Dear Colleagues,

On behalf of PDA Europe and the Scientific Program Planning Committee, welcome to our ongoing professional discourse of latest manufacturing technologies and business trends in the Parenteral Packaging arena!

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 share detailed information about opportunities and challenges the advancing pharmaceutical packaging market faces.

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 offers a comfortable yet exciting atmosphere for exchange during refreshment breaks, on-site lunches and evening receptions.

Welcome to Barcelona!

Roger Asselta, Genesis Packaging, Co-Chair
Derek Duncan, LIGHTHOUSE, Co-Chair
Bettine Boltres, SCHOTT
Renaud Janssen, Datwyler
Enric Jo, Reig Jofré
Roman Mathaes, LONZA
Galen Shi, Eli Lilly
Michael Spallek, Rommelag ENGINEERING
Daniel Wagner, Sanofi
Klaus Wuchner, Janssen J&J
Jörg Zürcher, Bayer
Sylvia Becker, PDA Europe
Georg Roessling, PDA Europe
### Schedule at a Glance

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Event</th>
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</table>
| 13 March | 19:30 – 22:00 | Welcome Reception<br>
|       |            | proudly presented by Rommelag ENGINEERING                           |
| 14 March | 9:00 – 19:00 | Parenteral Packaging<br>
| 14 March | 19:00 – 22:30 | Networking Event at “Can Cortada”                                    |
| 15 March | 8:00 – 9:00 | Open Forum: Packaging Science<br>
|          |             | Interest Group (IG) Meeting                                         |
| 15 March | 9:00 – 17:00 | Parenteral Packaging<br>
| 16 March | 9:00 – 17:00 | Container Closure Development<br>
| 16 March | 9:00 – 18:00 | Container Closure Integrity Testing<br>
| 17 March | 9:00 – 16:30 | Training Course                                                     |
| 16 March | 9:00 – 18:30 | Track and Trace<br>
| 17 March | 8:30 – 16:00 | Training Course                                                     |
| 16 March | 9:00 – 18:00 | Extractables & Leachables<br>
| 17 March | 9:00 – 16:30 | Training Course                                                     |

Join [@PDA_Europe](https://twitter.com/PDA_Europe) on Twitter and post pictures and highlights of this meeting! #pdapackaging

Follow us on [LinkedIn](http://linkedin.com/company/pda)
CONTAINER CLOSURE INTEGRITY (CCI)
A global leader in CCI, we deliver numerous state-of-the-art options for assessing package system integrity as outlined in USP <1207>.

CONTAINER TESTING
We provide testing of all containers and components and are fully functional on the new USP <661>.

PACKAGING AND DISTRIBUTION
Our laboratory covers all ISTA and ASTM requirements for your package and distribution testing needs.

MICROBIOLOGY
Antimicrobial effectiveness, enumeration, specified microorganisms, biological reactivity and water for pharmaceutical purposes.

EXTRACTABLES/LEACHABLES AND IMPURITIES
We are capable of determining extractables/leachables and impurities in bio/pharmaceutical products.

ANALYTICAL SERVICES
We offer heavy metals testing in accordance with USP <232> and <233>, ICP-MS testing and testing for residual solvents and other materials.

MEDICAL DEVICE AND DRUG DELIVERY
We perform physical and functional testing for drug delivery devices and ISO 11608, “Needle-Based Injection Systems for Medical Use — Requirements and Test Methods.”

VISIT US AT PDA AT TABLETOP 22
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 Audience Response System: Getting involved

9:30 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

10:10 EU Updates & Inspection Findings
Manuel Ibarra, AEMPS

10:40 Ongoing Revision on USP Chapter <381>, Elastomeric Closures for Injection
Renaud Janssen, Datwyler

11:10 Ongoing Revision on USP Chapters <660> and <1660>
Bettine Boltres, Schott

11:40 What’s New in Japanese Pharmacopoeia 17 – A User’s Perspective
Jörg Zürcher, Bayer

12:10 Q&A, Discussion

12:30 Lunch Break, Poster Session & Exhibition

PARALLEL TRACKS 1

<table>
<thead>
<tr>
<th>TRACK A</th>
<th>TRACK B</th>
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<tbody>
<tr>
<td>Components &amp; Materials</td>
<td>Processing</td>
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</tbody>
</table>

Moderator: Bettine Boltres, Schott
Moderator: Michael Spallek, Rommelag ENGINEERING

