

ABSTRACT

Challenges and Advanced Solutions for Aseptic Processes & Barrier Systems

Annex 1 indicates clear requirements for implementation for utilization of Barrier systems for aseptic filling, utilizing different technologies, having different material flow, various line set-up.

Different approaches as well as distinctive and inherent and corrective interventions will be covered during the case study and actively discussed during the roundtables with the matter experts.

Annex 1 indicates clear implementation requirements for the use of barrier systems for aseptic filling, using different technologies, with different material flows and different procedures considering different line settings. All possible approaches, as well as distinctive, inherent and corrective interventions will be described and evaluated with practical application cases during the congress.

Extensive discussion will be dedicated during the round tables with an open constructive debate with industry experts.



ORGANIZING COMMITTEE

Mirko Gabriele / President PDA Italy Chapter

Mauro Giusti / Lilly Italia / Past President PDA Italy Chapter

Filippo Trionfera / BSP Pharmaceuticals / President Elect PDA Italy Chapter

Gabriele Peron / Stevanato Group / Secretary PDA Italy Chapter

Claudio Puglisi / Entourage / Treasurer PDA Italy Chapter

Orazio Cultrera / Cultrera Consulting PDA Italy Chapter

Lucia Ceresa / PDA Italy Chapter

AGENDA DAY 1 – June 26th, 2024

- 12:30-14:00 Arrival, registration DAY-1 & Welcome buffet at IMA Life
- 14:00-14:15 Opening remarks and proposed discussion topic, **Mirko Gabriele - PDA Italy Chapter President**
- 14:15-14:30 Welcome and Introduction, **Michele Arduini - IMA LIFE**
- 14:30-14:45 Annex 1 GMP mandatory requirements for containment solutions: Key Points-To-Consider, **Mauro Giusti - PDA Italy Chapter**
- 14:45-15:15 Barrier technologies overview: design and use, **Giacomo Guidi - IMA LIFE**
- 15:15-15:30 **Sponsors' welcome**
- 15:30-16:00 **Coffee Break with the sponsors**
- 16:00-16:40 Material transfer and direct and indirect product contact concern, **Simone Riva - Fedegari** and **Alessandra Benassi - IMA LIFE**
- 16:40-17:10 Practical consideration on BIs approaching the Validation of a VHP decontamination cycle, **Maria Luisa Bernuzzi - MesaLabs**
- 17:10-17:40 Isolator & RABS Bio-Decontamination: Comparison and Solutions with automated validated VHP process for all RABS types, **Bruno Aze - Steris**
- 17:40-18:10 Speechpharma experience for training and performance support within barrier manual intervention, **Ivan Vecchione - Lilly**
- 18:10-18:40 **Panel discussion** with all speakers. Chairs: **Fernanda Ferrazin**, Life Science Consultant, former Senior AIFA GMP Inspector and **Marisa Delbò**, former AIFA Chief GMP Inspectorate.
- 18:40-18:45 Wrap-up and final remarks from Day-1, **PDA Italy Chapter**
- 18:45-19:15 **Happy hour with the Sponsors**
- 19:15-21:45 Direct Transfer to **Networking** dinner at Ristorante Villa Valfiore with bus.

AGENDA DAY 2 – June 27th, 2024

- 08.45-09:00 Arrival & registration DAY-2 at IMA Life
- 09.00-09:15 Opening remarks and proposed discussion topic, **Filippo Trionfera - PDA Italy Chapter**
- 09:15-09:45 High speed filling & stoppering machine: built in quality from mock-up to environment qualification, **Michela Bergamaschi - Chiesi**
- 09:45-10:15 “PUP-SIT-IN Isolator”: a case study from design to final testing, **Dario Bonanni - Merck Life Science and Laura Venezia - GlaxoSmithKline Parma site**
- 10:15-10:45 A robotic solution for automated aseptic filling, **Marco Elli - Thermo Fisher**
- 10:45-11:15 **Coffee Break with the sponsors**
- 11:15-11:45 Gloves management best practices, **Patrizia Muscas - Lilly**
- 11:45-12:15 Best practices for Interventions management in Barrier, **Eleonora Miccinatti - Catalent**
- 12:15-12:45 Viable monitoring with single use device: performance study and isolator integration, **Luca Calisi - Particle Measuring Systems**
- 12:45-13:45 **Lunch with the sponsors**
- 13:45-14:45 **IMA Life Factory tour.**
- 14:45-15:15 AIFA GMPMED office activities & main findings related to the new Annex 1 requirements, **Marco Paolo Fulfaro - Senior GMP AIFA Inspector**
- 15:15-15:45 **Panel discussion** with all speakers and **Marco Paolo Fulfaro**, Senior GMP AIFA Inspector. Chairs: **Fernanda Ferrazin**, Life Science Consultant, former Senior AIFA GMP Inspector and **Marisa Delbò**, former AIFA Chief GMP Inspectorate.
- 15:45-16:00 Wrap up and closing remarks - **PDA Italy Chapter**

