

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

***Milan – October 9<sup>th</sup>, 2019***

***Hotel FOUR POINTS by SHERATON***

# ***INTRODUCTION***

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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

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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**, Xepics 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**  
**Matteo Rocchi**, 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**, Xepics

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

# GENERAL INFORMATION

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## PLANNING COMMITTEE

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

## 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](http://www.pda-it.org) or contact: [pda@pda-it.org](mailto: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 Events & Organizing Secretariat



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