHOUSE*	**Opportunities and Limitations in the Application of Thermoplastic Elastomers as Substitute of Conventional Thermoset Rubber**	Norbert Vennemann, *University of Applied Sciences*
11:25	**Container Closure Integrity Issues of Rubber Stoppered Plastic Vials Stored under Cryogenic Conditions**	Thomas Pack, *Janssen R&D*	**TPE vs. Rubber for Pharmaceutical Closures - Critical Comparison**	Oliver Kluge, *KRAIBURG TPE*
11:50	**Critical Process Parameters of Capping Equipment used in GMP DP Manufacturing**	Roman Mathaes, *Lonza*	**Visible Particles and Elastomeric Components**	Renaud Janssen, *Datwyler*
12:15	**Container Closure Integrity Testing – A Crucial Part in the Development and Qualification of Integral Packaging Systems for Injectable Drug Products**	Florence Buscke, *SCHOTT* Fran de Grazio, *WEST*	**The Importance of a Thorough Material Selection for BFS Applications for the Complete Packaging System: An E/L Perspective**	Piet Christiaens, *Toxikon*
12:40	**Q&A, Discussion**		**Q&A, Discussion**	
13:00	**Lunch Break & Exhibition**			

PLENARY		
Session 5:	**Parenteral Administration**	*Moderator:* **Galen Shi,** *Eli Lilly*
14:00	**Preventing Errors Associated with the Preparation and Administration of IV Admixtures**	Michael Spallek, *rommelag*
14:25	**Modelling Needle Injection Processes in Gelatin**	Herbert Wachtel, *Boehringer Ingelheim*
14:50	**Microfluidic Structures for Disposable Devices in Parenteral Applications**	Reinhard Steger, *Braunform*
15:15	**Q&A, Discussion**	
15:45	**End of Conference & Farewell**	

in a professional yet friendly and comfortable atmosphere."

Friedrich Haefele, PhD, Boehringer-Ingelheim

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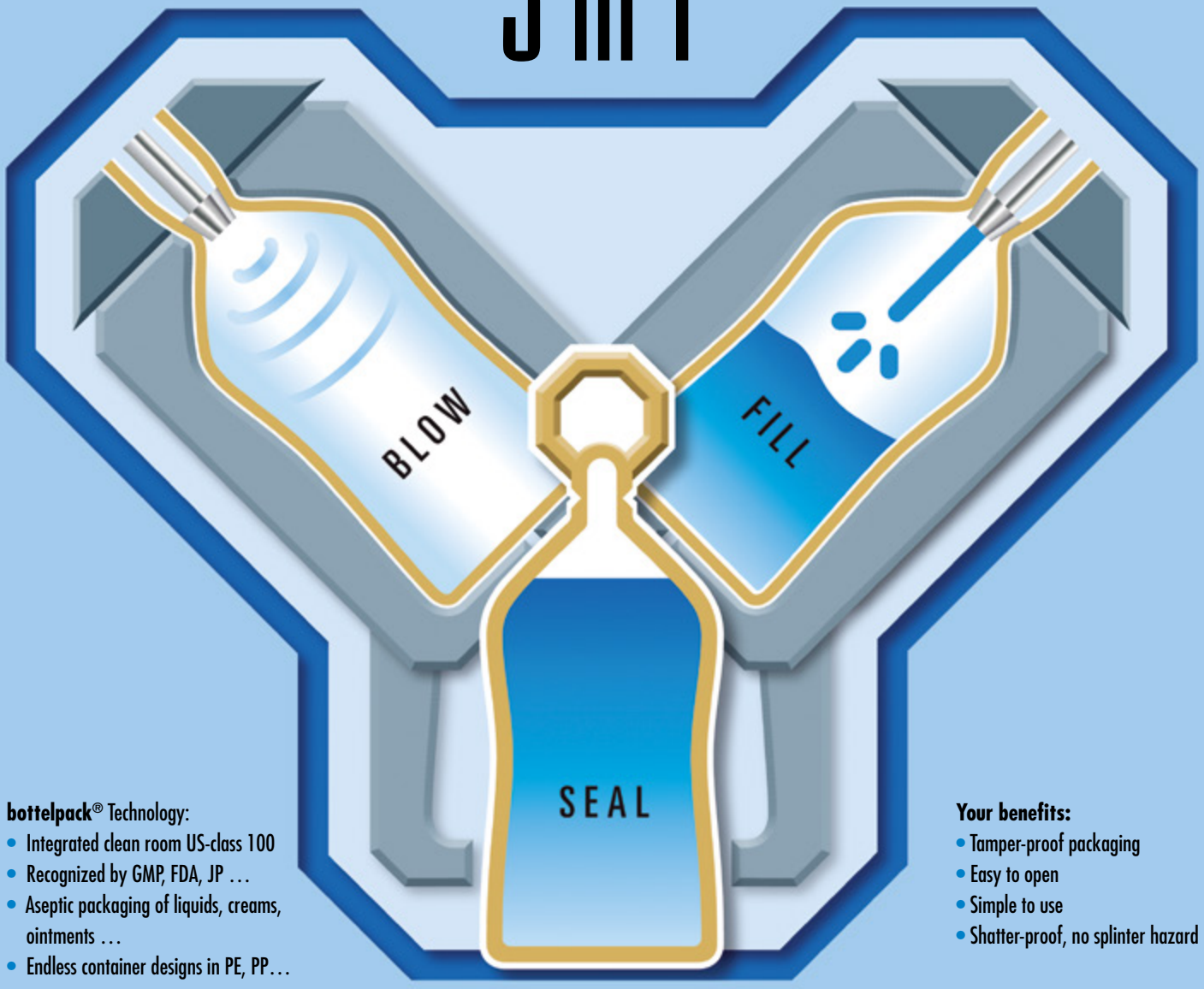

