PDA
Parenteral Drug Association

13 March
PDA IG Meeting
Pre-filled Syringes
2017

PDA Europe Conference, Exhibition, Education

Parenteral Packaging

Join us in our annual professional exchange on the latest on primary containers and test methods of container closure systems.

Register by
14 Feb 2017
and SAVE!

14-15 March 2017

Hotel Porta Fira
Barcelona | Spain

pda.org/eu-parpack-2017

LETTER FROM THE CO-CHAIRS

Dear Colleagues,

You are warmly invited to join us in our ongoing professional discourse of latest manufacturing technologies and business trends in the Parenteral Packaging arena.

PDA Europe's Conference has proven to be a must-attend event for professionals in this field.

Join us in Barcelona / Spain, 14-15 March 2017 to continue and further deepen scientific advancements and understanding of topics previously raised in this successful annual event.

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.

Different materials such as glass, 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. Barcelona will offer a comfortable yet exciting atmosphere for exchange during refreshment breaks, on-site lunches and evening receptions.

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

Welcome to Barcelona!

Roger Asselta, *Genesis Packaging, Co-Chair*

Derek Duncan, *LIGHTHOUSE, Co-Chair*

SCHEDULE AT A GLANCE

13 March	10:00 – 17:30	Pre-filled Syringes	Interest Group Meeting
13 March	9:00 – 18:00	Elastomers	Training Course
13 March	13:00 – 18:00	Secondary Packaging for Parenterals	Pre-Conference Workshop
14 March	9:00 – 18:30	Parenteral Packaging	Conference, Exhibition
15 March	7:30 – 9:00	Open Forum: Packaging Science Interest Group (IG) Meeting	Interest Group Meeting
15 March	9:00 – 17:00	Parenteral Packaging	Conference, Exhibition
16 March	9:00 – 17:00	Container Closure Development	Training Course
16 March 17 March	9:00 – 18:00 9:00 – 16:30	Container Closure Integrity Testing	Training Course
16 March 17 March	9:00 – 18:30 8:30 – 16:00	Track and Trace	Training Course
16 March 17 March	9:00 – 18:00 9:00 – 16:30	Extractables & Leachables	Training Course

For latest information, please visit: **pda.org/eu-parpack-2017**

PDA
Parenteral Drug Association

PDA Europe Interest Group Meeting

Pre-filled Syringes

Product Lifecycle Management (PLM)

Want to create value for your injectable drug? Consider a Pre-filled Syringe / Device!
PLM is critical for pharmaceutical and biotechnology manufacturers, especially when considering the enormity of the expense, time and effort it takes to bring a drug to fruition.
Get involved and talk at the meeting. Make use of the open forum a small Interest Group has to offer. Gain first-hand information about activities of the 'Interest Group Pre-filled Syringes'.

- Case Studies
- PLM Strategies
- Formulation Challenges
- Primary Packaging and Secondary Packaging
- Risk Management and Quality by Design
- Technology Transfers
- Regulatory Trends
- Collaboration with suppliers

A Roundtable Discussion: Business Drivers for Product Life Cycle Management

Make sure to register you and your colleagues for this Interest Group Meeting **online.**

Register by 13 Feb 2017 and SAVE!

https://goo.gl/oAZoD6

13 March 2017

Barcelona | Spain

Monday, 13 March 2017

10:00	**Welcome and Introduction**	Georg Roessling, *PDA Europe*
10:15	**IG Activities**	Brigitte Reutter-Haerle, *Vetter*
	Focus Topic: Life Cycle Management: From Pre-filled to Syringes / Combination Products	*Moderator:* **Brigitte Reutter-Haerle,** *Vetter*
10:30	**Life Cycle Management: Best Practices and Pitfalls**	Christian Herget, *BD Medical*
11:00	**Coffee Break**	
11:30	**Fully Integrated Safety System: A New Option for the Product Life Cycle Management from Vial to PFS**	Alessandro Morandotti, *OMPI*
12:00	**PLAJEX™ and Safe'n'Sound® - Compatibility Established to Serve Pharma Clients for Product Life Cycle Management**	Adrien Tisserand, *Nemera* William Dierick, *Terumo*
12:30	**Case Study: A Supplier's Perspective**	Holger Krenz, *SiO2 Medical Products*
13:00	**Lunch Break**	
	PDA Interactive: Roundtable Discussions of Different Case Studies	*Moderators:* **Christian Herget,** *BD Medical* **Ian Thompson & Andreas Schneider,** *Ypsomed*
14:00	**Case Study A: LCM - From Lyo Vial to Pre-filled Syringe**	
	Case Study B: LCM- From Pre-filled Syringe to Device	
	Case Study C: Autoinjection Devices and the Introduction of Connectivity as Part of the Life Cycle Management	
15:30	**Summary of Case Studies and Q&A**	
16:00	**Coffee Break**	
16:30	**Pre-filled Syringes and OPEs - The REACH Impact on Siliconization of Pre-filled Syringes with Emulsions**	Michael Betz, *Roche*
17:00	**What else in Pre-filled Syringes? Share your Questions, New Products, New Methods and more with the Interest Group.**	
17:30	**Conclusion of Interest Group Meeting**	