13:30 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
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>14:00</td>
<td>Premium Technology for Primary Glass Container Surface Control and Drug Stability</td>
<td>Dave Lisman, Nipro Pharma Packaging</td>
<td>Elke Sternberger-Ruetzel, Harro Hoefliger</td>
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<td>14:30</td>
<td>X-Cartridge: A New Generation of Glass Primary Containers for Modern Drug Delivery Devices (DDD)</td>
<td>Alessandro Morandotti, Ompi</td>
<td>Q&amp;A, Discussion</td>
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<tr>
<td>15:00</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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<td>Moderator: Michael Spallek, Rommelag ENGINEERING</td>
<td>Moderator: Galen Shi, Eli Lilly</td>
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<tr>
<td>15:30</td>
<td>Ethylene-Norbornene Copolymers as High Purity Olefinic TPEs for Primary Packaging</td>
<td>Wilfried Hatke, TOPAS Advanced Polymers</td>
<td>Bringing a Valuable Technology a Step Further: Advances in Vial Isolation 2017</td>
</tr>
<tr>
<td>16:00</td>
<td>Impact of the New USP &lt;661&gt; Guidance – a Resin Supplier’s View</td>
<td>James Stern, Borealis</td>
<td>How the Adoption of Single Use Systems (SUS) Improves the Safety, Efficiency and Flexibility of Final Filling Processes</td>
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<td>16:30</td>
<td>Q&amp;A, Discussion</td>
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<td>Components &amp; Glass</td>
<td>Process Analysis</td>
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<td>Moderator: Jörg Zürcher, Bayer</td>
<td>Moderator: Klaus Wuchner, Janssen J&amp;J</td>
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<tr>
<td>17:30</td>
<td>Risk Mitigation Addressing the Delamination Propensity of Tubular Glass Vials</td>
<td>Volker Rupertus, Schott</td>
<td>Glass Packaging Breakages: Optimization of Container Filling Lines by In-situ Shock-Logger Detection Investigation</td>
</tr>
<tr>
<td>18:00</td>
<td>Evaluation of Glass Delamination in Pharmaceutical Vials</td>
<td>Dominique Ditter, Hoffmann-La Roche</td>
<td>Finding the Weak Points in the Filling Line: Force Analysis by In-Line Monitoring</td>
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<td>Process Analysis</td>
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<td><strong>18:30</strong></td>
<td><strong>18:45</strong></td>
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<tr>
<td>Addressing Cracks in Pharmaceutical Containers with new Glass Material</td>
<td>Q&amp;A, Discussion</td>
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<td>Kyle Hoff, Corning</td>
<td>Q&amp;A, Discussion</td>
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<tr>
<td>Reducing Vial Breakage and Protecting Handlers of Highly Potent Drugs</td>
<td>Hironori Yoshida, Nipro Pharma</td>
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</tbody>
</table>

**19:00 End of Conference Day 1**

**19:30 Networking Event in Barcelona**

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*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**

19:30 - Shuttle Bus leaving  
20:00 - Dinner  
22:30 - Shuttle Bus returning to the Hotel Porta Fira
## Wednesday, 15 March 2017

