



**Training &
Education**
FEDEGARI | Tech Centers

**PASSION
THAT DRIVES
PERFORMANCE.**



**2017
CALENDAR**





COLLABORATION IN THE LIFE SCIENCES WORLD

Valued customer,

The need to increase efficiency and reliability in pharmaceutical manufacturing presents firms with unique opportunities to develop a new business model. Fedegari has been working on various innovative solutions taking an original approach: rather than focusing on a component or a technology, we are investing in developing deeper knowledge.

Our expertise in sterile processes extends beyond engineering and process equipment manufacturing to include knowledge sharing with customers and partners in various levels.

In this perspective, we collaborate with a strategic network of partners including Rowan University, Lehigh University, Jim Agalloco, Intel Corporation/Wind River Systems, B&R Automation, Ompi, Camfil, and Amphe-
nol/Kaye to offer continuous innovation and drive competitiveness for the pharmaceutical industry.

In addition, our Innovative Technology Centers are available to share experiences and allow our customers to develop a much deeper understanding of technologies and products through high-performance *Training & Education* programs designed specifically to increase the overall results obtained with Fedegari machines and technologies.

Today, we are proud to present you with our *Training & Education* calendar for 2017, as part of our ongoing commitment to collaborative innovation.

Giuseppe Fedegari
President



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FEDEGARI | Tech Centers

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Our *Tech Centers* are the perfect environment for end-users and experts to meet and exchange experiences for the development of new and cost-effective solutions to real-world problems.

Through state-of-the-art centers, Fedegari aims to increase the interaction with partners and customers for continuous education in the field of sterilization and contamination control. To accomplish that, our company have invested more than \$10 million in process equipment installed in the facilities in USA, Italy and UK (in partnership with Steritech).

With collaborative R&D projects, Fedegari encourages end-users and researchers to work together with us in the *Tech Centers* on strategically important areas like process design and technology. This way, we expect to successfully develop and introduce new processes, products and services that will contribute to cost-effectiveness in pharma manufacturing.

Our *Tech Centers* are an asset for the pharmaceutical community to achieve excellence through collaborative projects.

Tech Centers

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training@fedegari.com

Sellersville (PA) - USA T +1 215 4530400 F +1 215 4530406
training@fedegariusa.com

Salfords (Surrey) - UK In collaboration with Steritech
training@fedegari.com



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TECHNICAL TRAINING COURSES

Introduction

Fedegari offers different technical courses in the fields of sterilization, bio-decontamination and cleaning. These courses cover the science behind the processes and give practical advices on cycle development and performance as well as validation activities. Each course is developed to target personnel having specific job functions such as operators, maintenance technician and QR/QC professionals.

Additional training modules are available for personnel who seeks to acquire deeper knowledge about specific subjects.

Topics	Duration
INSIGHTS IN CHEMICAL BIO-DECONTAMINATION: DESIGN, APPLICATIONS & VALIDATION OF H ₂ O ₂ PROCESSES	1 day
MOIST HEAT STERILIZATION: PRINCIPLES, APPLICATION & CHALLENGES	1 day
CLEANING: BASIC PRINCIPLES & PROCESS VALIDATION	1 day
OVERCOMING CHALLENGES IN A STERILITY TESTING ISOLATOR: TESTING PROCEDURES AND ENVIRONMENTAL MONITORING	1 day
STEAM STERILIZERS: VALIDATION SPECIALIST COURSE	1 day



STEAM STERILIZERS Process Validation Specialist Course



The participants will learn how to select the proper validation methodology as well as the thermal and microbiological studies required during sterilization process validation. This knowledge will be applied to verify that the products meet the required sterility assurance level and to maintain the process in its validated state.

Duration: 1 day

Target: QA personnel, validation specialists and sterility assurance specialists.

Class size (min/max): 4-6

Outcome

- Select the validation methodologies according to load attributes
- Define the “worst case” load
- Perform physical and microbiological studies
- Select, handling, D-value calculation of biological indicators
- Demonstrate product sterility assurance level
- Maintain process validation state

Content

- Regulatory references for moist heat sterilization
- Sterility assurance concept, D-values, z-values, F_0 and their application
- Cycle design: overkill approach versus product specific approach
- Validation methods: overkill, bioburden/biological indicator, and bioburden-based methods
- Physical and biological process performance qualification
- Validation equipment (TCs, CIs, BIs): selection, placement and results interpretation
- Analysis of a sterilization process printout
- Ongoing process control

TECHNICAL
TRAINING
COURSES

Where?