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The Parenteral Drug Association presents...

PDA Education Program

14 April 2016

Container Closure Development
One-Day Training Course

14-15 April 2016

Container Closure Integrity: Regulations, Test Methods, Application
Two-Day Workshop

14-15 April 2016

Extractables and Leachables
Two-Day Workshop

14-15 April 2016

Good Glass Handling Practices in Parenteral Packaging
Two-Day Workshop

14-15 April 2016

Drug Delivery Combination Products
Two-Day Workshop

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 of 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:

- Setting up of a target product profile of a container closure system
- Selecting appropriate container closure materials, components, and systems
- Applying the appropriate regulations and standards to container closure systems for parenteral formulations
- Preparing a development plan of a container closure systems from the early development until market phase
- Specifying container closure system regarding technical aspects and regulatory requirements
- Understanding 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, 14 April 2016	9:00 – 17:00
9:00	**Welcome & Introduction**
9:10	**Setting up a Target Profile** – Influence of formulation (small molecule, biological) – Use of product (patient, nurse, physician....) – Regulatory requirement
9:30	**Material Selection** – Ph.Eur. / USP / JP – Plastics vs. glass – Coating of material – Stopper material
10:30	**Coffee Break**
11:00	**Selection of Packaging Solution**
11:30	**Assessment of Packaging Solutions – Development Data** – Testing of injection vials/bottles and their respective components – Testing of pre-filled syringes (PFS) and their respective components – Extractables & Leachables (E&L) testing – Mechanical and functional testing
12:30	**Lunch Break**
13:30	**Manufacturing of Packaging Solutions** – Test runs – Process validation (risk assessment, critical parameters) – Container closure integrity (physical vs. microbiological testing – USP 1207) – Shipping test for PFS
14:00	**Setting of Specifications** – Technical drawings – Technical / quality specification – Testing standard, defect evaluation list – Examples
15:00	**Coffee Break**
15:30	**Preparing the Submission** – Relevant eCTD sections (drug substance and drug product) – Regulatory drawings – DMF for US
16:00	**Routine and Release Testing** – Certificates – Routine E&L testing – Reduced testing
16:15	**Change Management** – EU requirements
16:30	**Wrap-up, Discussion, Q & A**
17:00	**End of Training Course**

Container Closure Integrity Testing

Overview

This PDA Europe Workshop focuses on theoretical and practical fundamentals of various CCI testing technologies and provides a systematic approach to applying 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.