1. February 2017, 4:12 PM

Tuesday, 14 March 2017

9:00	**Welcome and Introduction**	Georg Roessling, *PDA Europe* Roger Asselta, *Genesis Packaging, Conference Co-Chair* Derek Duncan, *LIGHTHOUSE, Conference Co-Chair*
9:10	**Keynote Presentation** Challenges for Biotech Drug Products at the Interface of Formulation, Process and Primary Packaging	**Hanns-Christian Mahler,** *Lonza*
	Opening Plenary Regulatory Update	*Moderator:* **Renaud Janssen,** *Datwyler*
9:40	**EU Updates & Inspection Findings**	Manuel Ibarra, *AEMPS*
10:10	**US Pharmacopeia Updates**	Desmond Hunt, *USP*
10:40	**Ongoing Revision on USP Chapters <660> and <1660>**	Bettine Boltres, *Schott*
11:10	**What's New in Japanese Pharmacopoeia 17 – A User's Perspective**	Jörg Zürcher, *Bayer*
11:40	**Q&A, Discussion**	
12:00	**Lunch Break, Poster Session & Exhibition**	

PARALLEL TRACKS 1

	TRACK A		TRACK B	
	Components & Materials		**Processing**	
	Moderator: **Bettine Boltres**, *Schott*		Moderator: **Michael Spallek,** *Rommelag ENGINEERING*	
13:00	Silicone-Free Pre-Filled Glass Syringes: From Feasibility to Reality	Jeffrey Brake, *Gore* Nicolas Eon, *Schott*	Particle Reduction with Stopper Processing	Thomas Jochimsen, *Atec Pharma*
13:30	Premium Technology for Primary Glass Container Surface Control and Enhancement to Container and Drug Stability	Dave Lisman, *Nipro Pharma Packaging*	Aseptic Powder Processing for New Dual Chamber Tubes A First Assessment	Elke Sternberger-Ruetzel, *Harro Hoefliger*

14:00	X-Cartridge: A New Generation of Glass Primary Containers for Modern Drug Delivery Devices (DDD)	Alessandro Morandotti, *Ompi*	Capping Operation and Qualification Concept	Kamila Rauch, *Hoffmann-La Roche*
14:30	**Coffee Break, Poster Session & Exhibition**			
	TRACK A		**TRACK B**	
	Components & Materials		**Processing**	
	Moderator: **Michael Spallek,** *rommelag*		Moderator: **Galen Shi,** *Eli Lilly*	
15:00	Ethylene-Norbornene Copolymers as High Purity Olefinic TPEs for Primary Packaging	Wilfried Hatke, *TOPAS Advanced Polymers*	Bringing a Valuable Technology a Step Further: Advances in Vial Isolation 2017	Tim Wenzel, *Friedrich-Alexander University, Erlangen*
15:30	Impact of the New USP <661> Guidance – a Resin Supplier's View	James Stern, *Borealis*	How the Adoption of Single Use Systems (SUS) Improves the Safety, Efficiency and Flexibility of Final Filling Processes	Mathieu Labedan, *Sartorius Stedim*
16:00	Q&A, Discussion		Q&A, Discussion	
16:30	**Coffee Break, Poster Session & Exhibition**			
	PARALLEL TRACKS 2			
	TRACK A		**TRACK B**	
	Components & Glass		**Process Analysis**	
	Moderator: **Jörg Zürcher,** *Bayer*		Moderator: **Klaus Wuchner,** *Janssen J&J*	
17:00	Risk Mitigation Addressing the Delamination Propensity of Tubular Glass Vials	Volker Rupertus, *Schott*	Glass Packaging Breakages: Optimization of Container Filling Lines by In-situ Shock-Logger Detection Investigation	Nicola Favaro, *Stazione Sperimentale Del Vetro*
17:30	Evaluation of Glass Delamination in Pharmaceutical Vials	Dominique Ditter, *Hoffmann-La Roche*	Finding the Weak Points in the Filling Line: Force Analysis by In-Line Monitoring	Evan R. Justason, *Smart Skin Technologies* Andreas Graser, *Hoffmann-La Roche*

	TRACK A		TRACK B	
	Components & Glass		**Process Analysis**	
18:00	Addressing Cracks in Pharmaceutical Containers with new Glass Material	Kyle Hoff, *Corning*	Reducing Vial Breakage and Protecting Handlers of Highly Potent Drugs	Hironori Yoshida, *Nipro Pharma Packaging*
18:15	Q&A, Discussion		Q&A, Discussion	
18:30	**End of Conference Day 1**			
19:00	**Networking Event in Barcelona**			

THE PARENTERAL DRUG ASSOCIATION IS PROUD TO INVITE YOU TO A VERY SPECIAL

Networking Event

Please join us for our Networking Event at "**Can Cortada**", an authentic catalan farmhouse, a historical heritage site of Barcelona.