### MORNING SESSION

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>8:00</td>
<td>Open Forum: Packaging Science Interest Group (IG) Meeting</td>
<td>Derek Duncan, LIGHOUSE</td>
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<td><strong>Parallel Tracks 3</strong></td>
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<td><strong>TRACK A</strong></td>
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<td></td>
<td><strong>Novel Sealing Concepts for Lyophilized Products</strong></td>
<td><strong>Modeling</strong></td>
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<td></td>
<td>Moderator: Roger Asselta, Genesis Packaging</td>
<td>Moderator: Derek Duncan, LIGHOUSE</td>
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<tr>
<td>9:00</td>
<td>Challenges for Vial Sealing in the Freeze Dryer</td>
<td>Michele Arduini, IMA Life</td>
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<td>The Appearance of Plastic Caps as a New Sealing Solution</td>
<td>Mike Schäfers &amp; Kolja Richlowski, WEST</td>
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<td>Using a Process Control Strategy to Enable an Adequate Container Closure System</td>
<td>Yusuf Oni, Bristol-Myers Squibb</td>
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<td>9:30</td>
<td>Q&amp;A, Discussion</td>
<td>Q&amp;A, Discussion</td>
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<tr>
<td>10:00</td>
<td>Using a Process Control Strategy to Enable an Adequate Container Closure System</td>
<td>Yusuf Oni, Bristol-Myers Squibb</td>
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<td>10:30</td>
<td>Q&amp;A, Discussion</td>
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<td>11:00</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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<td><strong>Parallel Tracks 3</strong></td>
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<td><strong>TRACK A</strong></td>
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<td></td>
<td><strong>CCI at Cryogenic Conditions</strong></td>
<td><strong>Pharmaceutical Companies’ Challenges</strong></td>
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<td>Moderator: Roman Mathaes, LONZA</td>
<td>Moderator: Daniel Wagner, Sanofi</td>
</tr>
<tr>
<td>11:30</td>
<td>Modeling of Container Closure for Cryogenic Storage of Parenteral Drug Products</td>
<td>Ronald Iacocca, Eli Lilly</td>
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<tr>
<td>12:00</td>
<td>Utilize Helium Leak Detection to Inform Packaging System Design - A Pre-filled Syringe Case Study</td>
<td>Lei Li, Eli Lilly</td>
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<tr>
<td>12:30</td>
<td>Q&amp;A, Discussion</td>
<td>Q&amp;A, Discussion</td>
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<td>13:00</td>
<td>Lunch Break, Poster Session &amp; Exhibition</td>
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<tr>
<td>14:00</td>
<td>An Industry Perspective on Application of CCIT for Sterile Biotech Products</td>
<td>Roman Mathaes, LONZA &amp; Klaus Wuchner, Janssen J&amp;J</td>
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<tr>
<td>14:30</td>
<td>USP Update on CCIT</td>
<td>Donald Singer, USP</td>
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<tr>
<td>15:00</td>
<td>A Case Study for a Renovated Approach to Seal Quality and Container Closure Integrity Testing across the Lifecycle of Sterile Products</td>
<td>James Mellman, Novartis</td>
</tr>
<tr>
<td>15:30</td>
<td>The Effect of a Plunger Surface Roughening Treatment on CCI: Evaluation of Inherent Package Integrity by Helium Leak Detection in the Vacuum Mode</td>
<td>Brandon Zurawlow, Whitehouse Labs</td>
</tr>
<tr>
<td>16:00</td>
<td>CCI Test Method Development using Headspace Analysis to Measure Gas Flow into a Defective Container</td>
<td>Derek Duncan, LIGHTHOUSE</td>
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<tr>
<td>16:30</td>
<td>Panel Discussion: Container Closure Integrity</td>
<td>Moderators: Roger Asselta, Genesis Packaging, Bettine Boltres, Schott</td>
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<td>Panelists:</td>
<td>• Donald Singer, USP</td>
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<td>• Derek Duncan, LIGHTHOUSE</td>
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<td>• Roman Mathaes, LONZA</td>
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<td>17:00</td>
<td>End of Conference &amp; Farewell</td>
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<td>Exhibitor</td>
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<td>Aften Scientific</td>
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<td>AMRI</td>
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<td>Bausch Advanced Technology Group</td>
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<td>Corning</td>
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<td>Genesis Packaging Technologies</td>
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<td>IGS GeboJagema</td>
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<td>IWATA LABEL Europe</td>
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<td>KISICO GmbH</td>
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<td>LIGHTHOUSE Instruments</td>
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<td>Nipro PharmaPackaging</td>
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<td>OMPI - A Stevanato Group Brand</td>
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<td>PTI Inspection Systems</td>
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<td>Rommelag ENGINEERING</td>
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<td>SCHOTT AG</td>
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<td>Seidenader Maschinenbau GmbH</td>
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<td>Smart Skin Technologies</td>
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<td>SiO2 Medical Products, Inc.</td>
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<td>Smithers</td>
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<td>Toxicon Europe NV</td>
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<td>West Pharmaceutical Services</td>
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<td>West Pharmaceutical Services Deutschland, GmbH &amp; Co. KG</td>
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<td>WILCO AG</td>
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Sponsor
EXHIBITION FLOORPLAN

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PDA Registration

Table Top 2 m x 2,5 m (5m²)
PDA #pdapackaging
Afton Scientific
2020 Avon Ct.
22902 Charlottesville, VA, USA
Tel. +1 434 979 3737
Fax. +1 434 979 3738
info@aftonscientific.com
www.aftonscientific.com

Afton is also the world premiere provider of pre-packaged empty sterile vials, stoppers and seals (Ready-to-Fill®) to companies worldwide for immediate use in cGMP aseptic filling operations. These components are used not only for small clinical fills, but also for approved marketed injectable drugs. Afton (DBA AnovaFill) provides cGMP contract sterile filling services of investigative new drugs, biologics, and commercial injectable pharmaceuticals. Capabilities to batch, sterilize, fill, label, and package. We specialize in small batch clinical and commercial runs. AnovaFill is a part of Afton Scientific. Afton's customers include small biotechs, multinational pharmaceutical companies and major research institutions. Afton ships worldwide.

