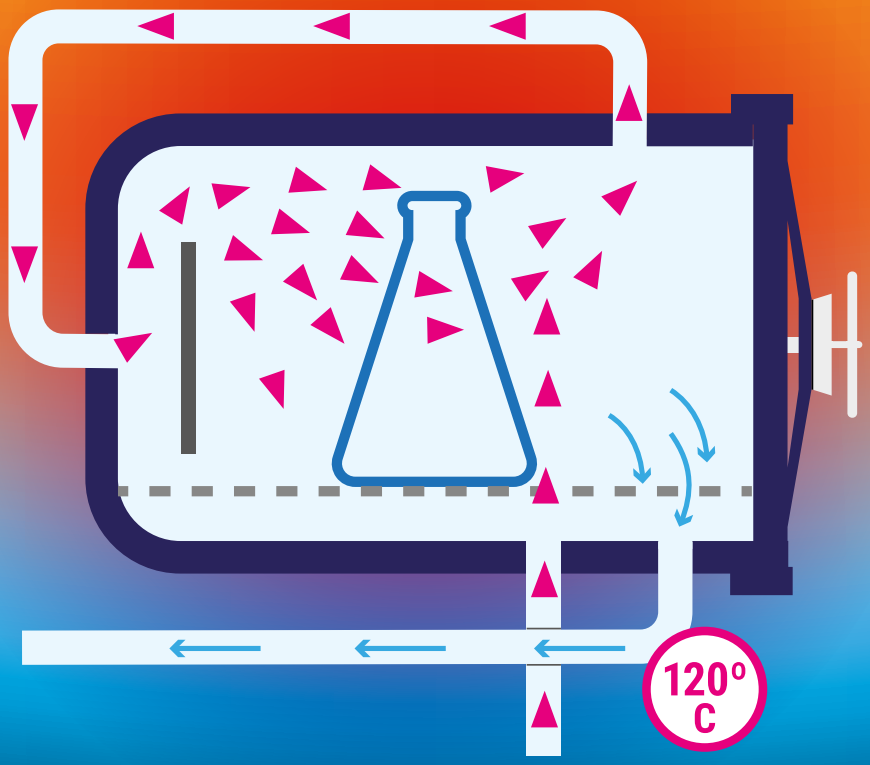
pda.org/EU/Sterile2020

2020 PDA EUROPE TRAINING

Understanding Sterilization



18-20 FEBRUARY 2020
FEDEGARI AUTOCLAVI SPA
ALBUZZANO, ITALY

CONNECTING PEOPLE SCIENCE AND REGULATION®

Overview

Three days fully dedicated to every sterilization aspect, from basic principles to validation activities. Starting from an overview of all sterilization methods, participants will have the opportunity to discover the secrets of moist-heat sterilization. Not only theoretical sessions, but also hands-on training with process machines for increasing your practical knowledge.

The course will be held at Fedegari's Tech Center, where participants will be able to discuss real-life problems while using Fedegari equipment to apply their new knowledge and capabilities. Finally, attendees will have the opportunity to share their experiences and challenges with experts in sterilization and contamination control.

Attendees will learn how to:

- select the right machine according to the product to be treated
- create the perfect cycle for liquid and porous loads
- run biological and thermal validation

Who Should Attend:

- Manufacturing Supervisors and Operators
- QA Managers
- QC Managers
- Facility Managers/Technicians
- Validation/Qualification Personnel
- Equipment Manufacturers
- Head of Production
- Process Engineers
- Process Developers

Learning Objectives:

The participants:

- Have understood concepts of decontamination, disinfection and sterilization
- Have understood the principles of moist heat/ dry heat sterilization
- Have an overview of other sterilization methods (gamma irradiation, E-Beam, EtO)
- Can calculate F and D values
- Have understood the different cycle requirements for various load types (solid, porous, liquid)
- Have understood approaches for qualification of equipment
- Have understood challenges and solutions for biological and chemical indicators

Welcome to the Fedegari Facilities

Maria Luisa Bernuzzi, *Manager R&D, Fedegari Group*

Graduated from University (Chemistry and Pharmaceutical Technology) at the University of Pavia, Maria Luisa started her career dealing with environmental analyses, and then moved to Chemical - Pharmaceutical industry. Being R&D manager and QC manager, in 2010, she also attended a Master degree about "Evaluation and control of the toxicological risk from environmental pollutants - legislation REACH, CLP - chemical risk assessment". Since 2011, Maria Luisa is R & D manager at Fedegari group: new technologies, a multidisciplinary approach at the Innovations, development of validation strategies ad assessment of process efficacy, also with microbiological tests, are her main tasks. Specialties: Validation of equipment, Sterilization processes, Isolation technology in aseptic and containment applications, Decontamination.

