



# Clean Utilities: Regulatory Challenges and Technological Trends in the Pharmaceutical Manufacturing Applications

May 4-5, 2023

Hotel ibis Styles Settala (MI)

& Stilmas facility



# ABSTRACT



PDA Italy Chapter is pleased to announce **“Clean Utilities: Regulatory Challenges and Technological trends in the pharmaceutical manufacturing applications”** in association with Stilmas S.p.A., a Masco Group Company Pharma on 4-5 May 2023. Two days fully dedicated to latest technological trends in relation to Clean Utility Systems, including Pharmaceutical Grade Water, Steam and Process Gases, with a focus on the impact of recent Regulatory Requirements from Annex 1 as well as the New Challenges to the Production Technologies coming from Sustainability and Energy Saving.

The event’s Speakers are representatives from the pharmaceutical industry, Regulatory Agencies and experts in the latest clean utilities technologies.

Case studies will be presented by Industry experts with practical information of their application to be presented and commented with all participants.



The agenda will also include a guided tour at Stilmas facility dedicated to the Manufacturing of Phama-Water & Steam Systems. Finally, attendees will have the opportunity to share their experiences and challenges with experts of Clean Utility Systems.

## ORGANIZING COMMITTEE

Paolo Curtò (DOC - Masco Group)  
Ilaria Brusamolino (Stilmas - Masco Group)  
Angela Molaschi (Pharmatex) Past PDA Italy President **Chair**  
Lucia Ceresa (Charles River Microbial Solution)  
Alessandro Pauletto (Charles River Microbial Solution)  
Gabriele Peron (Stevanato Group)  
Filippo Trionfera (BSP Pharmaceuticals)

# AGENDA DAY 1 – May 4<sup>th</sup>, 2023



- 12:40-14:00 Arrival, registration DAY-1 & Welcome buffet at Hotel ibis Style-Settala (MI)
- 14:00-14:15 Opening remarks and proposed discussion topic  
Lucia Ceresa, Senior Technology and Market Development Manager, Charles River Microbial Solution, ***PDA Italy Chapter Steering committee***
- 14:15-14:30 Welcome and Introduction  
***Luca Borella, CEO Masco Group***
- 14:30-15:15 *Clean utilities, Regulatory Challenges and Annex 1 Prospective*  
***Paolo Curtò, DOC Managing Director, Masco Group***
- 15:15-16:00 New Technological Trends for Clean Utility Systems -  
***Paolo Leani, Stilmas Technical Director, Masco Group***
- 16:00-16:15 Sponsors' welcome
- 16:15-16:30 Coffee Break
- 16:30-17:10 Water for Injection Generation by Membrane Technology: Global Industry applications overview –  
***Vincenzo Quarti, Director of Engineering, Jacobs Italia***
- 17:10-18:00 ***Panel discussion*** with all speakers, chair, ***Fernanda Ferrazin***, Life Science Consultant, former Senior GMP Inspector and ***Marisa Delbò***, former Senior GMP Inspector
- 18:00-18:15 Wrap-up and final remarks from Day-1 - ***Angela Molaschi Past President of PDA Italy Chapter***
- 18:15-19:00 Happy hour with the Sponsors
- 19:30-21:45 ***Networking*** dinner at Restaurant: Hotel ibis Style - Settala (MI)

## NOTES

Transfers from Milan Central rail Station to Hotel ibis Style as well as from Hotel ibis-Stilmas Facility to Milan Central rail Station will be arranged by Stilmas based on the scheduled timing. Participants are responsible for organizing and paying their own travel costs and accommodation to the Hotel.

# AGENDA DAY 2 – May 5<sup>th</sup>, 2023



- 9:00-9:15 Arrival & registration DAY-2 at Hotel ibis Style-Settala
- 9:15-9:45 Clean Utilities-GMP Inspection prospective  
**Adele Romani, AIFA Senior GMP Inspector - invited**
- 9:45-10:15 Pharmaceutical Water Systems: *Sanofi* Group prospective –  
**Florent Deleris, Clean Utilities & Engineering Standard Manager, Sanofi France**
- 10:15-10:45 Energy Saving and Sustainability in Clean Utilities  
**Paolo Leani, Technical Director- Demetrio Barbitta, Commissioning & Service Director, Stilmas, Masco Group**
- 10:45-11:00 Coffee Break
- 11:00-11:30 Clean Utilities, digital process monitoring and sustainability  
**Tiziano Avallone, Associate Director – Process Engineering Utilities, Eli Lilly Italia**
- 11:30-12:00 Energy Saving and Sustainability in Clean Utilities: INDUSTRY CASE STUDY 2 ,  
**BSP Pharmaceuticals**
- 12:00-13:00 Lunch
- 13:00-13:15 Transfers from Hotel IBIS Style to Stilmas Facility
- 13:15-14:30 Factory tour at Stilmas Facility  
Intro 5 minutes: Background info and Factory guidelines
- 14:30-14:45 Transfers from Stilmas Facility to Hotel IBIS Style, Settala (MI)
- 14:45-15:15 Commissioning and Qualification integration in Clean utilities -  
**Paolo Curtò, DOC Managing Director, MASCO Group**
- 15:15-15:30 Coffee Break
- 15:30-15:45 **Panel discussion** with all speakers, chair, **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

# GENERAL INFORMATION



## HOW TO REGISTER

For registration, general information, and payment enquiry, please visit [www.pda-it.org](http://www.pda-it.org) at the page dedicated to the Event.

## REGISTRATION FEES (VAT 22% included)

- € 122,00 University and Regulators
- € 366,00 PDA member
- € 549,00 PDA NON-member
- € 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 **20/03/2023**

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: C044/23 + Name/Surname of the participant and Company

IBAN: IT08X0306901000100000067336

BIC SWIFT: BCITITMM

Copy of the bank transfer should be sent to the Organizing Secretariat at [pda@pda-it.org](mailto: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](mailto:pda@pda-it.org) to know the opportunities for this event.

# 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



### Hotel ibis Style Milano

Via delle Industrie, Snc, 20090 Settala (MI)



### MANUFACTURING PLANT TOUR at Stilmas

Day-2, May 5<sup>th</sup>, 2023: 13:15 -14:30

## CONVENTIONED HOTEL

ibis Style Milano

Via delle Industrie, Snc, 20090 Milano MI

Telefono: +39-02-839901

<https://all.accor.com/hotel/9890/index.en.shtml>

While booking, refer to “MASCO-PDA Event”.

## PDA Events & Organizing Secretariat



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