AMRI
26 Corporate Circle
12212 Albany, United States
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info@amriglobal.com
www.amriglobal.com

Albany Molecular Research Inc. (AMRI) is a global contract research and manufacturing organization that has been working with the Life Sciences industry to improve patient outcomes and the quality of life for more than twenty-five years. With locations in North America, Europe and Asia, our key business segments include Discovery and Development Solutions (DDS), Active Pharmaceutical Ingredients (API), and Drug Product Manufacturing (DPM). Our DDS segment provides comprehensive services from hit identification to IND, including expertise with diverse chemistry, library design and synthesis, in vitro biology and pharmacology, drug metabolism and pharmacokinetics, as well as natural products. API supports the chemical development and cGMP manufacture of complex API, including potent, controlled substances, biologics, peptides, steroids, hormones, cytotoxic compounds and sterile API. DPM supports development through commercial scale production of complex liquid-filled and lyophilized parenterals, sterile suspensions and ophthalmic formulations. For more information about AMRI, please visit our website at www.amriglobal.com or follow us on Twitter (@amriglobal).

Bausch Advanced Technology Group
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07607 Hainspitz, Germany
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Fax. +49 36691 868914
fec@bausch-group.com
www.bausch-group.com

Bausch Advanced Technology Group designs, manufactures and markets a full line of innovative and customized packaging solutions dedicated to the pharmaceutical and biotechnology industries. Our product range includes semi-automatic machines as well as high-speed machines for the aseptic primary packaging of syringes, vials, cartridges, ampoules and IV bags.

Bausch + Ströbel
Maschinenfabrik Ilshofen GmbH + Co. KG
Parkstr. 1
74532 Ilshofen
Germany
Tel: +49 7904 70 10
Fax: +49 7904 70 12 22
info@bausch-stroebel.com
www.bausch-stroebel.com

The Bausch + Ströbel product range specializes in machines for pharmaceutical primary packaging, including equipment for washing, sterilising/depyrogenating, filling, closing and labelling of containers such as ampoules, cartridges, disposable syringes, vials and bottles of all kinds. Our systems are designed to comply with the latest FDA and GMP requirements and are available for all capacity ranges, starting from process development and clinical batches to fully integrated commercial production.
BD provides a broad range of microbiological solutions for industrial applications. From quality control for raw materials to product release, BD has the proven ability to fulfill your microbiology needs. You will have the assurance of continuous supply from a reliable, global partner.

Corning
One Riverfront Plaza
14831 Corning, USA
Tel. +1 607 974 9000
pharma@corning.com
www.corning.com

Corning is a world-leading innovator in materials science. For over 165 years, we have applied our unparalleled expertise in glass science and precision process technologies to solve tough industry challenges and transform lives. Our innovations enhance quality and drive efficiencies in every industry that we serve. Learn more about Corning Pharmaceutical Technologies’ solutions and services for the pharmaceutical industry.

Genesis Packaging Technologies
435 Creamery Way, Suite 100
19341 Exton PA, United States
Tel: +1 800 552 9980
Fax: +1 610 458 4939
info@gen-techno.com
www.gen-techno.com

Genesis Packaging Technologies is a worldwide leader in the science and technology of parenteral vial sealing and residual seal force testing. We provide the best capping equipment in the world and we offer both the global service and technical support to back it up. Offering our customers the tools and knowledge to consistently achieve container closure integrity remains our priority.

IGS GeboJagema
Esp 430
5633 AJ Eindhoven, The Netherlands
Tel.: +31 40 647 500
Fax: +31 40 647 591
jw.denhollander@igsgebojagema.nl
www.igsgebojagema.nl

As a Parental Packaging company, you may have a great idea for a packaging that will give you a competitive edge. But first you have to find a way to manufacture it according to the strict regulatory requirements for diagnostic/medical devices. IGS GeboJagema can help. For over 65 years, we have been delivering high precision moulds for some of the most successful primary drug packaging for metered dose inhalers, insulin pens and other drug delivery medical devices in the world. Many of the key players in the pharmaceutical/medical industry bring their toughest product challenges to IGS GeboJagema. That’s because we provide the solutions they need to help them innovate new products. Our problem-solving mindset, proven track record in the diagnostic industry, considerable medical experience and meticulously methodical way of working ensures you the highest quality, process control and traceability needed for your medical products. We make moulds for parental packaging products you still have to design.

IWATA LABEL Europe
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40212 Düsseldorf, Germany
Tel. +49 211 5403 9784
toshiaki_kurihara@iwatalabel.co.jp
www.iwatalabel.com

IWATA LABEL Europe GmbH is a specialty manufacturer of adhesive labels and labeling machines for pharmaceutical products. Our products add high value and multiple functions to pharmaceutical labeling needs. The need for labeling solutions, which protect medical staff, greatly helps us focus on innovation and develop new products and services.

