The Parenteral Drug Association presents:

Parenteral Packaging

Container Closure Best Practices Throughout the Product Life Cycle

CONFERENCE GUIDE

27-28 February 2018
Marriott Rome Park Hotel
Rome | Italy
Dear Colleagues,

Welcome to Rome!

On behalf of the program planning committee, thank you for joining our ongoing professional discourse on the latest manufacturing technologies and business trends in the Parenteral Packaging arena!

For the next two days, we have chosen some of the leading professionals for you to share their insights. Excellent speakers from industry as well as some key regulatory agencies will help us continue the discussions that further our understanding of scientific and technological advancements presented in this successful annual event.

Of equal importance to the quality of speakers and topics featured in the conference agenda is the interaction with them and fellow attendees.

PDA has selected Rome for its unique atmosphere to facilitate fruitful exchange during daytime coffee breaks and lunches.

An evening spent networking and enjoying a tour of Rome promises to become just one of the social highlights today! Please sign up at the PDA Registration Desk to reserve your seat for this joint bus trip into the city.

Enjoy your PDA experience in Rome!

Sincerely,

Roger Asselta, Chair, Genesis Packaging
Roman Mathaes, Chair, LONZA
Bettine Boltres, WEST
Derek Duncan, LIGHTHOUSE
Claudia Heinl, SCHOTT
Renaud Janssen, Datwyler
Enric Jo, ReigJofre Laboratories
Galen Shi, Eli Lilly
Michael Spallek, Rommelag ENGINEERING
Daniel Wagner, Sanofi
Klaus Wuchner, Janssen-J&J
Jörg Zürcher, Bayer
Kerstin Wilken, PDA Europe
Sylvia Becker, PDA Europe, Manager Programs & Events

Roger Asselta, Chair, Genesis Packaging
Roman Mathaes, PhD
Chair, LONZA
## SCHEDULE AT A GLANCE

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<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>27 February</td>
<td>9:00 – 18:30</td>
<td>Parenteral Packaging Conference, Exhibition</td>
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<tr>
<td>27 February</td>
<td>18:30 – 22:00</td>
<td>Sightseeing Tour &amp; Networking Dinner</td>
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<tr>
<td>28 February</td>
<td>9:00 – 16:30</td>
<td>Parenteral Packaging Conference, Exhibition</td>
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<tr>
<td>1 March</td>
<td>9:00 – 17:00</td>
<td>Container Closure Development Training Course</td>
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<tr>
<td>1 March</td>
<td>9:00 – 17:30</td>
<td>Container Closure Integrity Testing Workshop</td>
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<td>2 March</td>
<td>8:30 – 16:30</td>
<td>Container Closure Integrity Testing Workshop</td>
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<tr>
<td>1 March</td>
<td>9:00 – 18:00</td>
<td>Extractables &amp; Leachables Training Course</td>
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<tr>
<td>2 March</td>
<td>9:00 – 16:30</td>
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Join [@PDA_Europe](https://twitter.com/PDA_Europe) on Twitter and post pictures and highlights of this meeting! 📸 #pdapackaging

Follow us on LinkedIn [linkedin.com/company/pda](https://www.linkedin.com/company/pda)
## OPENING PLENARY

### Session 1  International Regulatory Updates
**Moderator:** Derek Duncan, LIGHTHOUSE

Current regulatory guidelines and recent updates have again confirmed the importance of primary and secondary packaging for delivering safe and effective product to the patient. This session will address the current hot topics of container closure integrity testing and control strategies, transport and last mile distribution, and a risk-based approach for assessing the packaging of parenterals.

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>9:15</td>
<td>Annex 1 Revision &amp; CCIT</td>
<td>Andrew Hopkins, MHRA</td>
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<tr>
<td>9:45</td>
<td>Secondary Packaging Considerations &amp; Last Mile Distribution</td>
<td>Umit Kartoglu, WHO</td>
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<tr>
<td>10:45</td>
<td>Q&amp;A, Discussion</td>
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<td>11:15</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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### Session 2  Packaging Technology Updates
**Moderators:** Roman Mathaes, LONZA

Responsive, flexible and innovative patient-centric packaging/device development is a key aspect in the competitive biopharmaceutical market. What key elements are to consider when designing/developing a pre-filled syringe or auto-injector, how is the drug product formulation interacting and impacting packaging functionality, and lastly, what are the main differences when comparing glass and polymer ampoules? All of these hot topics will provide a lot of room for discussion and exchange!