Annick Gillet, *Technical Director EO Pharma, Sterigenics*

Annick Gillet has a biochemistry background and began her career at Sterigenics up to 10 years ago as Quality Manager for one of the biggest EO Sterigenics plant located in Belgium. She acted as the main contact during customers and regulatory inspections (FDA, European Authorities …etc.). Annick also gained ten years of experience in Medical Device industry (wound dressings) in R&D, Quality, and consultancy. She also worked for about two years as SME in sterilization at Allergan (Pharmaceutical industry) in a site manufacturing terminally sterilized hormonal Intra Uterine device. As a Technical Director for 3 years, Annick currently leads ethylene oxide sterilization projects in different Sterigenics plants and is supporting the plants as technical expert with pharmaceutical project responsibilities.

Simone Riva, *Manager, Innovation Process, Fedegari Group*

Simone Riva obtained his bachelor's degree in Biomedical Engineering. From 2000 to 2017 he worked for Fedegari Group, in the beginning as Validation Engineer, where he was involved in many global projects for pharmaceutical industries. During his professional career, Simone increased his experience in multi pharmaceutical disciplines, like working at biopharma plants and API, always in contact with the Quality Assurance department, Biotechnologists, QC laboratories, and fill-finish plant. In 2017 Simone has been involved in a new challenge. Based in Singapore, he became Project Manager in Novartis Biopharma, leading the validation team to deliver a complete solution for SIP and PQ Validation. After his return to Italy, he became the Innovation Manager at Fedegari Group. Simone is in charge to bring, drive and deliver innovation, increasing the pharma knowledge inside the company group and to draw the road map for the new technologies in the fast-growing pharmaceutical market.

Tuesday, 18 February 2020
9:00 – 17:30

9:00 **Introduction to Current Decontamination Methods**
- Distinguish disinfection, sterilization and decontamination
- E- Beam
- EtO

10:30 **Coffee Break**

11:00 **Introduction to Current Decontamination Methods (cont.)**
- ɣ-Irradiation
- Hydrogen Peroxide: Principle and application in Pharma, Equipment
- Regulations

12:30 **Lunch Break**

13:30 **Plant Tour**

14:30 **Coffee Break**

14:45 **Hydrogen Peroxide Decontamination in Practice**
- Group session with practical examples of correct / wrong cycles
- Correct placement of probes and indicators for various load types

17:30 **End of Day 1**

Wednesday, 19 February 2020
8:30 – 17:00

8:30 **Wrap-up of Day 1 and Questions**

9:00 **Moist-heat Sterilization Principles**
- Sterility assurance concept (PNSU or SAL), D-values, z-values, F_0

10:30 **Coffee Break**

11:00 **Moist-heat Sterilization, Load Types and Process/ Autoclave Selection**
- Steam sterilization: general concepts
- Case studies

12:30 **Lunch Break**

13:30 **Moist-heat Sterilization, Load Types and Process/ Autoclave Selection**
- Counterpressure cycles
- Case studies

15:30 **Coffee Break**

15:45 **Practical session: How to create the right cycle for a specific load**

16:45 **Q&A Session**

17:00 **End of Day 2**

Thursday, 20 February 2020
8:30 – 16:45

8:30 **Wrap-up of Day 2 and Questions**

9:00 **Biological Indicators and Validation – Parametric Release**

10:30 **Coffee Break**

11:00 **Temperature Mapping and Practical Sessions Common Loads**

12:30 **Lunch Break**

13:30 **Routinely and Operational Tests**
- Vacuum and pressure leak test
- Bowie & Dick test
- Equilibration time
- Steam quality test