KISICO GmbH
Rieslingstr. 41
65375 Oestrich-Winkel, Germany
Tel. +49 6723 99650
Fax. +49 6723 9965550
verkauf@kisico.de
www.kisico.de

KISICO is a German producer of screw caps, laboratory caps, 2 and 3 component caps, desiccant caps, child resistant caps, tamper evident caps and caps with brushes or spoons. The clients of these caps are mostly from the diagnostic and pharmaceutical industry. Our R&D department will help you with the realization of your customized solution, but you can also choose from the wide range of our standard program.
LIGHTHOUSE Instruments
Science Park 408
1098 XH, Amsterdam, The Netherlands
Tel: +31 6 4226 7380
duncan@lighthouseinstruments.com
www.lighthouseinstruments.com

LIGHTHOUSE is the leading global provider of laser-based, non-destructive headspace inspection systems. LIGHTHOUSE introduced the laser-based headspace method into the pharmaceutical industry in 2000 and offers a range of benchtop and in-line platforms with patented laser sensor technology commercialized with the help of funding from the Food and Drug Administration. In addition to delivering equipment, Measurement Services & Support are delivered from laboratory facilities in Amsterdam and Charlottesville, Virginia. A staff of Application Scientists supports customers with outsourced testing services, scientific studies, and lease equipment projects.

OMPI - A Stevanato Group Brand
Via Molinella, 17
35017 Piombino Dese, Italy
Tel: +39 04 993 18611
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info@ompipharma.com
www.ompipharma.com

OMPI is part of the Pharmaceutical Systems division of Stevanato Group and boasts a unique expertise in providing superior pharmaceutical containers from glass tubing. With operations in Italy, Slovakia, Mexico and China, Ompi offers the widest range of glass primary packaging, from the traditional ones such as vials and ampoules, to the high value ones as syringes and cartridges for auto-injectors and pen-injectors. Vials, cartridges and syringes are available also sterile and ready to fill (Ompi EZ-fill®).

Pipiln PharmaPackaging
Weihoek 3h
1930 Zaventem, Belgium
Tel. +32 2 725 55 33
Fax. +32 2 725 70 41
info@nipro-pharmapackaging.com
www.nipro-pharmapackaging.com

Nipro PharmaPackaging (NPP) is specialized in developing and manufacturing advanced pharma packaging products and complete packaging solutions for early development drugs or enhancement of packaging solutions of existing drugs. With a worldwide manufacturing footprint of 19 plants, multiple sales offices and lab services, Nipro offers an exceptional service platform. Through its personnel, products and services, Nipro PharmaPackaging enables you to provide a safer and healthier administration to your customers. NPP is part of the Japanese Nipro Corporation, established in 1954. With over 20,000 employees worldwide, as a leading global healthcare company, Nipro serves the “Pharmaceuticals”, “Medical devices” and “Pharma packaging” industries.

PTI Inspection Systems
145 Main Street
10707 Tuckahoe, USA
Tel. +1 914 337 2005
Fax +1 914 337 8519
info@ptiusa.com
www.ptiusa.com

PTI is a global leader in package testing equipment. We manufacture non-destructive inspection technologies for package integrity testing, leak detection, container closure integrity, and seal integrity testing analysis. PTI’s inspection technologies are deterministic, non-subjective test methods that produce reliable, quantitative test data. Applications include all parenteral products as well as blister packs and may other packaging formats. Our technologies conform to ASTM, USP <1207> and other regulatory standards. We specialize in offering our customers comprehensive solutions including test method development.

Rommelag ENGINEERING
Fabrikweg 16
5003 Buchs, Switzerland
Tel. +41 62 834 55 55
Fax. +41 62 834 55 00
mail.rch@rommelag.com
www.rommelag.com

Rommelag, the inventor of Blow-Fill-Seal (BFS) Technology, is the worldwide leading manufacturer and supplier of BFS bottelpack® aseptic machines for the packaging of sterile liquids, creams and ointments. Rommelag ENGINEERING also manufactures leak detectors, cap welding machines and inspection systems which can be integrated inline into the packaging system. The machine capacities reach up to 30,000 containers per hour depending on container sizes which vary from 0.1 ml to more than 1,000 ml. Plastic materials used are PE, PP and others. For customer-specific container and closure developments as well as for test and contract fillings own laboratory test and production utilities are available.
SCHOTT AG
Hattenbergstr. 10
55122 Mainz, Germany
Tel. +49 6131 66 1589
Fax. +49 6131 66 1916
pharmaceutical_packaging@schott.com
www.schott.com/pharma

SCHOTT Pharmaceutical Systems is one of the world’s leading suppliers of glass tubing and primary packaging for the pharmaceutical industry. We provide our customers quality solutions while meeting their highest demands with our material expertise, specialized analytical lab services, and a broad product portfolio; including syringes, cartridges, vials, and ampoules made of glass and COC polymer. With our extensive production network of glass tubing and pharmaceutical packaging, we offer safe supply and local service. Our state-of-the-art production facilities and our products comply with the highest international quality standards for pharmaceutical needs.