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<tbody>
<tr>
<td>11:45</td>
<td>Usability of Glass versus Polymer Ampoules: A Comparison</td>
<td>Michael Spallek, Rommelag</td>
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<td>12:15</td>
<td>Impact of Drug Formulation Variables on Packaging Functionality</td>
<td>Galen Shi, Eli Lilly</td>
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<td>12:45</td>
<td>Engineering Considerations: Pressure and Strain Waves in Pre-Filled Syringes during Auto-Injector Activation</td>
<td>Julian Jazayeri, Amgen, Jean-Christophe Veilleux, California Institute of Technology</td>
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<tr>
<td>13:15</td>
<td>Q&amp;A, Discussion</td>
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<td>13:45</td>
<td>Lunch Break, Poster Session &amp; Exhibition</td>
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The PDA is proud to invite you to a very special Networking Event **Tuesday, 27 February 2018**

- **18:30h** – **Meeting Point:** Hotel Lobby  
  Joint Bus Transfer including Sightseeing Tour of Rome
- **20:00h** – **Dinner, Ristorante „Venerina“, Borgo Pio n 38, Roma 00193**
- **22:00h** – **Departure Bus Transfer to Conference Hotel**
### PARALLEL TRACKS

#### Session 3

**Track A**

**Manufacturing Process**

*Moderator: Daniel Wagner, Sanofi*

In this session, you will hear up-to-date information on well-established and as innovative manufacturing and filling processes of primary containers for injectables. Presentations will outline current trends and expectations from the pharmaceutical industry and offer top of the art solutions by manufacturing, filling machine as well as primary packaging components providers.

**Investigations Carried Out on Clean Room Injection Molding of Plastic Components for Parenteral Packaging**

*Reinhard Steger, Braunform*

**From Blow-Fill-Seal Ampoules to Advanced Container Closure Systems by Blow-Fill-Insert-Seal: A review based on three case studies**

*Otto Schubert, Rommelag*

#### Track B

**Packaging Material: Glass**

*Moderator: Claudia Heinl, SCHOTT*

In this session, all about glass as primary packaging material for parenteral will be discussed. Studies dealing with the latest innovations in this field such as alternative glass types and ready-to-use containers will be presented. Speakers will also outline optimization and fine-tuning possibilities of already installed filling lines.

