



# Sterilization: hot topics and innovation in the Pharmaceutical Applications

October 26th-27th, 2023

De Lama Plant

Via Piemonte 21

San Martino Siccomario

(PV) Italy



# ABSTRACT



PDA Italy Chapter is pleased to announce, in collaboration with De Lama, the event **“Sterilization: hot topics and innovation in the Pharmaceutical Applications”**.

The event will take place on October 26<sup>th</sup> and 27<sup>th</sup> 2023 at the De Lama Plant in San Martino Siccomario (PV). The event is focused on:

- Sterilization Hot topics (such as equilibration time, load configuration, cycle development, sterilization packaging, presterilized containers, etc..)
- Innovations aspects (such as new sterilization processes and automation of sterilization operations)
- Tour of the De Lama Plant

Case studies will be presented by Industry experts with strong experience in sterilization and commented with all participants.

The agenda will also include a guided tour at De Lama facility dedicated to the production of sterilization and washing equipment.

Finally, attendees will have the opportunity to share their experiences and challenges with experts.

## ORGANIZING COMMITTEE

Mauro Giusti / Lilly Italia – PDA Italy Chapter President

Filippo Trionfera / BSP Pharmaceuticals

Lucia Ceresa / Charles River Microbial Solution

Gabriele Peron / Stevanato Group

Mirko Gabriele / President-Elect PDA Italy Chapter

# AGENDA DAY 1 – October 26<sup>th</sup>. 2023



- 12:00-12:30      Arrival at **Hotel Moderno (PV)**
- 12:30-12:45      **Bus Transfer** from Hotel Moderno to De Lama Plant
- 12:45-14:00      **Arrival al De Lama Plant and welcome buffet & registration**
- 14:00-14:15      Opening remarks and proposed discussion topic: **Mauro Giusti – President PDA Italy Chapter**
- 14:15-14:30      Welcome and Introduction: **Marco Bianchi – De Lama S.p.A**
- 14:30-15:15      Innovative sterilization approach: Hyper pure technology key aspects : **Guido Rovera – De Lama S.p.A**
- 15:15-15:45      Equilibration time: how to fill the gap: **Saverio Paolini – Akkodis**
- 15:45-16:00      **Sponsors' welcome**
- 16:00-16:15      *Coffee Break*
- 16:15-16:45      Autoclave validation: the importance of load designing on validation and re-validation activities: **Giovanna Cantoni – PQE**
- 16:45-17:15      Annex 1 Hot Topic: Sterilization Process: **Renato Picchi – Pharma Process**
- 17:15-18:00      **Panel discussion** with all speakers, chairs: **Fernanda Ferrazin, Life Science Consultant, former Senior GMP Inspector and Marisa Delbò, former Senior GMP Inspector & Closing**
- 18:00-18:15      Wrap-up and final remarks from Day-1: **Filippo Trionfera – BSP Pharmaceuticals**
- 18:15-19:00      **Happy hour with the Sponsors**
- 19:00-19:30      **Transfer to Villa Botta**
- 19:30-21:45      **Networking dinner at Restaurant: Villa Botta Adorno di Torre d'Isola.**

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 Moderno.

Transfers from/back to Hotel Moderno (close to the Pavia train Station) and De Lama facility as well as from De Lama to Villa Botta and from Villa Botta, to Hotel Moderno will be arranged by De Lama based on the scheduled timing.

# AGENDA DAY 2 – October 27<sup>th</sup>, 2023



- 08:45-09:15 **Bus Transfer** from Hotel Moderno to **De Lama Plant** or arrive at **De Lama plant** by car
- 09:15-09:45 SUS X-ray sterilization method – Risk based approach: **Dario Bonanni – Merck**
- 09:45-10:15 Sterilization management of ready to use primary components: available options and industrial implementation :**Alice Bellini and Leonardo Furlan – Stevanato Group**
- 10:15-10:45 Packaging Solution for Sterilization Processes: **Massimo Mannini – AM instruments**
- 10:45-11:00 *Coffee Break*
- 11:00-11:30 Terminal Sterilization of single-dose injectable product: case study: **Davide Lucetti – Ellab**
- 11:30-12:00 Robotic & automation; how to impact the sterilization process: **A. Tanzini – Staubli**
- 12:00-13:00 *Lunch*
- 13:00-14:30 **Factory tour** at De Lama Facility  
Intro 5 minutes: Background info and Factory guidelines
- 14:30-15:15 Biological Validation for a Moist Heat Sterilization: an overview of the different approaches based on the load we have to treat: **Luisa Bernuzzi – Mesa Labs**
- 15:15-15:45 *Coffee Break*
- 15:45-16:15 **Panel discussion** with all speakers, chairs: **Fernanda Ferrazin - Life Science Consultant, former Senior AIFA GMP Inspector and Marisa Delbò, former Senior GMP Inspector & Closing**
- 16:15-16:30 Wrap up and closing remarks: **Mauro Giusti – President PDA Italy Chapter**
- 16:30-17:00 **Bus Transfer** from **De Lama Plant** to **Hotel Moderno**

# 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 September 10<sup>th</sup>, 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: C069/23 + Name/Surname of the participant and Company

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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



Process & Sterilization Solutions since 1949

**MANUFACTURING PLANT at  
De Lama site** Via Piemonte, 21,  
27028 San Martino Siccomario (PV) Italy  
Day-2, October 27<sup>th</sup>, 2023 - 13:15 -14:30  
**Factory tour**

## CONVENTIONED HOTEL



**Hotel Moderno**  
Viale Vittorio Emanuele II, 41 – 27100  
Pavia

While booking, refer to:  
**“PDA/DE LAMA Sterilization event”**.

## PDA Events & Organizing Secretariat



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The logo for MesaLabs. It consists of a teal square icon on the left containing a white stylized 'M' shape. To the right of the icon, the word 'MesaLabs' is written in a bold, sans-serif font. 'Mesa' is in black, and 'Labs' is in teal.