

& Agalloco Aseptic Processing: A Comprehensive Review Associates

April 26-28, 2011 - Nassau Inn, Princeton, NJ

Course Description

This course will provide comprehensive coverage of aseptic processing reviewing basic principles, technology choices, process design, environmental monitoring, and process simulation. The core technology of sterilizing filtration will be covered in depth. The last day of the course will address aseptic processing risk management, contemporary regulatory expectations and future technologies process. The course will draw upon FDA's 2004 Guideline on Sterile Drug Products Produced by Aseptic Processing and EMEA's – Annex 1 on Sterile Medicinal Products. There will be ample time for interactive discussion among the students and instructors on the topics being presented.

Who Should Attend

This course is intended for individuals involved with or considering the use of aseptic processing. Those experienced with aseptic processing will refine their knowledge of the subject through interaction with industry experts. Those without a strong background will learn the basics and develop an understanding of the more advanced considerations. The course is appropriate for personnel working in QA/QC, production, engineering, validation, and microbiology.

Your Instructors

James Agalloco is President of Agalloco & Associates, a technical service firm to the pharmaceutical and biotechnology industry. Jim has nearly 40 years of industry experience and has worked in organic synthesis, pharmaceutical formulation, pharmaceutical production, project and process engineering, validation and process automation during his career at Merck, Pfizer, Squibb and Bristol-Myers Squibb. He is a past President of the Parenteral Drug Association and served as an Officer or Director from 1982 to 1993. He is a member of USP's Microbiology Expert Committee for 2005-2010. He is a frequent author and lecturer on the subject of sterilization, aseptic processing and process validation.

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 served PDA as Acting President and was Senior VP Science and Technology. Before joining PDA, he was employed by Bristol-Myers Squibb, Sterling Drug and Winthrop Laboratories. He currently serves on the USP Microbiology Expert Committee, is a member of Pharmaceutical Technology's Editorial Advisory Board, and PDA's Science Advisory Board.

Location

The course will be held at Nassau Inn, located on Palmer Square in the center of Princeton, NJ. A wide selection of fine restaurants and shops are within easy walking distance, and Princeton University is just across the street. Princeton is 45 miles from either Newark or Philadelphia Airport, and also accessible by Amtrak / NJ Transit. There is ample parking nearby. Room reservations should be made directly with the Nassau Inn. The Nassau Inn can be reached at 609.921.7500 or 1.800.8.NASSAU, or on-line at www.nassauinn.com

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Associates April 26-28, 2011 - Nassau Inn, Princeton, NJ

Course Schedule

Tuesday, April 26, 2011

Day 1

8:00 - 8:30 AM

Registration
Continental Breakfast

8:30 - 10:15 AM - Session 1

Welcome / Introductions
History of Aseptic Processing
Comparison of Cleanrooms/RABS/Isolators

10:15 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 2

Aseptic System Design and Engineering

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 3

Facility / System Qualification

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 4

Process / Equipment Design

4:45 PM - Day 1 Ends

Wednesday, April 27, 2011

Day 2

8:00 - 8:30 AM

Continental Breakfast

8:30 - 10:15 AM - Session 5

Environmental Monitoring

10:15 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 6

Process Simulation

12:15 PM - 1:15 PM - Lunch

Wednesday, April 27, 2011 (continued)

Day 2

1:15 - 3:00 PM - Session 7

Sterilizing Filtration – Part 1

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 8

Sterilizing Filtration – Part 2

4:45 PM - Day 2 Ends

Thursday, April 28, 2011

Day 3

8:00 - 8:30 AM

Continental Breakfast

8:30 - 10:15 AM - Session 9

Aseptic Processing Risk Assessment

10:15 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 10

Future Directions in Aseptic Processing

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 11

Aseptic Processing Regulation & Compliance -1

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 12

Aseptic Processing Regulation & Compliance -2

4:45 PM - Course Ends

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Registration Form

1. Please type or print your name, address and company affiliation

Mr. <input type="checkbox"/>	Ms. <input type="checkbox"/>	Dr. <input type="checkbox"/>	First Name	Last Name
Title			Company	
Work Address			Internal Mail Code	
City	State / Province		Zip / Mail Code	Country
Phone			E-mail	

2. Course Fee:
- Early Registration Fee: \$1,900 - Must be received by no later than March 15, 2011
 - Normal Registration Fee: \$2,100
 - Three or more attendees from same firm receive 10% discount on all registrations

3. Please check the appropriate box (Sorry we do not accept Credit Cards)
- Check Enclosed
 - Purchase Order

Purchase Order Number
Company Name

4. Please make a copy of this page, and send the completed form with payment (You will not be registered, unless payment or purchase order number is received with your completed form) to:

Agalloco & Associates
PO Box 899
Belle Mead, NJ 08502-0899
FAX (908) 874-7558
registration@agalloco.com

Confirmation: Confirmation of your registration will be sent once payment or PO # has been received. Send an e-mail to registration@agalloco.com to obtain electronic payment details.

Substitutions: Substitutions are welcome without prior notice up to the day of the course.

Cancellations: Course fees are fully refundable, if written notice is received 7 days prior to the course. Within 7 days, your fee will be refunded less a \$150 service fee.

Travel Expenses: Transportation, accommodations and all other expenses are the responsibility of the attendee.