Tuesday, 14 March 2017 | Meeting Point: Hotel Porta Fira-Hotel Lobby

19:00 - Shuttle Bus leaving

19:45 - Dinner

22:30 - Shuttle Bus returning to the Hotel Porta Fira

Wednesday, 15 March 2017

MORNING SESSION

7:30	**Open Forum: Packaging Science Interest Group (IG) Meeting**	Derek Duncan, *LIGHTHOUSE*

PARALLEL TRACKS 3

	TRACK A		**TRACK B**	
	Novel Sealing Concepts for Lyophilized Products		**Modeling**	
	Moderator: **Roger Asselta,** *Genesis Packaging*		Moderator: **Derek Duncan,** *LIGHTHOUSE*	
9:00	Challenges for Vial Sealing in the Freeze Dryer	Michele Arduini, *IMA*	Modeling the Discharge Behavior of BFS Infusion Bottles by Finite Element Analysis and Experimental Verification	Christoph A. Kaschta, *Rommelag ENGINEERING*
9:30	The Appearance of Plastic Caps as a New Sealing Solution	Miriam Beyer & Kolja Richlowski, *WEST*	Investigation of Stopper Pop-out by Means of Finite Element Analysis	Raphael Kaelin, *Datwyler*
10:00	Using a Process Control Strategy to Enable an Adequate Container Closure System	Yusuf Oni, *Bristol-Myers Squibb*	Critical Consideration in Time-Dependent Evaluation and Modeling for Rubber Stopper Seal Performance of Vial Container Closure	Qingyu Zeng, *WEST*
10:30	Q&A, Discussion		Q&A, Discussion	
11:00	**Coffee Break, Poster Session & Exhibition**			
	TRACK A		**TRACK B**	
	CCI at Cryogenic Conditions		**Pharmaceutical Companies' Challenges**	
	Moderator: **Roman Mathaes,** *LONZA*		Moderator: **Daniel Wagner,** *Sanofi*	
11:30	Modeling of Container Closure for Cryogenic Storage of Parenteral Drug Products	Ronald Iacocca, *Eli Lilly*	Drug Product Vial Development, Key Challenges to Modernizing an Established Platform	Scott Stiffler, *Eli Lilly*
12:00	Cryogenic Parenteral Packaging	Chris Folta, *Janssen J&J*	PFS Stoppering Challenges: Optimisation of Filling Line Parameters to Avoid Liquid between Plunger Stopper and Syringe Glass Wall	Charlotte Pellet, *Sanofi*
12:30	Q&A, Discussion		Q&A, Discussion	
13:00	**Lunch Break, Poster Session & Exhibition**			

	Closing Plenary Container Closure Integrity (CCI)	*Moderator:* **Roger Asselta,** *Genesis Packaging*
14:00	**An Industry Perspective on Application of CCIT for Sterile Biotech Products**	Roman Mathaes, *LONZA* Klaus Wuchner, *Janssen J&J*
14:30	**USP Update on CCIT**	Donald Singer, *USP*
15:00	**A Case Study for a Renovated Approach to Seal Quality and Container Closure Integrity Testing across the Lifecycle of Sterile Products**	James Mellman, *Novartis*
15:30	**The Effect of a Plunger Surface Roughening Treatment on CCI: Evaluation of Inherent Package Integrity by Helium Leak Detection in the Vacuum Mode**	Brandon Zurawlow, *Whitehouse Labs*
16:00	**CCI Test Method Development using Headspace Analysis to Measure Gas Flow into a Defective Container**	Derek Duncan, *LIGHTHOUSE*
16:30	**Panel Discussion: Container Closure Integrity**	*Moderators:* **Roger Asselta,** *Genesis Packaging* **Bettine Boltres,** *Schott*
17:00	**End of Conference & Farewell**	

PDA
Parenteral Drug Association

The Parenteral Drug Association presents:

2nd PDA Europe Annual Meeting

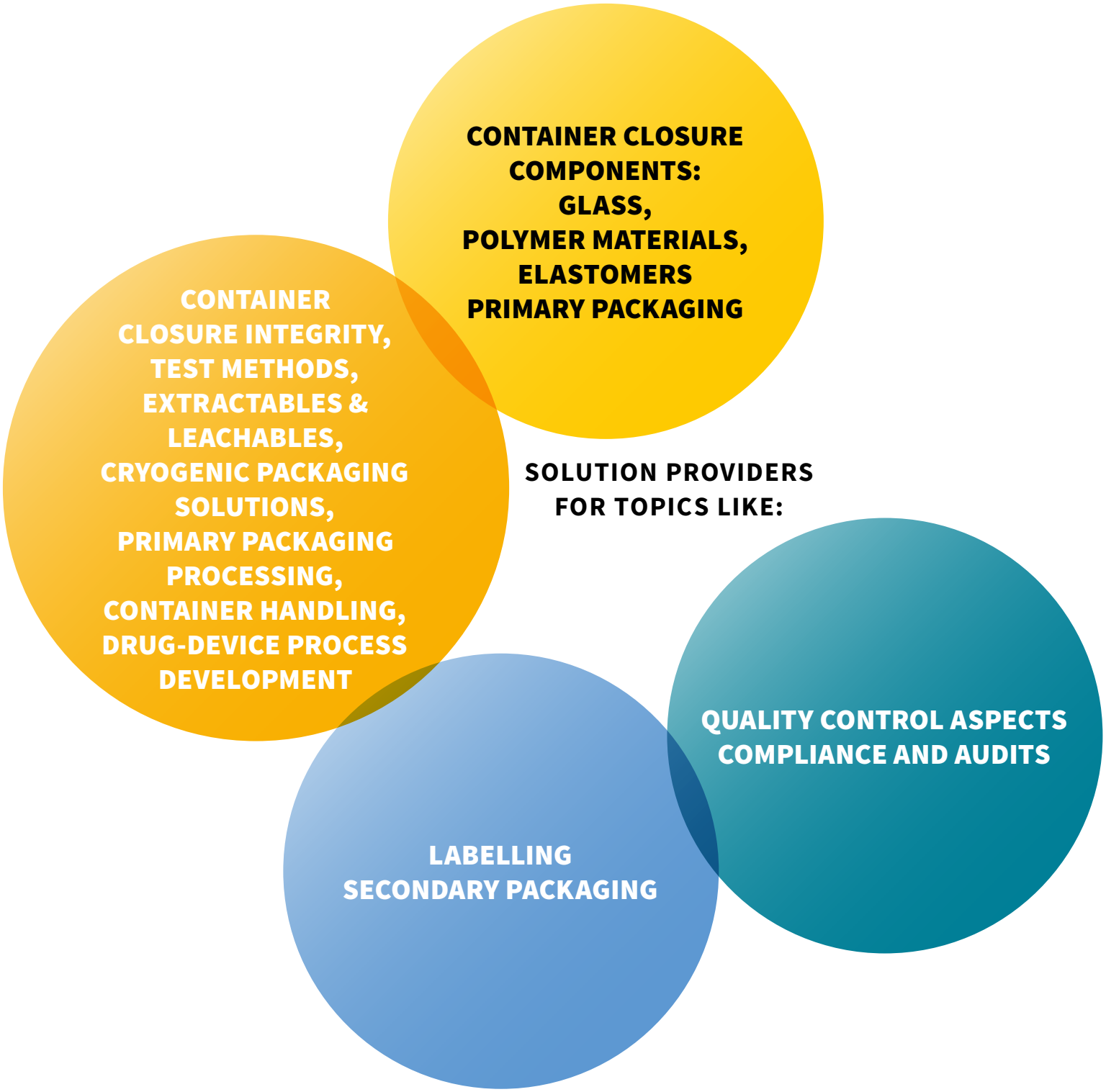
Global Healthcare of the Present & the Future

Register by 13 May 2017 and SAVE!