NOTES

Participants are responsible for their own travel costs and accommodation. A suitable number of rooms have been reserved at discounted rate at the Hotel Anusca (BO). Transfers from/back to Hotel and IMA facility as well as from IMA facility to the train Station will be arranged by PDA Italy CCI Secretariat, based on the scheduled timing. Contact CCI for more information.

GENERAL INFORMATION

LANGUAGE

The official languages are Italian and English. No simultaneous translation is provided.

The presentations (.ppt slides) will be in English.

CONGRESS VENUE

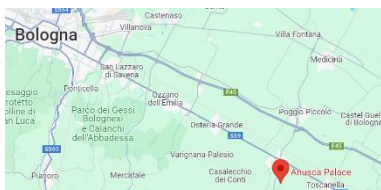


IMA S.p.A. - LIFE Division
Via Maestri del Lavoro 203
40024 Castel San Pietro Terme, Bologna

CONVENTIONED HOTELS



Hotel Anusca, Viale Terme, 1058
40024 Castel San Pietro Terme BO
Telefono: 051 948824



MEDIA PARTNER



PDA Events & Organizing Secretariat



Centro Congressi Internazionale s.r.l.
Via Guarino Guarini, 4 – 10123 Torino
Tel. 011/2446924 – fax 011/2446950
e-mail: pda@pda-it.org
web: www.pda-it.org - [linkedin.com/company/pda-italy](https://www.linkedin.com/company/pda-italy).

GENERAL INFORMATION

HOW TO REGISTER

For registration, general information, and payment enquiry, please visit www.pda-it.org at the page dedicated to the Event.

REGISTRATION FEES (VAT 22% included)

- € 122,00 University and Regulators
- € 366,00 PDA and AFI members (Friday only: € 219)
- € 549,00 PDA and AFI NON-members (Friday only: € 329)
- € 732,00 for 2 colleagues for the conference at the same time
- € 1.038,00 for 3 colleagues for the conference at the same time

Early bird discount: **10%** discount for confirmation received within February 1st, 2024

Registration fee includes badge, program, admission to the scientific sessions, certificate of attendance, welcome cocktail, coffee breaks, lunches, networking dinner.

METHOD OF PAYMENT

Bank Transfer Beneficiary: Centro Congressi Internazionale srl

Bank: INTESA SANPAOLO SPA

Mandatory causal: C033/24 + Name/Surname of the participant and Company

IBAN: IT08X0306901000100000067336

BIC SWIFT: BCITITMM

Copy of the bank transfer should be sent to the CCI Organizing Secretariat at pda@pda-it.org. After receiving the payment, the Organizing Secretariat (Centro Congressi Internazionale srl) will issue a regular invoice.

SPONSORSHIP OPPORTUNITIES

Exhibition and Sponsorship Opportunities are available. Exhibit at PDA Italy Chapter events and let your company's products or services become a valuable tool or resource for our attendees. Contact the CCI Organizing Secretariat at pda@pda-it.org to know the opportunities for this event (CCI, Via Guarini, 4, 10123 Torino, Tel.: 011 244 6911)

SPONSOR



A SPECIAL THANKS TO THE SPONSORS FOR THEIR CONTRIBUTION
TO THE REALIZATION OF THE CONGRESS