**Reduction of Particulate Contamination Generated During Bulk Vial Filling**

*Christopher Timmons, Corning*

**Extractables Profiles of Borosilicate and Aluminosilicate Glass – A Comparison**

*Folker Steden, SCHOTT*

#### Schedule

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Track A</th>
<th>Track B</th>
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<tr>
<td>14:45</td>
<td></td>
<td><strong>Investigations Carried Out on Clean Room Injection Molding of Plastic Components for Parenteral Packaging</strong></td>
<td><strong>Reduction of Particulate Contamination Generated During Bulk Vial Filling</strong></td>
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<td><em>Reinhard Steger, Braunform</em></td>
<td><em>Christopher Timmons, Corning</em></td>
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<tr>
<td>15:15</td>
<td></td>
<td><strong>From Blow-Fill-Seal Ampoules to Advanced Container Closure Systems by Blow-Fill-Insert-Seal: A review based on three case studies</strong></td>
<td><strong>Extractables Profiles of Borosilicate and Aluminosilicate Glass – A Comparison</strong></td>
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<td><em>Otto Schubert, Rommelag</em></td>
<td><em>Folker Steden, SCHOTT</em></td>
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<td>15:45</td>
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<td><strong>Coffee Break, Poster Session &amp; Exhibition</strong></td>
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<tr>
<td>16:15</td>
<td><strong>Case Study: Mid-Scale Production Line for Aseptic Filling and Sealing of IV-Bags</strong></td>
<td><strong>Lyophilization of Nested Glass Containers: Process Investigation</strong></td>
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<td><em>Bernhard Brugger, Harro Hoefliger</em></td>
<td><em>Lorensa Bonaldi, Ompi – A Stevanato Group Brand</em></td>
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<tr>
<td>16:45</td>
<td><strong>Robust Processes for Filling and Stoppering of Cartridges and Syringes</strong></td>
<td><strong>Fused Quartz Vials for Enhanced Chemical Stability</strong></td>
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<td><em>Klaus Ullherr, Robert Bosch Packaging</em></td>
<td><em>Ben Gauthier, Momentive</em></td>
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<td><em>Cathy Zhao, West</em></td>
<td><em>Nicola Favaro, Stazione Sperimentale del Vetro</em></td>
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<td>17:45</td>
<td><strong>Q&amp;A, Discussion</strong></td>
<td><strong>Q&amp;A, Discussion</strong></td>
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<tr>
<td>18:30</td>
<td><strong>Networking Dinner incl. Sightseeing Tour of Rome</strong></td>
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USP Expert panel members will present on the current activities of the USP on chapters relevant to parenteral packaging, including proposed significant revisions to the chapters covering glass and elastomers. Additionally, an update on proposed revisions to the ISO standards on container closure systems and components for injectable medicines will be presented by a member of the working group for the ISO technical committee.

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<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>9:00</td>
<td>USP Updates</td>
<td>Bettine Boltres, USP</td>
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<tr>
<td>9:25</td>
<td>Elastomeric Closures - Regulatory Updates</td>
<td>Renaud Janssen, Datwyler</td>
</tr>
<tr>
<td>9:50</td>
<td>ISO Norms Update: Rigid Container Systems and Related Accessories for Parenterals and Injectables ISO/TC 76/WG2</td>
<td>Volker Rupertus, SCHOTT</td>
</tr>
<tr>
<td>10:15</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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**PARALLEL TRACKS**

**Session 5**

**Track A**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>10:45</td>
<td>Critical Time &amp; Temperature - Dependent Container Closure Integrity (CCI) Through the Sealed Drug Product Life Cycle</td>
<td>Qingyu Zeng, West</td>
</tr>
<tr>
<td>11:10</td>
<td>Container Closure Integrity: Specific Strategies for Unique Applications</td>
<td>Oliver Stauffer, pti</td>
</tr>
<tr>
<td>11:35</td>
<td>Proposal for Implementing the RSF Tester in a Manufacturing Environment</td>
<td>Robert Ovadia, Genentech</td>
</tr>
<tr>
<td>12:00</td>
<td>Development of a Platform High Voltage Leak Detection Method for Drug Product Container Closure Integrity Testing</td>
<td>Jason E. Fernandez, Biogen</td>
</tr>
<tr>
<td>12:25</td>
<td>Q&amp;A, Discussion</td>
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**Track B**

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<tr>
<th>Time</th>
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<th>Speaker</th>
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<tbody>
<tr>
<td>10:45</td>
<td>Polymeric Materials in Primary Containers and Medical Devices – A Lilly Perspective</td>
<td>Karthik Vaideeswaran, Eli Lilly</td>
</tr>
<tr>
<td>11:10</td>
<td>Advancing Flexibility, Softness and Transparency with Polybutene-1 for Parenteral Applications</td>
<td>Isabelle Trocherie, LyondellBasell</td>
</tr>
<tr>
<td>11:35</td>
<td>Effect of Ageing of Elastomeric Closures on their Physico/Chemical Properties and their Extractables Profile</td>
<td>Bram Jongen, Datwyler</td>
</tr>
<tr>
<td>12:00</td>
<td>Extractables and Leachables Evaluation of Single Use Systems for Biopharmaceuticals Moving Toward Standardization by Up-Coming USP &lt;1665&gt;/&lt;665&gt;</td>
<td>Andreas Nixdorf, SGS Institut Fresenius</td>
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<tr>
<td>13:00</td>
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Successful Drug Product Development requires full integration of formulation, packaging and manufacturing process development. This holistic view and efforts to perfectly combine these aspects will facilitate and support a seamless commercial product launch. The closing plenary will discuss the latest trends in process and manufacturing as well as the ever-current topic of CCI.