13-14 June 2017

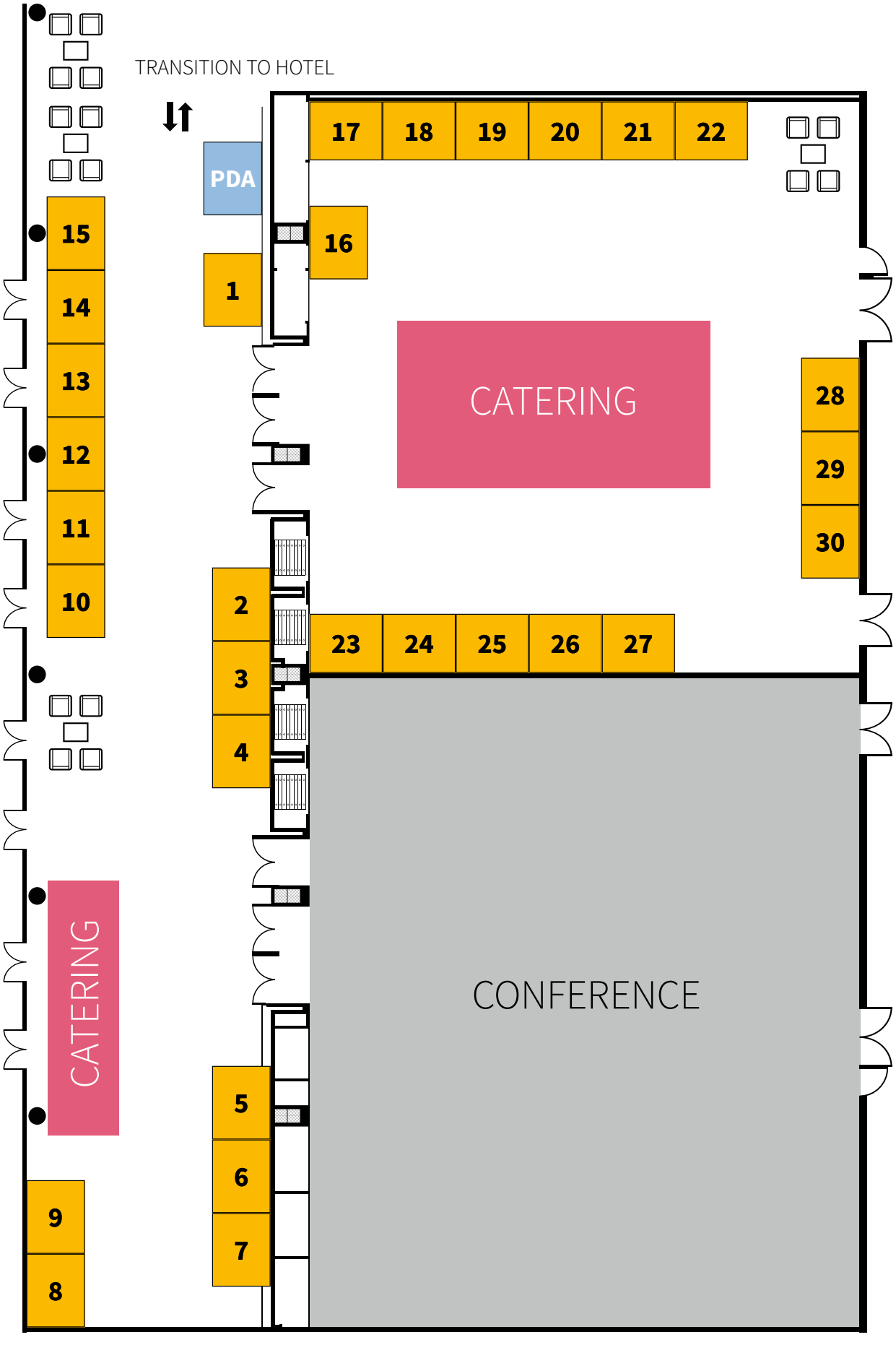
Hilton Berlin

Berlin | Germany



TO EXHIBIT:

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. Exhibition and Sponsorship Opportunities are available. A basic exhibition package for this event is priced **1.895 Euro net (table-top).** For more information please contact **expo-europe@pda.org**



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PDA Registration

Training & Education Program

europe.pda.org

PDA Education offers courses that are developed and taught by experts. They are uniquely targeted to professionals involved in the development and manufacturing of quality pharmaceutical and biopharmaceutical products.

Facts that Make a Difference

- Up-to date training courses and workshops taught by internationally renowned experts
- Wide range of training courses with hands-on experience to drive expertise, awareness, and innovation
- Customized in-house training courses and workshops available

PDA Education Program

13 March 2017
Elastomers
One-Day Training Course

13 March 2017
Secondary Packaging for Parenterals
Pre-Conference Workshop

16 March 2017
Container Closure Development
One-Day Training Course

16-17 March 2017
Container Closure Integrity Testing
Two-Day Training Course

16-17 March 2017
Track and Trace
Two-Day Training Course

16-17 March 2017
Extractables & Leachables
Two-Day Training Course

Elastomers

All participants are invited to submit their elastomer related questions, issues and practical problems until **24 February 2017** to PDA Europe training department **training-europe@pda.org**

All these and further questions will be addressed during this interactive workshop.

Overview

Among others the Agenda will cover the following topics:

- Elastomeric Compounds: Composition
- Manufacturing Process for Elastomeric Closures
- Extractables and Leachables
- Particles Reduction during Closure Processing
- Ready-for-Sterilization and Ready-To-Use Closures
- Regulatory Requirements for Elastomeric Closures

Who Should Attend

Scientific Officers, Operating Officers, Directors, Principal Scientists in

- Packaging
- Drug Product Manufacturing
- Product Design
- Technical Support
- Drug Product Process Development
- Drug Development, Design & Delivery
- Clinical Trial Material Supply
- Process Development
- Quality Assurance Compliance and Audit

Learning Objectives:

- Understand the origin of Extractables and Leachables from elastomeric closures
- Learn about the potential impact of component sterilization on closure properties
- Understand past and upcoming regulatory changes for elastomeric closures
- Learn about the effect of closure washing on visible particle reduction
- Inform yourself on possibilities and limitations in closure design
- Learn about the advantages of Ready-for-Sterilization and Ready-To-Use closures

Training Course Leader

Renaud Janssen, *Ph.D. , Head of Regulatory Affairs and Chemical Compliance, Datwyler*

Renaud Janssen graduated as a chemical engineer from Leuven University, Belgium. In 1988 he joined Helvoet Pharma, now Datwyler Sealing Solutions, in Belgium where he has been holding various positions in R&D, Quality and Technical Support on local and global level. Currently Renaud is Senior Manager Global Scientific Affairs for the Healthcare segments of Datwyler Sealing Solutions. Renaud serves on several standardization and pharmacopoeial committees.