Learning Objectives

This PDA Europe 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 regulatory and pharmacopeia requirements on CCI
- Defining CCI requirements for various container and drug product types
- Gaining fundamental understanding and hands-on experience of various CCI testing techniques: Microbial challenge ingress test; Tracer liquid leak test (dye test); 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; Various seal quality tests ; Microbial immersion challenge test.
- Applying appropriate testing methods for CCI verification as a necessary component of the product life cycle
- Mastering CCI testing method development and validation approach
- Avoiding common issues and pitfalls

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:

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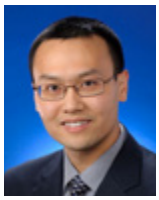

Lei Li , *PhD, Senior Consultant Engineer, Eli Lilly*

Lei Li currently serves as a senior engineer at Delivery and Device R&D, Eli Lilly and Company. Lei has 8 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 and applying CCI testing methods to evaluate container closure protection performance throughout drug product development, manufacturing, and shipping and distribution. 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, 14 April 2016 9:00 – 18:00

9:00 **Welcome**

9:30 **CCI Introduction, Regulatory Requirements, and Industry Trends**
- Introduction to container closure integrity
- Regulatory requirements

10:30 **Coffee Break**

11:00 **CCI Introduction, Regulatory Requirements, and Industry Trends (Continued)**
- Compendia updates: USP 1207 revision updates, EP
- PDA TR 27 revision updates

11:30 **Introduction to CCI Test Methodologies**
- Classification: deterministic vs probabilistic; microbiological vs physicochemical methods; by limit of detection
- Key method performance characteristics
- Laboratory bench-top testing v.s. online 100% inspection
- CCI v.s. Seal Integrity Testing

12:00 **Lunch Break**

16:00 **Advanced CCI Testing Technologies and Seal Quality Testing Technologies**
1. HVLD
2. Vacuum and pressure decay
3. Mass Extraction

15:30 **Coffee Break**

16:00 **Advanced CCI Testing Technologies and Seal Quality Testing Technologies**
4. Tracer gas (helium leak detection)
5. Headspace analysis
6. Seal Integrity methods

17:30 **Day-1 Summary; Case Study Assignment**

18:00 **End of Day 1**

Friday, 15 April 2016 9:00 – 16:30

9:00 **Day-1 Review**

9:30 **Development of CCI Testing Strategy**
- Testing requirement definition
- Testing strategy development
- Examples and case study exercise

10:00 **Approaches to CCI Testing Method Selection**
- Method selection considerations
- Testing method selection guidance
- Examples and case study exercise

10:30 **Coffee Break**

11:00 **Instrument Demo and Hands-on Training:**
1. HVLD station
2. Vacuum decay
3. Mass Extraction

12:30 **Lunch Break**

13:30 **Instrument Demo and Hands-on Training:**
4. Headspace
5. Helium leak detection
6. Seal quality tests

14:30 **Coffee Break**

15:00 **Development and Validation of Integrity Test Methods**
- Method development best practices
- Method validation strategy
- Pitfalls and solutions

16:00 **Course Summary**

16:30 **End of Workshop**

Justine Young, *Associate Director, Whitehouse Laboratories*
Justine Young is an Associate Director of Container Qualification and Container Closure Integrity Testing at Whitehouse Laboratories, a division of Albany Molecular Research Inc. In her role, Justine assists clients with the qualification of their container systems as well as the identification of optimal methods for the package integrity evaluation of various parenteral product-package systems. Having previously worked intimately with Dana Morton Guazzo in efforts to optimize and validate CCIT methods, Justine has an established understanding of the development and validation process utilizing deterministic leak test technologies pursuant to USP general chapter <1207>. Justine holds a B.E. in Chemical Engineering from Stevens Institute of Technology and is pursuing her Masters of Business and Science degree from Rutgers University.

