& Agalloco Associates

2015 TRAINING OFFERINGS

STERILIZATION: PRINCIPLES AND VALIDATION
ASEPTIC PROCESSING: A COMPREHENSIVE REVIEW
Take Either Course or Save on Both

OCTOBER 19-23, 2015, PRINCETON, NEW JERSEY

Course Descriptions

Sterilization: Principles and Validation – Monday (10/19) – Wednesday (10/21)
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 – Thursday (10/22) – Friday (10/23)
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.

Registration Discounts

Early registration for taking both courses and group discounts (three or more from the same firm in a single course) are available. The discounts can be combined for even greater savings.

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Course Location

Princeton, New Jersey

The courses will be held at the Chauncey Conference Center, 1½ miles from Princeton, NJ. Princeton is midway between the Newark, NJ and Philadelphia, PA airports. The hotel provides free shuttle service to/from Princeton. Room reservations should be made directly with the hotel. The Chauncey Conference center can be reached at (609) 921-3600 or on line at http://www.acc-chaunceyconferencecenter.com.

Discounts

Early registration must be received not less than 45 days 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.

Cancellations

Course fees are fully refundable, if written notice is received 7 days prior to the start of each course. Within 7 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. The Princeton venue has on-site hotel rooms. There are numerous additional hotels within a 10-15 mile radius to choose from as well.

Vegetarian Meals

Available if requested with registration.

Faculty

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 40 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: Laureate Bioservices; MEDInstill; and VanRX.

He has authored or co-authored more than 40 book chapters, over 110 papers and has lectured extensively on process validation, aseptic processing, and sterilization, domestically. He is co-editor of "*Validation of Pharmaceutical Processes*", 3rd edition and "*Advanced Aseptic Processing Technology.*"

Russell Madsen is President of The Williamsburg Group, engaged in pharmaceutical consulting in the areas of CGMP compliance and auditing, quality systems, design review, aseptic processing and sterilization technology, sterile filtration, due diligence evaluation, process validation, and regulatory liaison. Russ has over 45 years of experience in the pharmaceutical and related industries, including pharmaceutical manufacturing and quality control, medical devices, nutritional products, and consumer products.

Prior to establishing TWG, Russ was employed by PDA, Bristol-Myers Squibb, Sterling Drug and Winthrop Laboratories. He is a member of several USP's Expert Committees, a member of Pharmaceutical Technology's Editorial Advisory Board, and PDA's Science Advisory Board. He is a member of ASTM E55 and serves as Vice-chair of E55.03 General Pharmaceutical Standards. He is the author and co-author of more than 50 papers and book chapters and is co-editor of "*Contamination Control in Healthcare Product Manufacturing*."

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Sterilization Course Schedule

Day 1 - Monday

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

Day 2 - Tuesday

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

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

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

Aseptic Processing Course Schedule

Day 1 - Thursday

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

5:00 PM – Day 1 Ends

Day 2 - Friday

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
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: $ 2,500 ❒ Normal Registration Fee: $ 2,800

Aseptic Processing Course Fee – Thursday-Friday
❒ Early Registration Fee: $ 1,700 ❒ Registration Fee: $ 1,900

Combined Sterilization & Aseptic Processing Course Fee – Monday-Friday
❒ Early Registration Fee: $ 3,700 ❒ Registration Fee: $ 4,200

Early Registration – Payment or PO # must be received no later than 45 days before the start of each course.

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