Trainers

Bram Jongen, *Head of R&D Container Closures and Injection Systems, Datwyler*
Thomas Jochimsen, *Manager, Atec*
Reinhold Zimmermann, *Vice President Continous Improvement, West*

Monday, 13 March 2017 — 9:00 - 18:00

9:00	**Introduction** Presentation and clustering of submitted student questions, issues, and practical problems	Renaud Janssen, *Datwyler*
9:45	**What are the consequences of elastomeric compound selection for Extractables & Leachables?** • Composition of elastomeric closure compounds • Clean extractable profiles as key attribute of compound development • Translation of application requirements to closure compositions	Bram Jongen, *Datwyler*
10:30	**Coffee Break**	
10:50	**Which closure properties might be influenced by different sterilization methods?** • Extractables & Leachables, mechanical characteristics, functional performance • Steam versus gamma irradiation	Reinhold Zimmermann, *West*
11:10	**How are elastomeric closures related to ICH Q3D 'Elemental Impurities' and to pharmacopoeia ?** • Overview of pharmacopoeial requirements • Elastomeric closures in relation to 'Elemental Impurities' regulations • DMF's for elastomeric closures	Renaud Janssen, *Datwyler*
12:00	**How can helium leak testing be used for Container Closure Integrity Testing?** • A comprehensive overview of ongoing regulatory changes in the Container Closure Integrity Testing area • The most popular test methodologies explained • Method development using helium leak equipment • Some limitations using helium leak equipment	Bram Jongen, *Datwyler*
12:30	**What are the main aspects to consider for recommending closures?** • Material, drug compatibility, drug delivery, drug administration etc.	Reinhold Zimmermann, *West*
13:00	**Lunch Break**	
13:45	**How can particle reduction be qualified through stopper washing ?**	Thomas Jochimsen, *Atec*
14:30	**Which are the specific considerations pharmaceutical packaging development has to take into account when designing elastomeric components?** • An A-Z pictorial description of the closure manufacturing process Standard manufacturing | Coated closures | Lined seals	Bram Jongen, *Datwyler*
15:15	**Coffee Break**	
15:45	**Which impact do stopper elastomer material and closure processing steps have on residual moisture in the closure and in the freeze-dried product over long-term storage?** • Steam sterilization • Drying conditions	Reinhold Zimmermann, *West*
16:15	**What are the advantages of RfS and RTU closures ?** • Cost savings related to RfS and RTU elastomeric closures • Validation activities related to RfS and RTU closures • Market evaluation of RfS and RTU closures	Renaud Janssen, *Datwyler*
17:00	**Open Discussion** of student questions, issues, and practical problems with elastomers	
18:00	**End of 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:

- 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 system 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, 16 March 2017 — 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 • Plastic 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 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.

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:

ATC, Genesis Packaging Technology, Lighthouse, pti, Sartorius, Wilco

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, 16 Mar 2017 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, 17 Mar 2017 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

Jennifer Roark, *B.S., Manager Chemistry & Container Testing, Eurofins Medical Device Testing*

As Manager of Chemistry and Container Testing, Jennifer Roark oversees testing to support the container and package testing needs of both pharmaceutical and medical device clients. Her group specializes in various CCI testing technologies such as vacuum decay, high-voltage leak detection, FMS oxygen headspace, pressure decay, and dye immersion. She also supervises the physiochemical testing associated with the USP, EP, and JP General Chapters on plastics, elastomeric closures, glass, and container performance testing. Jennifer has more than 22 years of analytical testing experience and serves as one of Eurofins' leading subject matter experts for Extractables and Leachables Testing. She currently serves on ASTM Committee E55 on the Manufacture of Pharmaceutical and Biopharmaceutical Products, Subcommittee E55.04 General Biopharmaceutical Standards, leading the efforts to draft standard WK43945. Jennifer Roark has been involved with small molecule methods development and validation for over 12 years, and has co-published a series of articles on method validation.

Track and Trace

How to implement Pharma Serialization, Tamper Evidence and the EU-Falsified Medicines Directive

Overview

The training course will support you in collecting, sorting and proper understanding of the relevant contained information related to the defined two EU-safety features, which are a unique identifier, and tamper evident closures to be applied to the packaging of medicinal products within the EU 9th February 2019 the latest. Also this course will deal with the existing and emerging global serialization and track and trace requirements for medicines and their packaging in markets such as China, Korea, US and others.

