The Parenteral Drug Association presents:

Parenteral Packaging

Container Closure Best Practices Throughout the Product Life Cycle

27-28 February 2018
Marriott Rome Park Hotel
Rome | Italy

CALL FOR PAPERS & POSTERS
Dear Colleagues,

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

Join us 27–28 February 2018 to continue and further deepen scientific advancements and understanding of topics previously raised in this successful annual event.

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

The conference aims to keep its attendees updated about all regulatory aspects involved in the parenteral packaging process, such as new regulations from European and US agencies, the revision of Annex 1, and PDA Technical Reports. Different materials such as glass, polymers & elastomers and their characteristics regarding supplier issues and end-user preferences will also be discussed as well as the design of primary and secondary packaging.

The role of Container Closure Integrity (CCI) in product-package development, post-approval product changes and routine manufacturing will be explored, and information on aseptic processing will be given.

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

We look forward to meeting you in Rome!

Roger Asselta, Genesis Packaging, Chair

Roman Mathaes, PhD, LONZA, Co-Chair

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**Call for Papers and Posters**

Topics areas of interest will include but are not limited to the following

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1. **GLOBAL REGULATORY UPDATES**
   - New Regulations from Agencies, Pharmacopoeia & Industry Perspectives
   - USP <660>, <381>, <660>, <1207>, <1663>, <1664>, <790> and <1790>, Pharm. Eur. 3.1 and 3.2
   - Updates on PDA Technical Reports 27, 43, 73, 76 and 77
   - Update on FDA 1999 Container/Closure Guidance
   - FDA Guidance on Safety Considerations for Product Design
   - Impact of Post-Approval Regulatory Requirement Changes on Products
   - ICH Q3D - Elemental Impurities and their Application to Packaging Materials
   - Annex 1 Revision

2. **CONTAINER CLOSURE INTEGRITY (CCI)**
   - The Role of CCI in Product-Package Development
   - The Role of CCI in Post-Approval Product Changes
   - CCI in Routine Manufacturing
   - CCI for API Storage Containers and Single Use Equipment
   - CCI during Shipping - influence of pressure and mechanical stress
   - CCI for Complex Combination Products
   - CCI Testing vs. CCI Control Strategy in Manufacturing
   - CCI Testing as Part of Post-Approval Processing Changes
   - Coherent CCI Testing Strategy across the Product Life Cycle
   - Test Methods, On-line vs. Off-line Testing
   - Simulation Work, Failure Modeling
     - Modeling of Artificial Leaks
     - Modeling of Process Unit Operation Impact on CCS Components
   - Product Release Specification vs. Internal Quality Criterion
   - Approaches & Solutions for Cryogenic Storage
3. QUALITY OF COMPONENTS & CONTAINERS – DESIGN, MATERIALS, NEW TECHNOLOGIES

- Glass, Defects and Categorization
- Surface Modified Materials
- Alternative Container Closure Systems
- Polymers
- Large Volumes, Bags
- Blow-Fill-Seal
- Stoppers, Caps, Labels
- Drug/Container Interactions
- Extractables & Leachables Studies
- Supplier Issues
- Anticipating and Managing Post-Approval Component Changes
- Anti-Counterfeiting
- Simulation Work
- Container Closure System Qualification (for human use)
- Turn-Around-Cycles

4. PROCESSING, PRODUCT DISTRIBUTION & STORAGE

- Glass Handling
- Reduction of Breakage
- Formulation Considerations
- Fill-finish Operations
- Stoppering, Sealing, Capping, Crimping Operations
- Reduction of Variability during Capping
- Influence of Stopper Permeability on the Headspace of Sterile Vials during Storage
- Visual Inspection: Container-linked Particles
- Managing Processing Changes in a dynamic post-approval world
- Shipping & Distribution Challenges
- Last-Mile Distribution
- Statistical Risk Assessments
- Addressing the User Interface via Parenteral Packaging
- Solutions Addressing the FDA Guidance on Safety Considerations for Product Design to Minimize Medication Errors

5. FORMULATION-PACKAGING INTERACTIONS

- Silicon Oil Interactions
- Incompatibilities with Leachables from Glass/Elastomers
- Rubber Components leading to Drug Product Degradation
- Fogging
- Delamination

INFORMATION

VENUE
Marriott Rome Park Hotel
Via Colonnello Tommaso Masala, 54,
00148 Roma RM,
Italy
SUBMISSION PROCESS

**SUBMISSIONS RECEIVED MUST INCLUDE**
THE FOLLOWING INFORMATION:
- TITLE
- PRESENTER’S NAME AND CONTACT DETAILS
- PRESENTER’S BIOGRAPHY (APPROX. 100 WORDS)
- ADDITIONAL AUTHORS (IF APPLICABLE)
- KEY OBJECTIVES OF TOPIC
- 2-3 PARAGRAPH ABSTRACT, SUMMARIZING THE TOPIC

Paper abstracts must be non-commercial in nature, describing new developments or work that significantly contributes to the body of knowledge relating to Parenteral Packaging.

All submitted abstracts will be reviewed by the Scientific Program Planning Committee for acceptance. PDA Europe will provide one complimentary registration per podium presentation. Additional presenters and poster presenters are required to pay appropriate conference registration fees. Abstracts not selected for a 30 minute podium presentation may be invited to join as a scientific poster contribution.

Please click or scan the QR Code to submit your abstract.

**Deadlines**
Abstracts for Podium Presentation: **16 October 2017**
Poster Applications: **31 January 2018**

If you have any further questions, please do not hesitate to contact programs-europe@pda.org

**TO EXHIBIT:**
Exhibition and sponsorship opportunities are available and limited. Contact **expo-europe@pda.org**