

ABSTRACT



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Associazione Farmaceutici Industria
Società Scientifica

Managing disinfection within an advanced CCS.

Annex 1 indicates clear requirements for Cleaning and Disinfection which are key elements included in the Contamination Control Strategy (CCS) as a holistic and mandatory process for the manufacture of sterile products.

Based on the process understanding, appropriate risks assessment and mitigation measures should be applied considering potential impact on the quality of the final sterile product with the final goal to create a specific quality assurance-approved disinfection and monitoring program able to ensure the required compliance.

Materials utilized for the construction of the room and for items used within the cleanroom, should be selected to minimize particle generation and to allow the suitable use of the cleaning and disinfectant agents.

Several case studies will describe practical solutions for: glove management and materials handling, cleaning, sanitizing agents, disinfectants evaluation, materials compatibility, and frequency program and sanitization technologies.



ORGANIZING COMMITTEE

Mirko Gabriele / President PDA Italy Chapter

Mauro Giusti / Lilly Italia – PDA Italy Past Chapter President

Angela Molaschi / Pharmatex – Past-Past President PDA Italy Chapter

Filippo Trionfera / BSP Pharmaceuticals – President-elect PDA Italy Chapter

Gabriele Peron / Stevanato Group - PDA Italy Chapter Board

Claudio Puglisi / Entourage - PDA Italy Chapter Board

Lucia Ceresa / Charles River Microbial Solution - PDA Italy Chapter Steering

Francesco Boschi / Pfizer-AFI

AGENDA DAY 1 – March 14th, 2024



- 12:40-14:00 Arrival, registration DAY-1 & Welcome buffet at AM Instruments Limbiate site.
- 14:00-14:15 Opening remarks and proposed discussion topic – ***PDA Italy Chapter / AFI***
- 14:15-14:30 Welcome and Introduction – ***Maria Adele Imro & Massimo Mannini, AM Instruments***
- 14:30-15:00 *Clean rooms sanitizing technology* – ***Emanuele Salmaso & Antonio Evangelista, Fresenius Kabi iPSUM***
- 15:00-15:30 ***Tim Sandle (confirmed)***
- 15:30-16:00 **Managing residues** - How can cleaning and disinfectant residues be a risk to product quality? What can be done to control them in a cleanroom environment? – ***David Keen, Ecolab***
- 16:00-16:10 Sponsors' welcome
- 16:10-16:45 Coffee Break
- 16:45-17:15 *Suitability and effectiveness of Disinfectants* – ***Greta Franzoso & Francesca Squizzato, Stevanato Group***
- 17:15-17:45 Hard to Kill Bugs: Identifying resistant Species – ***Duncan Barlow, Microbial Solutions | Charles River***
- 17:45-18:15 Rationalization of the cleaning and disinfection program - ***Valentina Farsetti, Consultant***
- 18:15-18:45 ***Panel discussion*** with all speakers. Chairs: ***Fernanda Ferrazin, Life Science Consultant, former Senior AIFA GMP Inspector and Marisa Delbò, former AIFA Chief GMP Inspectorate***
- 18:45-19:00 Wrap-up and final remarks from Day-1 ***PDA Italy Chapter/AFI***
- 19:00-19:30 Happy hour with the Sponsors
- 19:45-22:00 ***Networking*** dinner at Palazzo Borromeo (Cesano Moderno - MI)

AGENDA DAY 2 – March 15th, 2024



- 08.45-9:00 Arrival & registration DAY-2 at AM Instruments Limbiate site
- 09.00-9:15 Opening remarks and proposed discussion topic **PDA Italy Chapter**
- 09:15-9:45 Cleaning and disinfection within CCS program – **Francesco Boschi, Pfizer/AFI**
- 9:45-10:15 Contamination control in aseptic production – Application of sterile **packaging** and protective solutions in the pharmaceutical industry – **Juha-Pekka Pöyry, Dupont Tyvek® Healthcare Packaging**
- 10:15-10:45 Managing cleaning and disinfection for Isolator use – **Massimiliano Frasca, BSP**
- 10:45-11:15 Coffee Break
- 11:15-11:45 Grade A continuity: contact parts management for transfer into isolator technology – **Fabrizio Gelli, GSK Vaccines Rosia**
- 11:45-12:15 Control and qualification of Rapid Transfer Port – **Lorenzo Mazzetti Thermo Fisher Scientific / Monza**
- 12:15-13:00 Lunch
- 13:00-14:30 AM Instruments Factories tour.
- 14:30-15:15 **AIFA Inspector - INVITED**
- 15:30-15:45 **Panel discussion** with all speakers. 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 / AFI**

NOTES

Transfers from MM3/Yellow – “COMASINA” to AM Instruments facility, as well as from AM Instruments facility to MM3/Yellow – “COMASINA” (15 minutes) will be arranged by CCI-PDA Italy Secretariat, based on the scheduled timing. Participants are responsible for organizing and paying their own travel costs to reach Milan Central rail Station (or to and accommodation to the Hotel). Reach AM Instruments Limbiate site/congress venue, from Milan Central rail Station by MM3/Yellow it takes around 40 minutes in total.

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 - AM Instruments Via Isonzo, 1/c, 20812 Limbiate MB



Day-2, Friday March 15th, 2024: 13:00 -14:30

MANUFACTURING PLANTS TOUR at AM Instruments Plant in Limbiate and AM Instruments Plant in Cesano Maderno MB. Transfer will be arranged by CCI/PDA Italy Secretariat - AM Instruments,

CONVENTIONED HOTELS

AS Hotel Limbiate Fiera, Corso Como 52 - 20812 Limbiate MB

When booking online, enter the reserved code “AMIN”

Hotel Parco Borromeo, Piazzale Ercole Procaccini 20811 Cesano Maderno MB

PDA Events & Organizing Secretariat



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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)

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|------------|--|
| € 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

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Copy of the bank transfer should be sent to the 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 Organizing Secretariat at pda@pda-it.org to know the opportunities for this event.