Tuesday, 27 February 2018

9:00  Welcome and Introduction  Kerstin Wilken, PDA Europe  
Roger Asselta, Genesis Packaging  
Roman Mathaes, LONZA

OPENING PLENARY

Session 1  International Regulatory Updates  
Moderator: Derek Duncan, LIGHHOUSE

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.

9:15  Annex 1 Revision & CCIT  Andrew Hopkins, MHRA

9:45  Secondary Packaging Considerations & Last Mile Distribution  Umit Kartoglu, WHO

10:15  A Risk-based Approach for Assessment of Pharmaceutical Packaging of Parenterals - A Regulatory Perspective  
Charudharshini Srinivasan, US FDA

10:45  Q&A, Discussion

11:15  Coffee Break, Poster Session & Exhibition

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!

11:45  Usability of Glass versus Polymer Ampoules: A Comparison  
Michael Spallek, Rommelag

12:15  Impact of Drug Formulation Variables on Packaging Functionality  
Galen Shi, Eli Lilly

12:45  Engineering Considerations: Pressure and Strain Waves in Pre-Filled Syringes during Auto-Injector Activation  
Julian Jazayeri, Amgen  
Jean-Christophe Veilleux, California Institute of Technology

13:15  Q&A, Discussion

13:45  Lunch Break, Poster Session & Exhibition

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

Supported by
### PARALLEL TRACKS

<table>
<thead>
<tr>
<th>Session 3</th>
<th>Track A</th>
<th>Track B</th>
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<tbody>
<tr>
<td><strong>Manufacturing Process</strong>&lt;br&gt;Moderator: Daniel Wagner, Sanofi</td>
<td><strong>Packaging Material: Glass</strong>&lt;br&gt;Moderator: Claudia Heinl, SCHOTT</td>
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<td>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.</td>
<td>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.</td>
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<td><strong>14:45</strong>&lt;br&gt;Investigations Carried Out on Clean Room Injection Molding of Plastic Components for Parenteral Packaging&lt;br&gt;Reinhard Steger, Braunform</td>
<td><strong>14:45</strong>&lt;br&gt;Reduction of Particulate Contamination Generated During Bulk Vial Filling&lt;br&gt;Christopher Timmons, Corning</td>
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<td><strong>15:15</strong>&lt;br&gt;From Blow-Fill-Seal Ampoules to Advanced Container Closure Systems by Blow-Fill-Insert-Seal: A review based on three case studies&lt;br&gt;Otto Schubert, Rommelag</td>
<td><strong>15:15</strong>&lt;br&gt;Extractables Profiles of Borosilicate and Aluminosilicate Glass – A Comparison&lt;br&gt;Folker Steden, SCHOTT</td>
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<td><strong>15:45</strong>&lt;br&gt;Coffee Break, Poster Session &amp; Exhibition</td>
<td><strong>15:45</strong>&lt;br&gt;Lyophilization of Nested Glass Containers: Process Investigation&lt;br&gt;Lorenza Bonaldi, Ompi – A Stevanato Group Brand</td>
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<td><strong>16:15</strong>&lt;br&gt;Case Study: Mid-Scale Production Line for Aseptic Filling and Sealing of IV-Bags&lt;br&gt;Bernhard Brugger, Harro Hoefliger</td>
<td><strong>16:15</strong>&lt;br&gt;Robust Processes for Filling and Stoppering of Cartridges and Syringes&lt;br&gt;Klaus Ullherr, Robert Bosch Packaging&lt;br&gt;Daniel Wagner, Sanofi</td>
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<td><strong>16:45</strong>&lt;br&gt;Fused Quartz Vials for Enhanced Chemical Stability&lt;br&gt;Ben Gauthier, Momentive</td>
<td><strong>16:45</strong>&lt;br&gt;Lyophilization of Nested Glass Containers: Process Investigation&lt;br&gt;Lorenza Bonaldi, Ompi – A Stevanato Group Brand</td>
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<td><strong>17:15</strong>&lt;br&gt;A Case Study to Address a Gap in the Device-to-Vial Interface: Stopper Push-in by Chemo Spikes – An Overlooked Oncology Safety Risk&lt;br&gt;Cathy Zhao, West</td>
<td><strong>17:15</strong>&lt;br&gt;Glass Packaging Breakages: A New Testing Protocol for the Optimization of Container Filling Lines&lt;br&gt;Nicola Favaro, Stazione Sperimentale del Vetro</td>
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<td><strong>17:45</strong>&lt;br&gt;Q&amp;A, Discussion</td>
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<td><strong>18:30</strong>&lt;br&gt;Networking Dinner incl. Sightseeing Tour of Rome</td>
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**Ristorante Venerina**

*Join us for a fabulous evening in a traditional Roman Restaurant.*
Wednesday, 28 February 2018

Session 4  Regulatory Updates  

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.

9:00  USP Updates
Bettine Boltres, USP

9:25  Elastomeric Closures - Regulatory Updates
Renaud Janssen, Datwyler

9:50  ISO Norms Update: Rigid Container Systems and Related Accessories for Parenterals and Injectables ISO/TC 76/WG2
Volker Rupertus, SCHOTT

10:15  Coffee Break, Poster Session & Exhibition

PARALLEL TRACKS

Session 5  

Track A  

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<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Presenter</th>
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<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>
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<td>11:10</td>
<td>Container Closure Integrity: Specific Strategies for Unique Applications</td>
<td>Oliver Stauffer, pti</td>
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<td>11:35</td>
<td>Proposal for Implementing the RSF Tester in a Manufacturing Environment</td>
<td>Robert Ovadia, Genentech</td>
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<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>
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Track B  

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<th>Time</th>
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<tr>
<td>10:45</td>
<td>Polymeric Materials in Primary Containers and Medical Devices – A Lilly Perspective</td>
<td>Karthik Vaideeswaran, Eli Lilly</td>
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<td>11:10</td>
<td>Advancing Flexibility, Softness and Transparency with Polybutene-1 for Parenteral Applications</td>
<td>Isabelle Trocherie, LyondellBasell</td>
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<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>
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<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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12:25  Q&A, Discussion

13:00  Lunch Break, Poster Session & Exhibition
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