& Agalloco Associates	2022 Training OCTOBER 24-28, 2022	Fedegari Autoclavi

STERILIZATION: PRINCIPLES AND VALIDATION
ASEPTIC PROCESSING: COMPLIANCE AND TECHNOLOGY
Take Either Course or Save on Both

OCTOBER 24-28, 2022, SELLERSVILLE, PENNSYLVANIA

Course Descriptions

Sterilization: Principles & Validation Monday – Wednesday 10/24-26)
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: Compliance & Technology Thursday – Friday (10/6-7)
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 includes 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. Experienced individuals will refine their knowledge through interaction with industry experts. Those without a strong background will learn the basics and develop an understanding of the more advanced considerations. The courses are appropriate for personnel working in QA/QC, regulatory affairs, R&D, production, engineering, process development, validation, and microbiology.

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Course Location
The courses will be held at Fedegari Technologies, 1228 Bethlehem Pike, Sellersville, PA 18960. Sellersville is 90 minutes from Princeton and is served by Newark, NJ and Philadelphia, PA airports. There are multiple hotels within a 15-20 minute drive of the facility. Attendees are responsible for their own accommodations.

Discounts
Early registration must be received not less than 42 days (September 12th) prior to the start of the course in the form of full payment or purchase order. Group discounts are offered on each registration when 3 or more registrants from the same company attend the same course. Early registration and group discounts will be combined for greater savings.

Credit Cards
Sorry but we do not accept credit cards for payment. Purchase order or check payments only.

Cancellations
Course fees are fully refundable, if written notice is received 14 days prior to the start of each course. Within 14 days, your fee will be refunded less a $250 service fee.

Confirmation
Electronic confirmation of registration will be sent once payment has been received.

Substitutions
Substitutions are welcome without prior notice.

Accommodations
Transportation, accommodation and other expenses are the responsibility of the attendee. We do not book accommodations for attendees.

Vegetarian Meals
These are available each day without prior notification.

Testimonials from Prior Attendees
“Great course for any level of experience”
“… packed with useful information to help me build a foundation of sterilization fundamentals”
“A must for everyone interested in aseptic processing”
“Course was very insightful and practical”
“Best course I’ve attended. Loved the level of detail”

Agalloco & Associates, PO Box 899, Belle Mead, NJ 08502-0899 jagalloco@aol.com

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Your Instructors

Russ Madsen & Jim Agalloco

James Agalloco is President of Agalloco & Associates, which provides a range of technical services to the pharmaceutical and biotechnology industry. Since the formation of A&A in 1991, Jim has assisted more than 200 pharmaceutical, biotechnology, medical device, equipment manufacturers and bulk pharmaceutical firms in a range of validation, sterilization, aseptic processing and compliance areas. Jim has more than 45 years of industrial experience. He was previously employed at Bristol-Myers Squibb, Pfizer and Merck. He has a BE and MS in Chemical Engineering and an MBA in Pharmaceutical Studies.

Jim is a past President of the Parenteral Drug Association and served as an Officer or Director from 1982 to 1993. He is a current member of USP's Microbiology Expert Committee. He serves on the Editorial Advisory Boards of *Pharmaceutical Technology* and *Pharmaceutical Manufacturing*. Jim participates on the Scientific Advisory Boards of:; MEDInstill and Eniware.

He has authored or co-authored more than 40 book chapters, over 140 papers and has lectured extensively on process validation, aseptic processing, and sterilization. He is co-editor of "*Validation of Pharmaceutical Processes*", 3rd edition and "*Advanced Aseptic Processing Technology."*

Russell Madsen holds a Bachelor of Science degree from St. Lawrence University and a Master of Science degree from Rensselaer Polytechnic Institute. He was President of The Williamsburg Group, LLC, a consulting firm located in Gaithersburg, Maryland.

Prior to forming The Williamsburg Group, he had served PDA as Acting President and was Senior VP Science and Technology. Before joining PDA, he was employed by Bristol-Myers Squibb Company as Director, Technical Services, providing technical and general consulting services to Bristol-Myers Squibb operations, worldwide.

He is a member of the Executive Committee of ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products, a member of the USP Microbiology Expert Committee, a member of Pharmaceutical Technology's Editorial Advisory Board, an Honorary Member of PDA and past Board member of that organization.