15:30 **Coffee Break**

15:45 **Variables Affecting Validation**

16:15 **Q&A Session**

16:45 **End of Day 3**

TRAINING LOCATION

Fedegari Group
Fedegari Autoclavi s.p.a.
SS 235 km 8
27010 Albuzzano (PV), Italy

CONTACT INFORMATION

Registration Customer Care
Tel: +49 30 436 55 08-10
registration-europe@pda.org

Training Program Inquiries
Elke von Laufenberg
training-europe@pda.org

PDA EUROPE EDUCATION PROGRAM

2020

18-20 February	Understanding Sterilization	TC	Albuzzano, Italy
27 February	Container Closure Development	TC	Basel, Switzerland
27-28 February	Extractables and Leachables	TC	Basel, Switzerland
27-28 February	Container Closure Integrity Testing – Basic Course	TC	Basel, Switzerland
27-28 February	CCIT for the Advanced User	TC	Wohlen, Switzerland
9-13 March	Freeze Drying in Practice	TC	Osterode am Harz, Germany
17-18 March	All About Virus Filtration	TC	Cologne, Germany
23-24 April	An Introduction to Visual Inspection	TC	Berlin, Germany
23-24 April	Mastering Automated Visual Inspection	TC	Berlin, Germany
26-27 May	Single-Use Systems – A New Age of Drug Making	TC	Göttingen, Germany
23 June	Practical Application of Risk-Based GMP and Quality Principles to Clinical Development of ATMPs	TC	Brussels, Belgium

Subject to change | For latest info: **europe.pda.org** | Shortlist 6 Dec 2019

GENERAL INFORMATION
PDA EUROPE GGMBH
AM BORSIGTURM 60
13507 BERLIN, GERMANY
TEL: +49 30 4365508-0
FAX: +49 30 4365508-66
INFO-EUROPE@PDA.ORG

For contact at PDA Europe
registration-europe@pda.org

3 WAYS TO REGISTER

1. **online: pda.org/EU/Sterile2020**
2. **FAX: +49 30 4365508-66**
3. **Email: registration-europe@pda.org**

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

GENERAL ADDRESS: **PDA Europe gGmbH | Am Borsigturm 60 | 13507 Berlin, Germany | Tel: +49 30 436 55 08-0 | Fax: +49 30 436 55 08-66**

1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

☐ Mr. ☐ Ms. ☐ Dr. ☐ Nonmember ☐ **I want to become a PDA Member.** Please send me a subsription form

☐ PDA Member ID Number

Name (Last, First, MI)

Job Title

Company Department

Mailing Address

City Postal Code

Country Email

Business Phone Fax

☐ Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

2 Registration

All fees given in Euro and excluding VAT (22 %)

Training Course (18-20 February 2020)		net
Day 1 + 2: Sterilization Overview and Practice	☐	**1595**
Day 3: Validation and Qualification	☐	**895**
Day 1 + 2 + 3: Sterilization – All You Need to Know	☐	**2345**

Your consent is important. We manage your personal data responsibly.
For more information, please visit pda.org/privacy-policy

RESPONSE REQUIRED – By checking the box(es) below, I consent to:

☐ My contact information (name, company, job title, city, state, country) being printed on the attendee list distributed at the event.

☐ PDA recording and/or photographing me and using those recordings and/or photographs in future PDA promotional and marketing materials.

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3 Payment Options

☐ **By Credit Card**

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For your credit card information safety:
Please send your details by fax only (+49 30 4365508-66) or register online.

☐ **By Bank Transfer**

Beneficiary: PDA Europe gGmbH

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(example: PDA Europe's country code starts with: DE | followed by the number)

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **19 January 2020** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **registration-europe@pda.org or fax to +49 30 4365508-66.**

PDA EUROPE EVENTS

2020

25-26 February	Parenteral Packaging	*	Basel, Switzerland
21-22 April	Visual Inspection Forum	*	Berlin, Germany
9-10 June	Quality and Regulations Conference	*	Dublin, Ireland
22-23 June	Virus Forum	*	Brussels, Belgium
24-25 June	Advanced Therapy Medicinal Products	*	Brussels, Belgium
8-9 September	Medical Devices and Connected Health	*	TBC, Europe
22-23 September	BioManufacturing	*	Dublin, Ireland
24-25 September	Pharmaceutical Freeze Drying Technology	*	Dublin, Ireland
20-21 October	Aseptic Animal Health	*	The Hague, The Netherlands

Subject to change | For latest info: **europe.pda.org** | Shortlist 6 Dec 2019

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