Who Should Attend

This course is designed for executive and operational managers of pharmaceutical companies, especially from packaging operations, as well as IT and engineering staff, responsible for the implementation or operation of the new system. Suppliers of packaging and authentication technology and pharmaceutical packaging companies are also welcome.

Learning Objectives

It is the course's goal to inform about the latest developments in serialization & authentication coming from the EU directive 2011/62/EC and the corresponding Delegated Regulation as published in the Official Journal of the European Union. Generally the challenges and solutions how to comply with serialization, tamper verification and packaging requirements of medicinal products in the different markets are core content of this course. Best practice examples will demonstrate how the new European requirements on verification of the authenticity of each single medicinal product can be put into practice.

Dieter Mößner, *Project Engineer Pharma, Edelmann GmbH*

For 19 years, Dieter has been working as a team leader in the pre-press area at Edelmann GmbH, responsible for artwork services and for print data communication. Dieter composed parts of the guidelines "Braille on Folding Cartons", published by the European Carton Makers Association ECMA. He is Convenor of CEN/TC 261/SC 5/WG 12 "Marking". This working group at the European Committee for Standardisation CEN has created the European standards EN 15823:2010 "Braille on Packaging for Medicinal Products" and EN 16679:2014 "Tamper Verification Features for Medicinal Product Packaging". Since March 2013, he has been chairman of the packaging standards committee NAVp at the German Standards Institute DIN.

Thomas Brueckner, *Head of Pharmaceutical Affairs, Medical Devices, Counterfeit Protection, Pharmacopoeial Matters and Standardization, BPI e.V.*

Since 2003 Thomas Brueckner holds the position as Head of Pharmaceutical Affairs, Medical Devices, Counterfeit Protection, Pharmacopoeial Matters and Standardization at BPI e.V. He is member of various DIN, CEN and ISO committees, the Board of Trustees of the Foundation for the Promotion of Standardization in the field of medicine, of the German Pharmacopoeia Commission and the Homeopathic Pharmacopoeia Commission and of the Executive Board of "securPharm e.V." From 1992 - 2003 he worked as Control Manager , Information Officer and DRA Manager at different pharmaceutical companies. Thomas Brueckner holds a diploma in Pharmacy from Martin Luther University of Halle-Wittenberg and a degree as Healthcare economist (ebs) from the European Business School in Oestrich-Winkel.

Klaus Egner, *Engineering and Maintenance, Merck*

Klaus Egner started his career in the area of automation at Merck in 1998. At first, he was responsible for laboratory and pilot plant units. From 2005 on he worked in the automation area, e.g. MES, production and packaging of solid dose. Since 2011 his focus topic is Track & Trace in Packaging. Klaus Egner obtained his degree in Engineering from Technical University Darmstadt . Additionally, he passed a continuing education as Master of Technical Management (CCI).

Thursday, 16 March 2017		9:00 – 18:30
9:00	**Welcome – Overview and Target of the Training Course**	
9:15	**Overview Global Serialization Requirements**	Thomas Brueckner
10:10	**Coffee Break**	
10:30	**Requirements EU-Falsified Medicines Directive 2019/securPharm**	Thomas Brueckner
11:15	**Implementation of Serialization – Technical Challenges**	Klaus Egner
12:00	**Lunch Break**	
13:00	**Print Quality of Barcodes and 2D Matrixcodes**	Dieter Moessner
13:45	**How to Comply to Serialization – Regulatory Tasks**	Thomas Brueckner, Klaus Egner
14:45	**Coffee Break**	
15:00	**Site Visit at a Packaging Manufacturer Facility**	Site Visit Requested
18:30	**End of Day 1**	

Friday, 17 March 2017		8:30 – 16:00
08:30	**DIN EN 16679 "Tamper Verification Features for Medicinal Product Packaging" – Practical Implementation**	Dieter Moessner
09:15	**Barcodes in the Pharmaceutical Manufacturing Process**	Dieter Moessner
10:00	**Coffee Break**	
10:30	**Technical and Organizational Implementation of Serialization at the Pharmaceutical Manufacturer**	Klaus Egner
11:30	**Coding / Serialization / Artwork at the Manufacturer of Printed Packaging Materials**	Dieter Moessner
13:00	**Lunch Break**	
14:00	**Coding Rules for Medicines Requiring Verification / securPharm**	Thomas Brueckner Klaus Egner
15:00	**Qualification and Validation of Serialization and Tamper Verification Technologies in Pharma Packaging**	Dieter Moessner
15:30	**Coffee Break**	
15:30	**Current Developments, Q & A, Discussion**	Dieter Moessner
16:00	**End of Course**	

Extractables & Leachables

Including: Important Regulatory Updates – Case Study Section: Selection of Toxikon's 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 form 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, 16 March 2017 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

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 its 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 the European business development team.