Seidenader Maschinenbau GmbH
Lilienthalstr. 8
85570 , Markt Schwaben, Germany
Tel: +49 8121 802 0
Fax: +49 8121 802 100
info@seidenader.de
www.seidenader.de

Seidenader is a competent partner to pharmaceutical companies, specialized in solutions for inspection and track&trace. We develop and build inspection machines and applications for manufacturers all over the world. State-of-the-art serialization and aggregation solutions for the traceability of products and for the protection from counterfeiting are part of the comprehensive Seidenader Track&Trace Solutions. As an innovative and well-established company with more than 120 years of experience in the market Seidenader is now one of the leading suppliers for inspection and track&trace solutions, worldwide. Seidenader is part of Medipak Systems, the Pharma Systems business area of the international Körber technology group.

Smart Skin Technologies
527 Queen St. Suite 210
E3B188 Fredericton Canada
Tel: +1 506 206 8778
info@smartskintech.com
www.smartskintech.com

At Smart Skin, we believe the first step in management is measurement. We market a smart-sensor based quality assurance platform that enables customers to measure and manage previously unmeasurable adverse forces experienced by containers throughout their operations and supply chain. Smart Skin’s patented QuantifeelTM platform utilizes wireless smart sensor vials to simultaneously stream production and quality information pertaining to pressure, shock, rotation, tilt, and precise line location to a tablet PC running our award-winning visualization software.

SIO2 Medical Products, Inc.
350 Enterprise Drive
36832 Auburn, AL, USA
Tel: 334-321-5000
Fax: 334-321-5005
sio2-info@sio2med.com
www.sio2med.com

SiO2 Medical Products manufactures precision-molded primary containers molded from medical grade engineered polymer, such as cyclic olefin polymer (COP). SiO2’s products incorporate a silicon-based barrier coating system that combines the durability, pH stability, and dimensional consistency of plastic with the barrier properties and low extractables of silica glass (i.e., quartz). The containers have unique features not found in any containers on the market today and are ideally suited for sensitive, biopharmaceutical drugs. On-line inspection systems deliver containers meeting a six-sigma quality level for critical defects and each container has a unique ID for unparalleled track and trace capabilities.

Smithers
Shawbury SY4 4NR
Shrewsbury, United Kingdom
Tel: +44 1939 250383
info@smithers.com
www.smithersrapra.com

Smithers is a world leader in rubber, plastics and composites testing. We provide independent polymer and packaging expertise to companies across the medical device supply chain. Our services include device, primary pack and shipment testing along with extractable and leachable testing for products, devices, and manufacturing systems.
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3001 Leuven, Belgium
Tel: +32 16 38 12 11
Ireen.stanford@terumo-europe.com
www.terumo-ps.com

Terumo Pharmaceutical Solutions Carefully Crafted We develop alliances with pharmaceutical companies on a global scale, using Terumo technology to develop, manufacture and supply carefully crafted solutions to their injectable drug delivery challenges. We pride ourselves on offering a full portfolio of products and services for the pharmaceutical industry, backed by unrivalled scientific expertise and know-how. By anticipating new trends and maintaining a constant dialogue, we provide a first class customer experience.

Toxikon Europe NV
Romeinsestraat 12
3001 Leuven, Belgium
Tel: +32 164 004 84
Fax: +32 164 013 04
info@toxikon.be
www.toxikon.be

Toxikon Europe, an FDA registered and ISO 17025 accredited CRO, contracts and partners with Pharmaceutical, Biotech and Medical Device industries to deliver worldwide analytical and microbiological compliances and release testing. Toxikon has great expertise in: Extractables and Leachables testing - (Bio)Pharmaceutical services - Microbiology services - Medical Devices testing We provide services with state-of-the-art equipment and the technical expertise of our people to generate timely reports with high quality data. Contact details: info@toxikon.be – www.toxikon.be

West Pharmaceutical Services
Deutschland, GmbH & Co. KG
Stolberger Straße 21-41
52249 Eschweiler, Germany
Tel. +49 2403 7960
West.Pharmaceutical.Services@westpharma.com
www.westpharma.com

West Pharmaceutical Services, Inc. is a leading manufacturer of packaging components and delivery systems for injectable drugs and healthcare products. Working by the side of its customers from concept to patient, West creates products that promote the efficiency, reliability and safety of the world’s pharmaceutical drug supply. West is headquartered in Exton, Pennsylvania, and supports its customers from locations in North and South America, Europe, Asia and Australia. West’s 2015 sales of $1.4 billion reflect the daily use of approximately 110 million of its components and devices, which are designed to improve the delivery of healthcare to patients around the world.