Albuzzano (PV), Italy

Sellersville (PA), USA

Salfords (Surrey), UK

When?

March 23rd

March 9th

May 8th / Sep. 5th / Nov. 21st



INSIGHTS IN CHEMICAL BIO-DECONTAMINATION: design, applications & validation of H₂O₂ processes



This workshop provides an overview of vaporized hydrogen peroxide technology describing process design, applications and challenges. Through system demonstration and case studies, by the end of the course trainees will also have a deeper understanding of the validation activities related to this new technology.

Who should attend?

This training class is intended for personnel in the pharmaceutical & biotech industry using or considering the application of hydrogen peroxide processes. It is appropriate for individuals working in QA, engineering, production, microbiology and validation activities.

Duration: 1 day

Outcome

- List the critical process parameters
- Cycle optimization according to load type and effectiveness level
- Calculate D-value system and process effectiveness

Content

- Vaporized H₂O₂ process description and associated challenges
- Cycle development and examples of relative case studies
- Validation activities: enclosure evaluation and CIs, BIs and TCs utilization

Where?

Albuzzano (PV), Italy

Sellersville (PA), USA

When?

April 20th

June 14th

TECHNICAL
TRAINING
COURSES



MOIST-HEAT STERILIZATION: principles, applications & challenges



The participants will learn the basics of moist-heat sterilization, how to select the appropriate steam sterilizer according to load type and the main factors that may strongly impact the outcome of a sterilization process.

Who should attend?

This seminar is intended for personnel working in QA/QC, research & development, regulatory affairs, engineering, microbiology and validation activities.

Duration: 1 day

Outcome

Upon completion of this course, the participant will be able to:

- Calculate the lethality of a moist heat sterilization process
- Select a steam sterilizer according to load type
- Identify steam sterilization parameters that may affect drying, packaging deformations and product degradation
- Select steam and water of suitable quality

Content

- Sterility assurance concept, D-values, z-values, F_0 and their application
- Moist heat sterilization process phases & autoclave types
- Treatment of porous and liquid loads
- Steam and water quality requirements

TECHNICAL
TRAINING
COURSES

Where?

Albuzzano (PV), Italy

Sellersville (PA), USA

Salfords (Surrey), UK

When?

March 22nd

March 8th

May 8th / Sep. 4th / Nov. 20th



CLEANING: basic principles & process validation



The participants will gain a basic knowledge of different cleaning methods and what are the variables that affect the outcome of a cleaning procedure (ex. detergent, soil and product properties, cleaning equipment). They will also learn how to approach cleaning validation and establish cleaning process efficacy.

Who should attend?

This seminar is intended for personnel working in QA/QC, research & development, regulatory affairs, engineering, microbiology and validation activities.

Duration: 1 day

Outcomes

Upon completion of this course, the participant will be able to:

- Define worst case locations for sampling
- Define acceptable limits
- Select the appropriate cleaning protocol according to soil types
- Evaluate cleaning effectiveness

Content

- Regulatory references
- Cleaning methods and procedures
- Cleaning validation: acceptance criteria, sampling points and procedures, product and equipment arrangement
- Case study examples

TECHNICAL
TRAINING
COURSES

Where?

Sellersville (PA), USA

Salvors (Surrey), UK

When?

July 19th

October 18th



OVERCOMING CHALLENGES IN A STERILITY TESTING ISOLATOR: testing procedures and environmental monitoring

In collaboration with 

This workshop provides guidance on conducting sterility testing and environmental monitoring in a Sterility Isolator, including practical advice on critical process aspects: consumables, equipment design, application and challenges. Through system demonstration and case studies, by the end of the course trainees will also have a deeper understanding of how to face common challenges related to the use of hydrogen peroxide.

Who should attend?

This training class is intended for personnel in the pharmaceutical & biotech industry involved with sterility testing process. It is appropriate for individuals working in QA, QC, microbiology and validation activities.

Duration: 1 day

Outcomes

Upon completion of this course, the participant will be able to:

- Overcome daily challenges and recognize critical parameters influencing the process (i.e. appropriate media usage for sterility and EM)
- Identify and minimize the risk of process failure due to false positives and/or negatives results in sterility testing
- Optimize handling issues and sterility testing procedures
- Achieve the highest level of safety and testing confidence

TECHNICAL
TRAINING
COURSES

Where?