Good Glass Handling Practices in Parenteral Packaging

Overview

Glass vials, syringes and cartridges are commonly used in the packaging of parenteral pharmaceuticals. Good glass handling practices are essential to assuring that the glass-based container performs as intended in maintaining the safety and efficacy of the drug product. The two-day workshop will offer insight into the science of glass and its inherent properties. It will review container design and dimensioning. It will cover glass strength and fracture mechanics. It will review the fundamental principles of good glass handling and will follow, step-by-step, the processes for packaging parenterals in vials, cartridges and syringes. Further insight into glass breakage including an overview of fracture analysis using fractography will be presented.

Who Should Attend:

- Packaging engineers
- Quality personnel
- Filling line technicians
- Supervisors and engineering support
- Those responding to failure complaints
- Root cause investigators

Learning Objectives:

- Understanding the nature of glass
- Learning what triggers glass breakage
- Knowing how to inspect glass containers for breakage-relevant defects
- Applying the knowledge to avoid glass breakage in the filling line
- In case of breakage applying a structured way of evaluating it
- Being able to read from the splinters and broken glass

Roger Asselta, *Genesis Technical Advisors*

Roger Asselta is Vice President of Technical Affairs at Genesis Packaging Technologies, and also a Senior Advisor at Genesis Technical Advisors, a consortium of independent consultants focusing on parenteral packaging. Mr. Asselta has over twenty-five years of experience in pharmaceutical packaging, working for firms producing glass containers, plastic containers and closures, elastomeric closures and seals, and sealing technology equipment. Roger has long been a member of PDA, serving on a number of planning committees and task forces including those on glass defects, elastomer defects, glass handling practices and container/closure integrity. He has authored several papers and a chapter on sealing parenteral vials for the text: Practical Aseptic Processing (PDA 2008). He holds a B.S. in Biology from Maine's Nasson College and received a certificate in Quality Management from Pennsylvania State University.

Thursday, 14 April 2016 9:00 – 18:00

9:00 Welcome

9:15 Glass Science
- **Chemical structure**
- **Physical properties**

Bettine Boltres

11:00 Coffee Break

11:30 Glass Making
- **Melting**
- **Molded containers**
- **Tube drawing and container conversion**

Bettine Boltres

13:00 Lunch Break

14:00 Glass Strength and Fracture Mechanics
- **Trigger for glass breakage**
- **Crack formation and propagation**
- **Theory of Fractography**

Bettine Boltres

15:30 Coffee Break

16:00 Container Design
- **Dimensioning and tolerancing**
- **Variation and performance**
- **Review of Standards (ISO 8361)**

Roger Asselta

18:00 End of Day 1

Friday, 15 April 2016 9:00 – 16:30

9:00 Visual Inspection of Glass Containers
- **Inspection Techniques**
- **Sampling Plans**
- **Overview of TR-43**

Roger Asselta

11:00 Coffee Break

11:30 Good Glass Handling Practices
- **Principles**
- **Vial processing**
- **Cartridge processing**
- **Syringe processing**

Roger Asselta

12:30 Lunch Break

13:30 Fracture Analysis: Picking up the Pieces
- **Observe and Describe**
- **Investigate and Document**
- **Preserve the Samples**

Roger Asselta, Bettine Boltres

14:30 Coffee Break

15:00 Fracture Analysis: Fractography
- **Technical Review**
- **Practical Part**

Roger Asselta, Bettine Boltres

16:30 End of Workshop

Bettine Boltres, *PhD, SCHOTT AG*
Since joining SCHOTT in 2010, Bettine Boltres' primary role has been in providing global scientific support and glass training for converters and pharmaceutical companies. In the past 3 years she has held over 70 glass trainings at pharmaceutical companies, converters, and universities. She is a frequent speaker at industry conferences and has chaired and moderated technical training events on glass for the PDA. A number of articles for several global magazines have also been penned by her. In the 2015 – 2020 cycle Bettine is member of the USP Packaging, Storage and Distribution Expert Committee. Bettine is a (bio)chemist by training, receiving a diploma in chemistry from the university of Frankfurt, Germany and a PhD in biochemistry from the University of Cologne, Germany.

