



Cleaning Process and Cleaning Validation: Relevant Aspects in the Pharmaceutical Manufacturing Applications

September 29-30, 2022
Riese Pio X (TV)
Steelco Facility



INTRODUCTION

PDA Italy Chapter is pleased to announce “Cleaning and Validation: relevant aspects in the pharmaceutical manufacturing applications” in association with Steelco S.p.A., Pharma division on day 29_30 of September 2022. Two days fully dedicated to latest developments in relation to cleaning validation with a deep focus on impact of new regulations, automated systems and best practices learnt by real cases.

Present on the day will be representatives from the pharmaceutical industry and experts in the latest cleaning validation advances for pharmaceutical production. Case studies will be presented with practical information on risk and science-based approaches that showcase effective implementation of cleaning processes.

The agenda will also include a guided tour at Steelco’s facilities and latest generation in regard to sterilization and washing equipment. The event will also feature case studies & industry speakers from Eli Lilly and GSK. Finally, attendees will have the opportunity to share their experiences and challenges with experts in cleaning and validation.



ORGANIZING COMMITTEE

Filippo Trionfera (BSP Pharmaceutical) **Chairman**

Lucia Ceresa (Charles River Microbial Solution)

Saverio Cornacchia (Steelco)

Fernanda Ferrazin (LifeScience Consultant, former Senior GMP Inspector)

Angela Molaschi (Pharmatex)

Gabriele Peron (Stevanato Group)

Claudio Puglisi (Entourage)

Andrea Simonetti (DOC Validation)

AGENDA DAY 1 – September 29th, 2022

- 12:00-12:15 Meeting point at Hotel Roma lobby and transfer to Steelco Academy
- 13:00-14:00 Arrival, registration & Welcome buffet
- 14:00-14:15 *Opening remarks and proposed discussion topic*
Filippo Trionfera, Quality Operations Manager & QP BSP
Pharmaceutical and **Lucia Ceresa**, Senior Technology and Market
Development Manager, Charles River Microbial Solution
- 14:15-14:30 *Welcome and Introduction*
Saverio Cornacchia, Steelco Sales Director Pharma Division
- 14:30-15:15 *Clean Utilities for Pharmaceutical Cleaning Processes: a regulatory
Perspective*
Paolo Curtò, Managing Director DOC Validation, MASCO Group
- 15:15-16:00 *Highlights on Annex 15 - Quality Risk Management vs Cleaning
Validation*
Valentina Farsetti, Senior Pharmaceutical Consultant
- 16:00-16:10 **Sponsors welcome**
- 16:10-16:30 Coffee Break
- 16:30-17:00 *Operazioni di cleaning e problematiche emerse in corso di ispezioni
regolatorie*
Fernanda Ferrazin, Life Science Consultant, former Senior GMP
Inspector
- 17:30-17:55 Panel discussion with all speakers, chair, **Fernanda Ferrazin**, Life
Science Consultant, former Senior GMP Inspector and **Marisa
Delbò**, former Senior GMP Inspector
- 17:55-18:00 Wrap-up and Closure 1st day

Pickup and transfer at 18:30 to Hotel Roma, La Torre and Al Moretto provided by Steelco
Networking dinner at Restaurant: Hotel Roma – Castelfranco Veneto (TV)



AGENDA DAY 2 – September 30th, 2022

- 8:30 Meeting point at Hotel Roma lobby and transfer to Steelco Academy
- 9:15-10:00 *Cleaning validation approach for a new Prefilled syringe line*
Linda Favaro, TS/MS Periodic Validation Sr. Associate, Eli Lilly
- 10:00-10:45 *Automatic Part washers cleaning validation approach: contaminant selection and sampling points worst case*
Valentina Farsetti, Senior Pharmaceutical Consultant
- 10:45-11:15 Coffee Break
- 11:15-11:45 *Digitizing your Cleaning Validation Program and Strategy*
Marc Vorderman, Director Europe Novatek International
- 11:45-12:30 *Glassware washers validation approach end execution – GSK Rosia site Case Study*
Giorgio Maccari, Cleaning Validation Leader, GSK Vaccines
- 12:30-13:30 Lunch
- 13:30-14:45 Factory tour at Steelco Facility
Intro 5 minutes: Background info and Factory guidelines
- 14:45-15:30 *Highlights on Annex 1 and EMA guideline on cleaning validation aspects*
Gilberto Dalmaso, Technical Science Director For Europe And Asia Veltek Associated
Lucia Ceresa, Senior Technology and Market Development Manager, Charles River Microbial Solution
- 15:30-16:00 Coffee Break
- 16:00-16:45 Panel discussion with all speakers, chair, **Fernanda Ferrazin**, Life Science Consultant, former Senior GMP Inspector and **Maria Delbò**, former Senior GMP Inspector
- 16:45-17:00 Wrap up e closing words

Pickup and transfer to Hotel Roma, La Torre and Al Moretto provided by Steelco

Transfers from Hotel Roma, La Torre and Al Moretto to Facility and back will be arranged by Steelco based on the scheduled timing. Hotel Torre and Hotel Moretto are at 5 minutes walking distance from Hotel Roma. Participants are responsible for organizing and paying their own travel costs and accommodation to the Hotel.

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)

€ 61,00	University and Regulators
€ 403,00	PDA member <i>for 2 colleagues for the conference at the same time</i>
€ 604,00	PDA NON-member <i>for 2 colleagues for the conference at the same time</i>

Early bird discount: **10% discount** for confirmation received within **30/07/2022**

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: C005/22 + 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. 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 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.

GENERAL INFORMATION

LANGUAGE

The official language is Italian. No simultaneous translation is provided. The presentations (ppt slides) will be in English.

CONGRESS VENUE



STEELCO S.p.A.

Via Balegante, 27 31039 Riese Pio X (TV)
info@steelcogroup.com

MANUFACTURING PLANT TOUR at STEELCO

Day 2, September 30th, 2022: 13:30-14:45



CONVENTIONED HOTEL

Albergo Roma – Castelfranco Veneto (TV) www.albergoroma.com *preferred choice*

Hotel Alla Torre – Castelfranco Veneto (TV) www.hotelallatorre.it

Albergo Al Moretto – Castelfranco Veneto (TV) www.albergoalmoretto.it

While booking, refer to “**Steelco Event**”.

PDA Events & Organizing Secretariat



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