WILCO AG
Rigackerstrasse 11
5610 Wohlen, Switzerland
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Fax. +41 566 184 344
info@wilco.com
www.wilco.com

WILCO AG provides in-line, off-line and laboratory machines with non-destructive testing methods for monitoring the oxygen content and container closure integrity simultaneously. Our patented leak detection methods based on the process analytical technologies (PAT) offers the opportunity for monitoring the finishing processes as well. We have newly implemented Visual Inspection technologies in our portfolio. With CCIT and Visual Inspection WILCO AG now covers all inspection expectations for pharmaceutical products and our customers benefit from WILCO AG’s vast experience in quality inspection.
From Production to Patient

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Pick up your copy of PMPS February, containing our Inhalation Technology Supplement, available at the PDA’s Parenteral Packaging Conference 2017

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PDA Education Program

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
ONE-DAY TRAINING COURSE

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.
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00</td>
<td>Welcome &amp; Introduction</td>
<td></td>
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<tr>
<td>9:10</td>
<td>Setting up a Target Profile</td>
<td>Influence of formulation (small molecule, biological)</td>
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<tr>
<td></td>
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<td>Use of product (patient, nurse, physician...)</td>
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<tr>
<td></td>
<td></td>
<td>Regulatory requirement</td>
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<tr>
<td>9:30</td>
<td>Material Selection</td>
<td>Ph.Eur. / USP / JP</td>
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<tr>
<td></td>
<td></td>
<td>Plastic vs. glass</td>
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<td></td>
<td>Coating of material</td>
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<td></td>
<td></td>
<td>Stopper material</td>
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<tr>
<td>10:30</td>
<td>Coffee Break</td>
<td></td>
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<tr>
<td>11:00</td>
<td>Selection of Packaging Solution</td>
<td></td>
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<tr>
<td>11:30</td>
<td>Assessment of Packaging Solutions – Development Data</td>
<td>Testing of injection vials/bottles and their respective components</td>
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<td></td>
<td>Testing of pre-filled syringes (PFS) and their respective components</td>
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<td></td>
<td></td>
<td>Extractables &amp; Leachables (E&amp;L) testing</td>
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<td></td>
<td></td>
<td>Mechanical and functional testing</td>
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<tr>
<td>12:30</td>
<td>Lunch Break</td>
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<tr>
<td>13:30</td>
<td>Manufacturing of Packaging Solutions</td>
<td>Test runs</td>
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<td></td>
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<td>Process validation (risk assessment, critical parameters)</td>
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<td></td>
<td></td>
<td>Container closure integrity (physical vs. microbiological testing – USP 1207)</td>
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<td></td>
<td></td>
<td>Shipping test for PFS</td>
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<tr>
<td>14:00</td>
<td>Setting of Specifications</td>
<td>Technical drawings</td>
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<td></td>
<td></td>
<td>Technical / quality specification</td>
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<td>Testing standard, defect evaluation list</td>
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<td></td>
<td></td>
<td>Examples</td>
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<tr>
<td>15:00</td>
<td>Coffee Break</td>
<td></td>
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<tr>
<td>15:30</td>
<td>Preparing the Submission</td>
<td>Relevant eCTD sections (drug substance and drug product)</td>
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<tr>
<td></td>
<td></td>
<td>Regulatory drawings</td>
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<td></td>
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<td>DMF for US</td>
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<tr>
<td>16:00</td>
<td>Routine and Release Testing</td>
<td>Certificates</td>
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<td></td>
<td></td>
<td>Routine E&amp;L testing</td>
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<td>Reduced testing</td>
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<tr>
<td>16:15</td>
<td>Change Management</td>
<td>EU requirements</td>
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<tr>
<td>16:30</td>
<td>Wrap-up, Discussion, Q &amp; A</td>
<td></td>
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<tr>
<td>17:00</td>
<td>End of Training Course</td>
<td></td>
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</table>
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

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.

Presentation of Technology, Instruments Demo and Hands-on Training kindly supported by:
ATC, Genesis Packaging Technology, Lighthouse, pti, Sartorius, Wilco
### Thursday, 16 March 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

**13:00** Advanced CCI Testing Technologies and Seal Quality Testing Technologies  
1. Vacuum decay  
2. Mass Extraction  
3. Headspace analysis  
4. Headspace moisture

**15:00** Coffee Break

**15:30** Advanced CCI Testing Technologies and Seal Quality Testing Technologies (Continued)  
5. HVLD  
6. Helium leak detection  
7. Seal quality test

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

**18:00** End of Day 1

---

### 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.

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### Friday, 17 March 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