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Vials

Nest & Tub

Tray

Cartridges

Nest & Tub

Syringes

Nest & Tub

Thursday, 14 April 2016 9:00 – 18:00 | Friday, 15 April 2016 9:00 – 16:30

Extractables & Leachables

Including: Important Regulatory Updates – E/L Requirements for Injection Devices

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.

In addition, during the workshop, a full session will be dedicated to an in-depth update on regulations, standards and recommendations in this field (PQRI, USP, ISO 10993, BPOG…).

Learning Objectives

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

- Explain in detail the current regulatory requirements for container / closure qualification form an E/L perspective.
- Explain the upcoming changes in regulations, standards and recommendations from PQRI, USP, ISO 10993 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

Faculty

Piet Christiaens, *PhD, Scientific Director, Toxikon Europe*

John Iannone, *Program Manager/Technical Specialist, Toxikon Corporation*

Dennis Jenke, *PhD, Distinguished Scientist, Baxter Healthcare*

Thursday, 14 April 2016 9:00 – 18:00 | Friday, 15 April 2016 9:00 – 16:30

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

Analytical Techniques to Perform Extractables & Leachables Research

- The importance of sample preparation: the corner stone in E/L research
- What are the target compounds for material research
- How does a classification of these compounds assist in finding the right analytical technique
- From basic "screening" methodologies to state-of-the-art equipment

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

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
  - The BPOG protocol
  - 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 it's suggested staged approach
- The Threshold Concept of PQRI (OINDP and PDP/ODP)
- Examples

Piet Christiaens, *PhD, Scientific Director, Toxikon Europe*
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 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 Toxikon Europe and is also supports th e European business development team.

E/L Testing for a Pre-filled Syringe (Glass & Polymer)

- 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 extractables & leachables studies for a pre-filled Syringe

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

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

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

John Iannone, *Program Manager/Technical Specialist, Toxikon*
John Iannone has a background in Biomedical Engineering from Boston University, where he later became a research engineer. Since joining Toxikon, John has assisted many drug & medical device companies with the development of their product safety evaluation strategies. His areas of expertise include Material Qualification/ Biocompatibity, E&L/Chemical Characterization, and attainment of either biological or toxicological risk assessments for medical devices, pharmaceutical container systems, bioprocessing systems, and combination products. John has given numerous technical presentations and has lead several workshops on Extractable & Leachable Considerations, Biocompatiblity, Microbiology, and Regulatory Testing Requirements. John participates in the development of both industry groups' recommendations and regulatory guidelines. Additional responsibilities include providing technical assistance to clients regarding unique testing requirements in an effort for them to meet global regulatory expectations.

Dennis Jenke, *PhD, Distinguished Scientist, Baxter Healthcare*
Dennis Jenke is a Baxter Distinguished Scientist at Baxter Healthcare Corporation where he works with 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 industry groups whose charter is to establish best demonstrated practices in the area of material/solution compatibility.

Drug Delivery Combination Products

Understanding and Addressing Technical, Quality and Regulatory Challenges

Overview

The number and market value of medicinal products that require delivery by a medical device have increased exponentially over the last ten years. These products bring an increased level of complexity to the development and approval process. Also, the way these products are addressed by the regulatory agencies has changed and continues to evolve. This course will contain a combination of presentations, open discussions and hands-on exercises to enhance the knowledge and skills of the attendees.

Who Should Attend:

This course will be geared towards individuals that have input to, oversight for, or actively participate on drug delivery combination product development teams. This includes the following practitioners, managers and directors in medical device, pharmaceutical or consulting companies:

- Project Management
- Marketing
- Regulatory Affairs
- Quality Assurance
- Clinical Affairs
- Human Factors Engineering
- Device Development Engineering
- Design Verification Department
- Packaging Development
- Testing Laboratories
- Quality Engineering
- Manufacturing
- Formulation

Learning Objectives:

Upon completion of this workshop you will be able to:

- Explain the basic elements and requirements behind the regulation of Drug Delivery combination Products in the USA and EU
- Plan, propose and choose appropriate regulatory strategies
- Understand requirements of Design Controls (USA) /Product Realization (EU) including Risk Management, Human Factors and Clinical Requirements
- Develop a set of criteria with which to assess, choose and manage Device Partners
- Develop a set of criteria with which to verify device design, including Functional Requirements
- Identify the appropriate testing schemes and requirements specific to their products
- Learn about Post Market Requirements, including Complaints, Reportable Events, Customer Service, Change Management, and Non-conformances including Recalls

