

Take either course or combine them for more comprehensive training

Course Descriptions

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; Emerging sterilization methods; US and EU Compendia and Regulatory Considerations.

The aseptic course will provide comprehensive coverage of aseptic processing reviewing basic principles, technology choices, process design, environmental monitoring, and process simulation. The last sessions in this 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 EMA'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

These courses are intended for individuals working with sterile products where sterilization and aseptic processing knowledge is critical for their continued success. Those experienced with these technologies will refine their knowledge of the subjects 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, regulatory affairs, R&D, production, engineering, validation, and microbiology.

Location

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>. Visit their website for driving directions.

Travel Expenses / Directions:

Transportation, accommodation and other expenses are the responsibility of the attendee. Contact the Chauncey Conference Center directly to book your accommodations.

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 member of USP's Microbiology Expert Committee for 2010-2015. 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. Prior to establishing TWG, Russ was employed by PDA, Bristol-Myers Squibb, Sterling Drug and Winthrop Laboratories. He is a member of USP's Microbiology Expert Committee for 2010-2015, a member of Pharmaceutical Technology's US Editorial Advisory Board, and PDA's Science Advisory Board.

Course Schedule

Monday, May 21, 2012

Day 1

8:00 - 8:30 AM

Registration – Sterilization Course
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

Steam Sterilization Fundamentals
Parts Sterilization

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 3

Terminal Sterilization by Moist Heat

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 4

Dry Heat Sterilization &
Depyrogenation
Application of the Half-Cycle Method
Equivalence in Sterilization

4:45 PM – Day 1 Ends

Tuesday, May 22, 2012

Day 2

8:00 - 8:30 AM

Morning Coffee

8:30 - 10:00 AM - Session 5

Gas Sterilization
Liquid Sterilization
Vapor Sterilization

10:00 - 10:30 AM - Break

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

Radiation Sterilization

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 7

Sterilizing Filtration – Principles

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 8

Sterilizing Filtration – Application &
Operation

4:45 PM – Sterilization Course Ends

Wednesday, May 23, 2012
Day 1

8:00 - 8:30 AM

Registration –Aseptic Course
Morning Coffee

8:30 - 10:15 AM - Session 9

Regulatory & Compendial
Expectations for Sterilization
Processes

10:15 - 10:30 AM - Break

10:30 - 12:15 AM - Session 10

History of Aseptic Processing
Comparison of
Cleanrooms/RABS/Isolators

12:15 – 1:15 PM - Lunch

1:15 - 3:00 PM - Session 11

Process / Equipment Design

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 12

Facility / System Qualification

4:45 PM – Day 1 Ends

Thursday, May 24, 2012
Day 2

8:00 - 8:30 AM

Morning Coffee

8:30 - 10:15 AM - Session 13

Environmental Monitoring
Process Simulation

10:15 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 14

Aseptic Processing Risk Assessment

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 15

Future Directions in Aseptic
Processing

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 16

Aseptic Processing Regulation &
Compliance

4:45 PM – Aseptic Course Ends

Registration Form

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

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

2. **Single Course Fee – Course being taken** _____
- Early Registration Fee: \$1,800 – **Must be received by no later than April 1, 2012**
- Normal Registration Fee: \$2,000
- Combined Course Fee**
- Early Registration Fee: \$3,500 – **Must be received by no later than April 1, 2012**
- Normal Registration Fee: \$3,800
- Three or more attendees from same firm receive 10% discount on all registrations

3. Please check the appropriate box - **Sorry we do not accept charge cards**

Check Enclosed Purchase Order

PO Number	Firm Name
Name of Attendee(s)	

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 is received with your completed form) to:

Agalloco & Associates
PO Box 899
Belle Mead, NJ 08502-0899

Confirmation: Written confirmation of your registration will be sent once payment has been received.
Substitutions: Substitutions are welcome without prior notice up to the day of the course.
Vegetarian Meals: Available if requested with registration.
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, accommodation and other expenses are the responsibility of the attendee. Contact the Chauncey Conference Center directly to book your accommodations.