14:00  Use of a Wireless Drone System for Improvement of Pharmaceutical Manufacturing Processes
        Avi Mehari, Genentech
        David Brückner, F. Hoffmann-La Roche

14:30  State of Packaging and Testing Technology: Parenteral Cryo Solutions
        Chris Folta, Janssen J&J

15:00  Coffee Break, Poster Session & Exhibition

15:30  Systematic Assessment of pCCIT Method Performance and Commonly Used Artificial Leaks
        Roman Mathaes, Lonza
        Christoph Herdlitschka, Wilco

16:00  Q&A, Discussion

16:30  End of Conference & Farewell
The Parenteral Drug Association presents:

Visual Inspection Week

Particle Identification in Parenterals | 10 April 2018

An Introduction to Visual Inspection: A hands-on course | 11-12 April 2018

Mastering Automated Visual Inspection | 11-12 April 2018

Interest Group Meeting Visual Inspection | 13 April 2018

10-13 April 2018
Courtyard by Marriott Berlin
Berlin | Germany
Corning is a global supplier of pharmaceutical glass products. With a continuous commitment to innovation, Corning designed ‘Valor™’ Glass, a glass composition engineered for pharmaceutical packaging that has improved chemical durability and **eliminates** delamination.

The interior drug-contacting surface of Corning Valor™ Glass containers are never predisposed to delaminate and have low extractable concentrations, making Valor Glass ideally-suited to protect drug products. In addition, Valor Glass containers reduce the probability of contamination or loss of sterility due to glass particles.

**Learn more at: corning.com/valor**

Corning is one of the world’s leading innovators in materials science, with a 166-year track record of life-changing inventions. Corning applies its unparalleled expertise in glass science, ceramics science, and optical physics, along with its deep manufacturing and engineering capabilities, to develop category-defining products that transform industries and enhance people’s lives.
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- Protects against Breakage and Exposure
- Tamper Evident Solution

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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.

Alfasigma S.p.A.
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20125 Milano, Italy
Tel: +39 085 857 1226
mauro.mancinelli@alfasigma.com
manufacturing.alfasigma.com

Alfasigma was founded in 2015 by the aggregation of Alfa Wassermann and Sigma-tau, two Italian companies that, by bringing together assets and know-how, create a new important player on the international scene. It operates in Italy through 5 offices with a distinct focus: in Bologna there is the business center, in Milan the international division, in Pomezia (Rome) other operational departments. The pharmaceutical production of the group is carried out in Alanno (Pescara) and in Pomezia (Rome), while the chemical production in Sermoneta (Latina). Both Bologna and Pomezia (Rome) host research and development laboratories focused on the gastro area and biotech projects. Alfasigma has subsidiaries in 16 countries and in other 70 its products are present through qualified local distributors. It employs over 3000 employees and the 2017 turnover will exceed 1 billion euros.

AMRI
26 Corporate Circle
12212 Albany, United States
Tel. +1 518 522 3453
corie.rowe@amriglobal.com
www.amriglobal.com

AMRI, a global contract research and manufacturing organization, partners with the pharmaceutical and biotechnology industries to improve patient outcomes and quality of life. With locations in North America, Europe and Asia, AMRI’s team combines scientific expertise and market-leading technology to provide a complete suite of solutions in Discovery, Development, Analytical and Solid State Services, API Manufacturing and Drug Product.

Bausch + Ströbel Maschinenfabrik Ilshofen GmbH & Co. KG
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74532 Ilshofen, Germany
info@bausch-stroebel.de
www.bausch-stroebel.com

Design and construction of filling and packaging machines for the pharmaceutical and similar industries. Containers such as ampoules, vials, syringes and cartridges are processed from cleaning to labeling.