He has authored or co-authored over 90 publications and is co-editor of "*Contamination Control in Healthcare Product Manufacturing*."

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Sterilization: Principles & Validation Schedule

Day 1 – Monday – 10/24

8:00 - 8:30 AM
Registration for Sterilization & Combined
Morning Coffee

8:30 - 10:00 AM - Session 1
Welcome / Introductions
Prerequisites for Sterilization Validation
Microbiology of Sterilization

10:00 - 10:15 AM - Break

10:15 AM - 12:15 PM - Session 2
Biological Indicators Preparation & Use
Steam Sterilization Fundamentals

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 3
Parts Sterilization

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 4
Terminal Sterilization by Moist Heat
Equivalence in Sterilization

Reception follows

Day 2 – Tuesday – 10/25

8:00 - 8:30 AM
Morning Coffee

8:30 - 10:00 AM - Session 5
Sterilization-in-Place
Bulk Liquid Sterilization

10:00 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 6
Dry Heat Sterilization & Depyrogenation
Application of the Half-Cycle Method

Day 2 (continued)

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 7
Gas Sterilization
Liquid Sterilization
Vapor Sterilization

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 8
Radiation Sterilization
New Sterilization Methods

Day 3 – Wednesday – 10/26

8:00 - 8:30 AM
Morning Coffee

8:30 - 10:15 AM - Session 9
Sterilizing Filtration – Principles

10:15 - 10:30 AM - Break

10:30 - 12:15 AM - Session 10
Sterilizing Filtration – Application &
Operation

12:15 – 1:15 PM - Lunch

1:15 - 3:00 PM - Session 11
US Regulatory & Compendial Expectations

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 12
EU Regulatory & Compendial Expectations

4:45 PM – Sterilization Course Ends

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Aseptic Processing: Compliance and Technology Schedule

Day 1 – Thursday – 10/27

Aseptic Course Begins

8:00 - 8:30 AM
Registration – Aseptic Course
Morning Coffee

8:30 – 10:00 AM - Session 1
History of Aseptic Processing
Aseptic Processing Technologies

10:00 – 10:30 AM - Break

10:30 AM – 12:15 PM - Session 2
Sterility by Design

12:15 AM – 1:15 PM - Lunch

1:15 - 3:00 PM - Session 3
Facility / System Qualification

3:00 - 3:15 PM - Break

3:15 – 5:00 PM - Session 4
Environmental Monitoring

Reception Follows

Day 2 – Friday – 10/28

7:30 - 8:00 AM
Morning Coffee

8:00 - 9:45 AM - Session 5
Interventions / Process Simulation

9:45 - 10:00 AM - Break

10:00 – 11:45 AM - Session 6
Aseptic Processing Risk Assessment

11:45 AM - 12:45 PM - Lunch

12:45 – 2:30 PM - Session 7
Aseptic Processing Regulation & Compliance

2:30 - 2:45 PM - Break

2:45 - 4:15 PM - Session 8
Review of Changes to EMA's Annex 1
Future Directions in Aseptic Processing

4:15 PM – Aseptic Course Ends

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Registration Form

1. Please print your name, address and company affiliation (use separate page for each attendee)

Mr. □ Ms. □ Dr. □ First Name Last Name

Title Company

Work Address

Country Zip/Mail Code City

Phone E-mail

Course Attending

2. **Sterilization Course Fee** – Monday-Wednesday
❒ Early Registration Fee: $ 2,700 ❒ Normal Registration Fee: $ 3,000

Aseptic Processing Course Fee – Thursday-Friday
❒ Early Registration Fee: $ 1,900 ❒ Registration Fee: $ 2,100

Combined Sterilization & Aseptic Processing Course Fee – Monday-Friday
❒ Early Registration Fee: $ 4,300 ❒ Registration Fee: $ 4,800

Early Registration – Payment or PO # must be received no later than 42 days before the start of each course – September 12, 2022

Group Discount - Three or more attendees from same firm receive 10% discount on all registration for the same course.

3. Payment & Registration - Please make a copy of this page, and send the completed form along with your payment. You will not be registered, unless payment or purchase order is received with your completed registration form.

Please send all correspondence to:

Agalloco & Associates Inc., PO Box 899, Belle Mead, NJ 08502-0899 or jagalloco@aol.com