Lee H. Leichter, *MBA, President, P/L Biomedical*

Lee Leichter has over 35 years of experience in the health care industry. He has been providing direct, hands-on assistance to domestic and international Pharmaceutical, Biotechnology and Medical Device companies for the last 20 years. Projects have encompassed a multitude of business, technical, regulatory and quality issues, mostly relating to drug delivery and combination products for marketing in the USA, Europe and Canada. He has worked with large multi-national companies and start-ups successfully navigating the challenges posed during the development, testing and marketing approval of products that merge pharmaceutical substances with high-tech device systems. He serves as an independent expert on ISO technical committees for injection and respiratory products, infusion pumps, needles and catheters, and AAMI Injection and Infusion Devices and Human Factors committees, helping establish international standards for safety and performance of these products. Lee holds a Bachelor's degree from the State University of New York at Stony Brook and an MBA with Honors from Florida Gulf Coast University. He was certified as a Quality Engineer from ASQ and is currently certified in USA and EU Regulatory Affairs from RAPS.

Mark A. Chipperfield, *MSc, Principal Consultant, Corvus Device Limited*

Mark serves as an Independent Consultant to the Pharma and Medical Device industries. He has spent 20 years working within large Pharma (GSK, sanofi-aventis, Novartis, F. Hoffmann-La Roche) in the field of drug delivery devices and special purpose packaging. Through his career to date he has been heavily involved in development of medical devices for drug delivery combination products in several forms. He has performed numerous due diligence and technical evaluations of novel delivery technologies, developed products through the full design control phases to market, maintained and remediated commercial products. Mark has experienced many of the challenges associated with delivery device development and device product maintenance within large pharmaceutical companies and implemented Medical Device development guidance, quality systems and business processes. He is an active presenter in the field and during 2013 Mark co-authored the PDA publication on 'Combination Products: Implementation of cGMP requirements'. He is currently working with RAPS to co-author the introduction for their upcoming publication; 'Global Medical Device Strategy' and with PDA to co-author a further Combination Product publication. Mark is a Mechanical Engineer by first degree and later earned his Master of Science in Engineering Management.

Thursday, 14 April 2016 9:00 – 17:30

9:00 **Combination Product Basics in USA and EU**
- General overview of how different types of devices are defined and regulated
- Types of products and submissions
- Overview of Quality Systems and GMP
- Potential regulatory strategies
- Drug submissions - Keeping the eCTD Common – USA vs EU

11:00 **Coffee Break**

11:30 **Product Development - Part 1**
- Design controls (USA) / product realization (EU)
- Risk Management

13:00 **Lunch Break**

14:00 **Product Development - Part 2**
- Human factors
- Clinical requirements (clinical evaluations and clinical studies)

15:30 **Coffee Break**

16:00 **Interactive Workshop**
- Development of a regulatory strategy, including clinical requirements, for different types of combinations
- Each group to identify risks and hazards for specified product types

17:30 **End of Day 1**

Friday, 15 April 2016 9:00 – 17:30

9:00 **Post Market Requirements**
- Complaints
- Reportable events
- Customer service
- Change management
- Risk managements and HFE
- Non-conformances
- Recalls

11:00 **Coffee Break**

11:30 **Partnership expectations**
- Typical activities
- Types of contributors & relationships
- Design controls
- Purchasing controls
- Quality agreements

13:00 **Lunch Break**

14:00 **Design Verification**
- Physical testing vs other forms of verification
- Sample size
- Storage and pre-conditioning
- Instrument calibration
- Equipment qualification
- Statistical analysis
- Test method validation
- Using RM to drive DV

Functional Requirements
- Translation of URS into DIR
- ISO/other Norms
- Guidance
- Typical tests for Pre-filled Syringes, Auto-Injectors, Injection Pens, Needle Safety Systems