Corning
1 Riverfront Plaza
14831 Corning, USA
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tracycr@corning.com
www.corning.com/valor

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.
**Eye-Tec**  
**Ballaarstraat 72**  
**2018 Antwerpen, Belgium**  
**Tel. +32 0497708607**  
**info@eye-tec.eu**  
**www.eye-tec.eu**

Eye-Tec provides support in the domain of Visual Inspection to pharmaceutical companies around the globe. We are the ‘bridge’ between pharmaceutical manufacturers and inspection machine builders. We do this through our combined competence in both compliance and technology and our own past experience in parenterals manufacturing. Our projects can be on corporate strategies but just as well about hands-on vision process improvements or qualification. With the enhanced focus on Container Closure Integrity (CCIT) we provide Leak Test Samples with pinholes from 5µ onward. The client chooses pinhole location and diameter and provides us with his own empty containers.

**Genesis Packaging Technologies**  
**435 Creamery Way, Suite 100**  
**19341 Exton PA, United States**  
**Tel: +1 800 552 9980**  
**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.

**Gerresheimer**  
**Klaus-Bungert-Str. 4**  
**40468 Düsseldorf, Germany**  
**info@gerresheimer.com**  
**www.gerresheimer.com**

Gerresheimer is a leading global partner to the pharma and healthcare industry. With our specialty glass and plastic products, we contribute to health and well-being. We have worldwide operations and about 10,000 employees manufacture our products in local markets, close to our customers. With our plants in Europe, North America, South America and Asia, we generate revenues of approximately EUR 1.4 billion. The comprehensive product portfolio includes pharmaceutical packaging and products for the safe, simple administration of medicines: Insulin pens, inhalers, prefilled syringes, injection vials, ampoules, bottles and containers for liquid and solid medicines with closure and safety systems.

**IWATA LABEL Europe**  
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**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**  
**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**  
**dduncan@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.
Lonza Pharma & Biotech
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drugproduct@lonza.com
lonza.com/drugproduct

As a leader for contract development and manufacturing, Lonza Pharma & Biotech is recognized for reliable, high-quality services, global capacity, innovative technology platforms and extensive experience. Our broad capabilities span across biologics, small molecules, bioconjugates, and cell and gene therapies. We manage projects from pre-clinical stage through to commercialization and our expertise covers both drug substance and drug product. We believe that the best outcome – for you and your patients – can only come as a result of a successful collaboration. Together, we can solve the next challenge and bring your next medicine to life.

OMPI - A Stevanato Group Brand
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35017 Piombino Dese, Italy
Tel: +39 04 993 18611
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®).

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

PTI is a global leader in package testing equipment. We manufacture non-destructive solutions for package integrity testing, leak detection, container closure integrity (CCI), and seal integrity testing. PTI’s inspection technologies are deterministic test methods that produce reliable quantitative test data. Our technologies conform to ASTM, USP 1207 and other regulatory standards. We specialize in offering our customers comprehensive solutions including test method development. Applications include testing parenteral products: vials, ampoules, auto-injectors, cartridges, pre-filled syringes as well as pouches and flexible packaging, bottles & other rigid containers.

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www.qualimetrix.gr

QualiMetrix is a third-party contract laboratory that provides services to the pharmaceutical industry. QualiMetrix is focused on supporting pharmaceutical products throughout their whole lifecycle; from the development of the product to the registration and post marketing stages. Services range from routine to highly complex products; with full support given to the regulatory requirements and research challenges; and performance consistently taking place in an environment of Good Laboratory and Manufacturing Practices. Services include but not limited to: Pharmaceutical development - Analytical development and validation - Leachables and Extractables - Filter Validation - Elemental Impurities - Stability Studies - Batch release

Rommelag ENGINEERING
Fabrikweg 16
5003 Buchs, Switzerland
Tel. +41 62 834 55 55
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  
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Tel. +49 6131 66 1589  
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.

Smart Skin Technologies  
527 Queen St. Suite 210  
E3B1B8 Fredericton Canada  
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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 Quantifeel™ 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.