**11:30** Instrument Demo and Hands-on Training:  
4. Headspace  
5. Helium leak detection  
6. Seal quality tests

**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
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 Standardisation 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).
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Welcome – Overview and Target of the Training Course</td>
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<tr>
<td>09:15</td>
<td>Overview Global Serialization Requirements</td>
<td>Thomas Brueckner</td>
</tr>
<tr>
<td>10:10</td>
<td>Coffee Break</td>
<td></td>
</tr>
<tr>
<td>10:30</td>
<td>Requirements EU-Falsified Medicines Directive 2019/securPharm</td>
<td>Thomas Brueckner</td>
</tr>
<tr>
<td>11:15</td>
<td>Implementation of Serialization – Technical Challenges</td>
<td>Klaus Egner</td>
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<tr>
<td>12:00</td>
<td>Lunch Break</td>
<td></td>
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<tr>
<td>13:00</td>
<td>Print Quality of Barcodes and 2D Matrixcodes</td>
<td>Dieter Moessner</td>
</tr>
<tr>
<td>13:45</td>
<td>How to Comply to Serialization – Regulatory Tasks</td>
<td>Thomas Brueckner, Klaus Egner</td>
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<tr>
<td>14:45</td>
<td>Coffee Break</td>
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<tr>
<td>15:00</td>
<td>Site Visit at a Packaging Manufacturer Facility</td>
<td>Site Visit Requested</td>
</tr>
<tr>
<td>18:30</td>
<td>End of Day 1</td>
<td></td>
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<tr>
<td>08:30</td>
<td>DIN EN 16679 “Tamper Verification Features for Medicinal Product Packaging” – Practical Implementation</td>
<td>Dieter Moessner</td>
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<tr>
<td>09:15</td>
<td>Barcodes in the Pharmaceutical Manufacturing Process</td>
<td>Dieter Moessner</td>
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<tr>
<td>10:00</td>
<td>Coffee Break</td>
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<tr>
<td>10:30</td>
<td>Technical and Organizational Implementation of Serialization at the Pharmaceutical Manufacturer</td>
<td>Klaus Egner</td>
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<tr>
<td>11:30</td>
<td>Coding / Serialization / Artwork at the Manufacturer of Printed Packaging Materials</td>
<td>Dieter Moessner</td>
</tr>
<tr>
<td>13:00</td>
<td>Lunch Break</td>
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<tr>
<td>14:00</td>
<td>Coding Rules for Medicines Requiring Verification / securPharm</td>
<td>Thomas Brueckner, Klaus Egner</td>
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<tr>
<td>15:00</td>
<td>Qualification and Validation of Serialization and Tamper Verification Technologies in Pharma Packaging</td>
<td>Dieter Moessner</td>
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<tr>
<td>15:30</td>
<td>Coffee Break</td>
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<tr>
<td>15:30</td>
<td>Current Developments, Q &amp; A, Discussion</td>
<td>Dieter Moessner</td>
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<tr>
<td>16:00</td>
<td>End of Course</td>
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</table>
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.
TRAINING COURSE AGENDA

Friday, 17 March 2017

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.
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**CONFERENCE REGISTRATION HOURS**
Tuesday, 14 February: 8:00 - 12:00  
Wednesday, 15 February: 8:00 - 10:00

**COURSE REGISTRATION HOURS**
Thursday, 16 February: 8:00 - 12:00  
Friday, 17 February: 8:00 - 10:00

**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
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<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>26 – 27 April</td>
<td>Current Trends in Aseptic Fill &amp; Finish of Pre-filled Syringes</td>
<td>Lindau, Germany</td>
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<tr>
<td>30 May – 1 June</td>
<td>Virus &amp; TSE Safety Forum</td>
<td>Dubrovnik, Croatia</td>
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<tr>
<td>13 – 14 June</td>
<td>2nd PDA Europe Annual Meeting</td>
<td>Berlin, Germany</td>
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<td>27 – 28 June</td>
<td>Advanced Therapy Medicinal Products</td>
<td>Valencia, Spain</td>
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<tr>
<td>19 – 20 September</td>
<td>Pharmaceutical Freeze Drying Technology</td>
<td>Cologne, Germany</td>
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<td>26 – 27 September</td>
<td>Particles in Injectables</td>
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<td>26 – 27 September</td>
<td>10th Workshop on Monoclonal Antibodies</td>
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<tr>
<td>10 – 11 October</td>
<td>Pharmaceutical Cold &amp; Supply Chain Logistics</td>
<td>Prague, Czech Republic</td>
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<td>7 – 8 November</td>
<td>The Universe of Pre-filled Syringes and Injection Devices</td>
<td>Vienna, Austria</td>
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<tr>
<td>21 – 22 November</td>
<td>Outsourcing &amp; Contract Manufacturing</td>
<td>Munich, Germany</td>
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Subject to change

For latest info: pda.org/pda-europe

Shortlist 3 March 2017

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