15:30 **Coffee Break**

16:00 **Interactive Workshop**
- Development of a plan to qualify and interact with Device CMOs
- Development of a verification plan for different devices

17:30 **End of Workshop**

Scientific Program Planning Committee

Jörg Zürcher, *Bayer, Conference Chair*
Roger Asselta, *Genesis Packaging*
Bettine Boltres, *SCHOTT*
Paolo Golfetto, *OMPI*
Renaud Janssen, *Datwyler*
Stefan Merkle, *Janssen*
Anna Malori, *Bormioli Rocco*
Galen Shi, *Eli Lilly*
Michael Spallek, *rommelag*
Georg Roessling, *PDA Europe*

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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.

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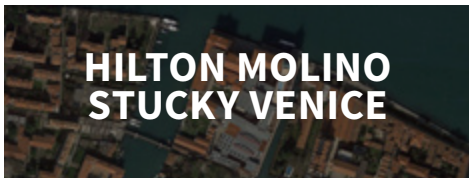

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Your Contact Person is
Antje Petzholdt at PDA Europe
petzholdt@pda.org

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PDA Europe Conference, Exhibition, Workshops, Training Course

Parenteral Packaging

12-13 April 2016 | Hilton Molino Stucky | Venice | Italy

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

1 Registration

No PDA membership included

EARLY BIRD DISCOUNT ☐ **Book by 12 March to receive € 150 off the conference fee only**

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

11 April	**Interest Group Meeting**	**Meeting Fee**		**net**
Interest Group Meeting Pre-filled Syringes		All Participants	☐	**400**
11 April	**One-Day Workshop**	**Workshop Fee**		**net**
Molded Glass: From Manufacturing Process to Applications		All Participants	☐	**400**
12-13 April	**Conference only**	**Conference Fee**		**net**
Parenteral Packaging		PDA Member	☐	**1495**
		Nonmember	☐	**1745**
		Regulatory/Academic	☐	**750**
14 April	**One-Day Training Course**	**Training Course Fee**		**net**
Container Closure Development		All Participants	☐	**695**
14 -15 April	**Two-Day Workshop**	**Workshop Fee**		
Extractables and Leachables		All Participants		SOLD OUT BOOK NOW FOR THE SEPTEMBER EVENT!
14 -15 April	**Two-Day Workshop**	**Workshop Fee**		**net**
Container Closure Integrity: Regulations, Test Methods, Application		All Participants	☐	**1495**
14 -15 April	**Two-Day Workshop**	**Workshop Fee**		**net**
Good Glass Handling Practices in Parenteral Packaging		All Participants	☐	**1495**
14 -15 April	**Two-Day Workshop**	**Workshop Fee**		**net**
Drug Delivery Combination Products		All Participants	☐	**1495**

The fee includes course 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.

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Registration Form – Page 2

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petzholdt@pda.org

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PDA Europe Conference, Exhibition, Workshops, Training Course

Parenteral Packaging

12-13 April 2016 | Hilton Molino Stucky | Venice | Italy

4 WAYS TO REGISTER

1. **ONLINE: europe.pda.org/ParPack2016**
2. **FAX: +49 30 4365508-66**
3. **EMAIL: petzholdt@pda.org**
4. **MAIL: PDA Europe, Am Borsigturm 60, 13507 Berlin, Germany**

1 Your Contact Information

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(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

2 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).

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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.** You must have a written confirmation (including invoice) to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. Payment must be received or guaranteed by Purchase Order or credit card details on 1st day of event, at the very latest. **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 per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **12 March 2016,** 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 **info-europe@pda.org or fax to +49 30 4365508-66. DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

MAKING IT EASIER FOR BOTH OF US

1 Please include your member ID number on registration form if available/known

If uncertain about your member ID number and/or your membership status, call or email Ms. Antje Petzholdt.
+49 30 4365508-10 **petzholdt@pda.org**

2 Do not send money in advance

Please wait until we send our invoice to you.
It is helpful to reference our invoice number in your bank transfer details.

3 Complete and sign the event registration form

Please note the registration and cancellation policies at the bottom of the form.