Soitra SpA  
Via Carlo Torre 22  
20143 Milano, Italy  
Tel. +39 02 8978571  
info@soitra.it  
www.soitra.it  

Soitra is an agent company founded in 1956. Soitra represents the most important process and packaging manufacturers in world for pharmaceutical but also in chemical and food. We represent: All-Fill, Apex, Atec Pharmatechnik, Bausch+Ströbel, Belimed, Effytec, Enercon Industris, Fryma-Koruma, Glatt, Harro Höfliger, Koch, Idroinox Impianti, Meridon Technologies, Pharma Packaging System, Proditec, Riera Nadeu, Schwerdtel, Solo Containment, Uhlmann

TASITEST Packaging Test & Inspection - Bonfiglioli Engineering S.r.l.  
Via Rondona, 33  
44049 Vigorano Pieve (Ferrara), Italy  
Tel. +39 0532 715631  
info@tasitest.com  
www.tasitest.com  

TASITEST Packaging Test & Inspection is the world leader focused on container closure integrity, measurement and inspection. It provides dedicated solutions based on quality, innovation, expertise & support to the global packaging markets. Superior quality is the core of the 3 TASITEST products lines: ALPS, BONFIG and SEPHA and relevant operations. BONFIG brand line equipments are based on advanced expertise in Container Closure Integrity Testing, Visual Inspection and Headspace Gas Analysis for Laboratory and Inline testing. They guarantee high quality, safe products to the end-user while protecting manufacturers from financial loss due to recalls, lawsuits and potential adverse publicity.

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.

TERUMO  
Interleuvenlaan 40  
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, 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

Weiler Engineering, Inc., is a leading provider of aseptic custom Blow/Fill/Seal liquid packaging equipment for pharmaceutical and healthcare applications. Weiler’s proprietary ASEP-TECH® B/F/S packaging machines produce shatterproof, durable, aseptically packaged products in one uninterrupted operation. This hands-free manufacturing process ensures that parenteral, ophthalmic solutions and respiratory drugs reach the marketplace sterile, in the most cost-effective manner possible. The ASEP-TECH® System is the culmination of more than 50 years of innovation in machine design and sterile process development, producing the most advanced aseptic liquid packaging process machinery available today.

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 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.
REACHING HIGH IN PHARMACEUTICAL FORMS

PREFILLED SYRINGES AND CARTRIDGES: INVESTING FOR QUALITY
As part of our commitment to continuous improvement, we've invested in new sterile departments with state-of-the-art, high performance production lines. This means higher quality delivered to our customers, taking their business to higher levels. Yet another reason Alfasigma is your ideal partner for pharmaceutical outsourcing.

BECAUSE YOUR PROJECT IS OUR PROJECT
PDA Education Program

1 March 2018
Container Closure Development
One-Day Training Course

1-2 March 2018
Container Closure Integrity Testing
Two-Day Workshop

1-2 March 2018
Extractables & Leachables
Two-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 a product profile of the final product container, all aspects will be covered, like selection of materials, assessment of container closure systems, specification and documentation of components and entire systems. In addition, current hot topics such as glass delamination and container closure integrity testing will be discussed.

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

Who Should Attend:
• Scientists in Drug Product Development
• Scientists/Engineers in Packaging Development
• Regulatory Affairs Experts

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

Jörg Zürcher, Senior Scientist, Bayer
Jörg Zürcher is a pharmacist by education. After his studies and PhD thesis at the Free University in Berlin, he started his career in the pharmaceutical industry 1990 with the former Schering AG. He is responsible for the development of container closure systems and application devices at Bayer Healthcare and has more than 25 years’ experience in that field. His current focus is the development of systems/devices for liquid and parenteral as well as ophthalmic dosage forms.
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>9:00</td>
<td>Welcome &amp; Introduction</td>
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<td>9:30</td>
<td>Definitions</td>
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<td>Regulatory Background</td>
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<td>• Relevant eCTD sections</td>
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<td>Coffee Break</td>
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<td>11:15</td>
<td>Development of Container Closure Systems</td>
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<td>• Set-up of target profile</td>
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<td>• Container closure integrity (CCI)</td>
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<td>• Shipping assessment</td>
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<td>• Combination products</td>
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<td>12:30</td>
<td>Lunch Break</td>
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<td>13:30</td>
<td>Workshop: Develop Your CCS</td>
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<td>15:00</td>
<td>Coffee Break</td>
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<td>Presentation of Workshop Results</td>
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<td>Setting of Specifications / Submission Documentation</td>
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<td>• Technical/ Quality specification</td>
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<td>16:30</td>
<td>Wrap-up and Final Q&amp;A</td>
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<td>17:00</td>
<td>End of Training Course</td>
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TWO-DAY WORKSHOP