Albuzzano (PV), Italy

When?

TBD
Contact us at:
training@fedegari.com



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CUSTOMIZED TRAINING COURSES



Delivering a unique experience

Developing completely customized solutions is our passion and our Training & Education division is also oriented in the same direction.

Fedegari provides customized technical trainings and seminars tailored to address customers' specific needs. Each course is developed to be a unique experience. We work together with customers from the first contact to the lessons for delivering the best outcomes.

We design custom programs focusing on the application of theory in practice. Fedegari combines core business skills and technical knowledge with innovative training programs to support customers on achieving the highest process performances.

Our customized courses will be held at Fedegari Tech Centers or at your company site.

In the following pages you will find some examples of subjects to build up your customized training course. The program will be developed according to your equipment and needs.



SUGGESTED TRAINING MODULES



CUSTOMIZED TRAINING COURSES

BASIC MAINTENANCE

Content

- Machine components and their role in the process
- Safety devices
- Utility connection and verification
- Thema4 process controller configuration (ex. I/O signals, system parameters, alarms)
- Troubleshooting examples (ex. electrical, mechanical and/or process problems)

INSTRUMENT CALIBRATION

Content

- Instrument selection and acceptance criteria
- Technical characteristic of Fedegari instruments
- Practice on calibration activities

MECHANICAL MAINTENANCE

Content

- Valve assembly/disassembly (ex. on/off valves, modulating valves, butterfly valve)
- Filter replacement
- Door gasket replacement



SUGGESTED TRAINING PROGRAMS



PROCESS CONTROLLER MAINTENANCE

Content

- Software installation and upgrade
- Back up & restore procedures
 - Automatic backup
 - Manual backup
 - Data restore

THEMA4 INTEGRATION WITH NETWORK SERVICES

Content

- General overview
- Setting of Thema4 integration functions (ex. Remote GUI, automatic backup, SCADA communication, clock synchronization, external centralized database, external data recorder)

PID CONTROL

Content

- PID control description and example of application
- Practical exercise using simulator

CUSTOMIZED
TRAINING
COURSES

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REGISTRATION FEES

Training & Education
FEDEGARI | Tech Centers

SEMINARS

Albuzzano (PV), Italy

Sellersville (PA), USA

Salfords (Surrey), UK

Per person/day

€ 450* *plus tax*

\$ 500* *plus tax*

£ 400* *plus tax*

TECHNICAL TRAINING

Albuzzano (PV), Italy

Sellersville (PA), USA

Salfords (Surrey), UK

Per person/day

€ 450* *plus tax*

\$ 500* *plus tax*

£ 400* *plus tax*

**10% discount for 2 or more delegates from the same company.*

CUSTOMIZED TRAINING COURSES

Upon request

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& Agalloco Associates

STERILIZATION: PRINCIPLES AND VALIDATION

The sterilization course covers the entire range of sterilization processes utilized in the pharmaceutical, biotechnology and medical device industries. Sterilization methods, validation practices and related subjects to be covered include: Prerequisites for Sterilization; Microbiology of Sterilization; Use of Biological Indicators; Steam Sterilization for Porous Loads; Terminal Sterilization using Steam; Steam Sterilization-in-Place; Dry Heat Sterilization and Depyrogenation; Gas, Liquid and Vapor Sterilization (including isolator decontamination); Radiation Sterilization; Filtration Sterilization for Liquids; Compendial and Regulatory Considerations.

ASEPTIC PROCESSING: A COMPREHENSIVE REVIEW

The aseptic course will provide comprehensive coverage of aseptic processing reviewing basic principles, technology choices, process design, environmental monitoring, and process simulation. The course will include sessions on aseptic processing risk assessment, contemporary regulatory expectations and future technologies process. The course materials and recommendations are wholly compatible with the regulatory expectations of FDA's 2004 Guideline on Sterile Drug Products Produced by Aseptic Processing and EMA's – Annex 1 on Sterile Medicinal Products.

Who should attend

These courses are intended for individuals working with sterilization, aseptic processing or process validation. The courses are appropriate for personnel working in QA/QC, regulatory affairs, R&D, production, engineering, process development, validation, and microbiology.

Suggested dates & locations

May 29 - June 2 - Dublin, Ireland

For further information:

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Interested? Contact us.

Fedegari Tech Centers

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Check our website for up to date information on courses and dates:

www.fedegari.com

Register now!



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