4 Purchase Orders

Registration cannot be completed by sending Purchase Order alone. A Purchase Order is only accepted if a complete registration form is enclosed or follows very soon.

5 Please state VAT ID number if European-based Company

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7 Confirmation of your registration

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8 Refund/Credit Notes

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9 Substitutions

If a participant is unable to attend, substitutions are welcome at any time. Changes are free of charge until 3 weeks prior to the start of the event. After this date, there will be a charge of € 50 per name change.

10 For assistance contact: Antje Petzholdt, PDA Europe

Tel: +49 30 4365508-10 **Email: petzholdt@pda.org**

THANK YOU FOR YOUR COOPERATION!

2016 PDA EUROPE ACTIVITIES & EVENTS

11 April	Interest Group Meeting Pre-filled Syringes	IG	
11 April	Molded Glass: From Manufacturing Process to Applications	TC	
12-13 April	**Parenteral Packaging** | Conference		
14 April	Container Closure Development	TC	**Venice, Italy**
14-15 April	Extractables and Leachables	TC	
14-15 April	Container Closure Integrity: Regulations, Test Methods, Application	WS	
14-15 April	Good Glass Handling Practices in Parenteral Packaging	WS	
14-15 April	Drug Delivery Combination Products	WS	
19-20 April	**Data Integrity**	**WS**	**London, UK**
25-29 April	**Praxis der Pharmazeutischen Gefriertrocknung**	**TC**	**Osterode, Germany**
2-3 May	**Critical Demands on Modern Pharmaceutical Packaging**	**WS**	**Bern, Switzerland**
9 May - 10 May	**DoE Basics for Validation by Design®**	**TC**	**Berlin, Germany**
31 May - 1 June	**Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision**	**WS**	**Berlin, Germany**
6 June	**Viral Safety of ATMPs** | Conference		
7-8 June	**Advanced Therapy Medicinal Products** | Conference		**Berlin, Germany**
9 June	Practical Application of GMP for Development of ATMPs	TC	
28-29 June	**1st PDA Europe Annual Meeting**		
30 June	Test Methods for Pre-filled Syringe Systems	TC	
30 June	Cleaning and Disinfection	TC	**Berlin, Germany**
30 June	How to Find the Right GMP for APIs	TC	
30 June - 1 July	Root Cause Investigation	TC	
30 June - 1 July	Development of a Pre-filled Syringe	WS	
20-21 September	**9th Workshop on Monoclonal Antibodies**		
22 September	Elastomers	TC	
22-23 September	CMC Regulatory Compliance for Biopharmaceuticals	TC	**Rome, Italy**
22-23 September	Extractables and Leachables	TC	
22-23 September	Introduction to Aseptic Processes Principles	TC	
22-23 September	Statistics of Production Monitoring and Capability	TC	
27-28 September	**Pharmaceutical Freeze Drying Technology** | Conference		
29 September	Application of a Risk-Based Approach to Freeze-Drying Processes	TC	**Strasbourg, France**
29-30 September	Development of a Freeze Drying Process	WS	
5-6 October	**Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision**	**WS**	**Dublin, Ireland**
10 October	Interest Group Meeting Pharmaceutical Cold Chain	IG	**Amsterdam, The Netherlands**
11-12 October	**Pharmaceutical Cold & Supply Chain Logistics**		
13-14 October	Good Cold Chain Practices	WS	
24 October	Particle Identification in Parenterals	TC	
25-26 October	**Visual Inspection Forum**		**Berlin, Germany**
27-28 October	An Introduction to Visual Inspection: A Hands-on Course	TC	
8-9 November	**Data Integrity**	**WS**	**Berlin, Germany**
14 November	Risk-based Approach for Prevention and Management of Drug Shortages	TC	
15-16 November	**Outsourcing & Contract Manufacturing** | Conference		**Barcelona, Spain**
17 November	Quality by Design for Biopharmaceuticals	TC	
17-18 November	Root Cause Investigation	TC	

Subject to change

For latest info:

Shortlist 31 Mar 2016

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Legend
IG – Interest Group Meeting
TC – Training Course
WS – Workshop

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