Friday, 17 March 2017 9:00 – 16:30

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 extractable & leachable 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, *Director of Extractables/Leachables and Impurities, Albany Molecular Research, Inc. (AMRI)*

John Iannone has a background in Biomedical Engineering from Boston University, where he later became a research engineer. Since going from Academia to Industry 13 years ago, John has assisted multiple pharmaceutical & medical device companies with the development of their product safety evaluation strategies. Previously a Technical Specialist at Toxikon, he now is the Director of Extractables/Leachables and Impurities at Albany Molecular Research, Inc (AMRI). 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 several 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. Additional responsibilities have included providing technical consultation to clients regarding unique testing requirements in an effort for them to meet global regulatory expectations.

The Parenteral Drug Association presents:

2017 PDA Europe Conference, Exhibition

The Universe of Pre-filled Syringes & Injection Devices

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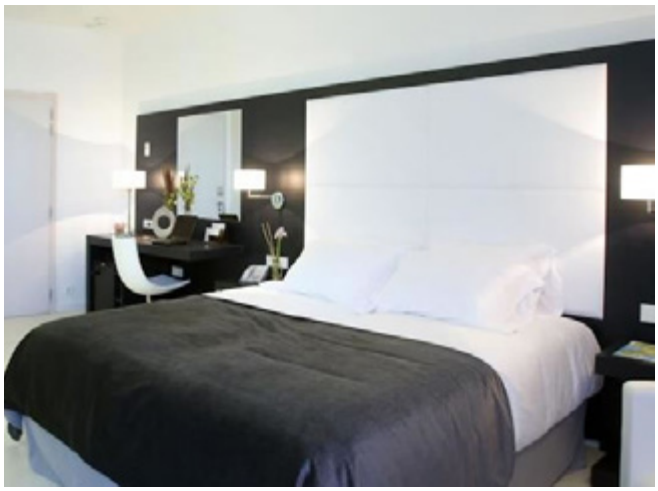
SPECIAL REQUIREMENTS

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



14-15 March 2017 | Barcelona | Spain

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1 Registration

EARLY BIRD DISCOUNT ☐ Book by 8 January to receive € 150* off the conference fee only

All fees given in Euro, excluding VAT (21 %)

13 March	**Interest Group Meeting**	**IG Meeting Fee**		
IG Meeting Pre-filled Syringes		All Participants	☐	**400**
13 March	**Pre-Conference Workshop**	**Workshop Fee**		
Secondary Packaging for Parenterals		All Participants	☐	**450**
13 March	**One-Day Training Course**	**Training Course Fee**		
Elastomers		All Participants	☐	**845**
14-15 March	**Conference only**	**Conference Fee**		
Parenteral Packaging		PDA Member	☐	**1495**
		**Nonmember	☐	**1795**
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16 March	**One-Day Training Course**	**Training Course Fee**		
Container Closure Development		All Participants	☐	**845**
16-17 March	**Two-Day Training Course**	**Training Course Fee**		
Container Closure Integrity: Regulations, Test Methods, Application		All Participants	☐	**1495**
16-17 March	**Two-Day Training Course**	**Training Course Fee**		
Track and Trace: How to implement Pharma Serialization, Tamper Evidence and the EU-Falsified Medicines Directive?		All Participants	☐	**1495**
16-17 March	**Two-Day Training Course**	**Training Course Fee**		
Extractables & Leachables		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.

****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

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- 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.)
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2017 PDA EUROPE CONFERENCES

14 – 15 February	Pharmaceutical Microbiology	* Porto, Portugal
14 – 15 March	Parenteral Packaging	* Barcelona, Spain
26 – 27 April	Current Trends in Aseptic Fill & Finish of Prefilled Syringes	* Lindau, Germany
30 May – 1 June	Virus & TSE Safety Forum	* Dubrovnik, Croatia
13 – 14 June	2nd PDA Europe Annual Meeting	* Berlin, Germany
27 – 28 June	Advanced Therapy Medicinal Products	* Valencia, Spain
19 – 20 September	Pharmaceutical Freeze Drying Technology	* Cologne, Germany
26 – 27 September	10th Workshop on Monoclonal Antibodies	* Berlin, Germany
10 – 11 October	Pharmaceutical Cold & Supply Chain Logistics	* Prague, Czech Republic
7 - 8 November	The Universe of Pre-filled Syringes and Injection Devices	* Vienna, Austria
21 – 22 November	Outsourcing & Contract Manufacturing	* Munich, Germany

Subject to change

For latest info: **pda.org/pda-europe**

Shortlist
1. February 2017, 4:12 PM

*** Events with additional Education Program. More information – pda.org/pda-europe**

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