

**Focus on the latest
technological developments
about
Container Closure Integrity,
Visual Inspection
and worldwide regulatory
directions**

Milan – October 9th, 2019

Hotel FOUR POINTS by SHERATON

INTRODUCTION

This conference is aiming at presenting, discussing and reviewing the present status of parenteral sterile drugs manufacturing and the focus is on three main topics:

- Parenteral Packaging: evolving trends, industry perspective and CCI considerations
- Visual Inspection of Parenterals
- FDA Regulatory Update and PDA Insights

The program has been designed to present technological development by users and suppliers with a solid industrial experience and to provide a valuable feedback about PDA community current thinking.

This program will give a good balance between industry recent developments delivered by key opinion leaders and SME and also direct interactions at the supplier's booths. The multidisciplinary nature of the conference as well as the unique interactive atmosphere of all PDA Italy Chapter events, are creating the real differentiating factors among other forum.

Beyond that, a unique opportunity is given to each and every exhibitor and a suitable time to present its product and service portfolio is available in the agenda.

Moderators:

Fernanda Ferrazin, Consultant and EX AIFA GMP Senior Inspector

Mauro Giusti, Lilly Italy TSMS Director & Manufacturing Sourcing and Vendor Management

AGENDA

08:30 – 09:00 Welcome and Registration

09:00 – 09:15 **Opening remarks and proposed discussion topic**
Angela Molaschi NTC and PDA IT Chapter President

09:15 – 10:45 **Parenteral Packaging: evolving trends, industry perspective and CCI considerations**
Andrea Simonetti, Consultant and **Gabriele Peron**,
Stevanato Group

Session 1 **Packaging Considerations for Cold Storage**

Session 2 **Glass**

Session 3 **Considerations on Container Closure Integrity**

Session 4 **Regulatory Updates**

Session 5 **Sterilization of Packaging**

Session 6 **Primary Packaging Choices and Their Technical Impact**

10:45 – 11:15 Coffee Break at the sponsors area

11:15 – 12:15 **FDA and PDA Perspective: Regulatory harmonization, regulatory science policy and current good Manufacturing practices**
Claudio Puglisi, PQE

12:15 – 13:15 **News from the SPONSORS**

13:15 – 14:15 Networking Lunch at the sponsor area

14:15 – 15:00 **Latest outcomes from Visual Inspection Forum**
Mauro Giusti, Lilly Italy

15:00 – 15:30 Case study: **Compliant Approach to Implementation of Multi-Staged Inspection that Combines Automated and Manual Methods Techniques**
Andrea Cedrola, Patheon, part of Thermo Fisher Scientific

15:30 – 16:00 Coffee Break at the sponsors area

16:00 – 16:30 **Overview of the PDA Interest Groups activities**
Andrea Simonetti, Consultant

16:30 – 17:00 **Open Panel Discussion with Q & A and Final Consideration**

GENERAL INFORMATION

PLANNING COMMITTEE

Ceresa Lucia – Charles River
Giusti Mauro – Eli Lilly Italia
Molaschi Angela – NTC
Peron Gabriele – Stevanato Group
Simonetti Andrea – Consultant

VENUE

Hotel FOUR POINTS by SHERATON

Via Gerolamo Cardano, 1 - 20124 Milan
Metro stop: M2 - Gioia and M3 - Centrale

REGISTRATION

For registration, general information and payment enquiry, please visit www.pda-it.org or contact: pda@pda-it.org

CONFERENCE FEES (VAT 22% included)

- € 183 University and Regulators
- € 549 PDA member
- € 671 PDA NON-member
- € 854 for 2 colleagues for the conference at the same time
- € 1.037 for 3 colleagues for the conference at the same time

Early bird discount: 10% discount for confirmation received within **August 31st, 2019**

EXHIBITION/SPONSORSHIP OPPORTUNITIES

Exhibition and Sponsorship Opportunities are welcome:

- A basic exhibition package for this event is priced **€ 1.300+VAT 22%** (table-top + 2 people pass for the conference).
- Also available the following additional options:
+ € 500+VAT 22% including two invited attendees

PDA and Event Organizing Secretariat



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