Container Closure Integrity Testing

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

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

Who Should Attend
• Parenteral drug packaging engineers and formulation scientists
• Laboratory scientific staff and managers
• Parenteral manufacturing staff
• Sterility Quality Assurance
• Regulatory affair scientists
• Pharmaceutical packaging component manufacturing staff

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
Genesis Packaging Technology, Lighthouse, Pfeiffer Vacuum, pti, Sartorius Stedim, Wilco
WORKSHOP AGENDA

Thursday, 1 March 2018 9:00 – 17:30

9:00 Welcome and Introduction

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

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

10:30 Coffee Break

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

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

12:00 Lunch Break

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

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

15:00 Coffee Break

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

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

17:00 Group Exercise #2: Method Characteristics
• review, discussion
Day 1 Review, Q&A

17:30 End of Day 1

Friday, 2 March 2018 8:30 – 16:30

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

9:10 Hands-on Training

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

10:30 Coffee Break

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

11:40 Instrument Demo and Hands-on Training

12:40 Lunch Break

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

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

15:00 Coffee Break

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

16:00 Class Discussion, Recognition, Certification

16:30 End of Workshop

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

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

Dennis Jenke, PhD, Chief Executive Scientist, Triad Scientific Solutions
Dennis Jenke is the Chief Executive Scientist for Triad Scientific Solutions, a provider of science-based solutions to plastic/product compatibility challenges associated with packaging, manufacturing equipment and delivery devices in the pharmaceutical, cosmetic, food and related industries. He was a Distinguished Scientist at Baxter Healthcare Corporation where for more than three decades he lead a team whose primary responsibility includes the assessment of material/product compatibility, specifically with respect to establishing the suitability for use of packaging systems, manufacturing systems and administration devices for pharmaceutical products (for example, extractables/leachables and product ingredient binding). He has published extensively in the areas of analytical chemistry, environmental science and material/solution compatibility and serves as an expert reviewer for numerous pharmaceutical and analytical journals. He is the author of the book Compatibility of Pharmaceutical Solutions and Contact Materials; Safety Considerations Associated with Extractables and Leachables and a contributing author to the Leachables and Extractables Handbook. Dennis Jenke is a member of numerous industry groups whose charter is to establish best demonstrated practices in the area of material/solution compatibility.
Thursday, 1 March 2018
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, Nelson Labs

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

Friday, 2 March 2018  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.
INFORMATION

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Italy

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Fax: +49 30 4365508-66

CONFERENCE REGISTRATION HOURS
Monday, 26 February: 9:00 – 17:00
Tuesday, 27 February: 8:00 – 17:30
Wednesday, 28 February: 8:00 – 12:00

COURSE REGISTRATION HOURS
Thursday, 1 March: 8:00 – 16:30
Friday, 2 March: 8:00 – 12:00

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.

PDA Europe supports the children's hospice „Sonnenhof”
The Sonnenhof Hospice, located near PDA’s office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases. At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering. Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy:

buy a package of chewing gums at the registration desk. THANK YOU!

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

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GENERAL ADDRESS
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CONFERENCE REGISTRATION HOURS
Monday, 26 February: 9:00 – 17:00
Tuesday, 27 February: 8:00 – 17:30
Wednesday, 28 February: 8:00 – 12:00

COURSE REGISTRATION HOURS
Thursday, 1 March: 8:00 – 16:30
Friday, 2 March: 8:00 – 12:00

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.

PDA Europe supports the children's hospice „Sonnenhof”
The Sonnenhof Hospice, located near PDA’s office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases. At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering. Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy:

buy a package of chewing gums at the registration desk. THANK YOU!

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

VENUE
Marriott Park Hotel Rome
Via Colonnello Tommaso Masala 54
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Save the Date
Parenteral Packaging
19 - 20 March 2019
Venice | Italy