

Course Description

This course covers the entire range of sterilization processes utilized in the pharmaceutical, biotechnology and medical device industries. Sterilization methods to be covered in the course include:

- Steam sterilization for porous loads (fill parts, stoppers, utensils, etc);
- Terminal Sterilization for products, intermediates and media;
- Steam sterilization-in-place (SIP for tanks, freeze dryers, bioreactors, etc.);
- Dry heat sterilization and depyrogenation (ovens and tunnels);
- Gas sterilization for materials and equipment (medical devices and intermediates);
- Vapor and liquid sterilization (including isolator decontamination);
- Radiation sterilization (gamma, electron beam and other methods);
- Filtration sterilization for liquids and gases; and
- Emerging sterilization methods

An overview of the validation requirements for each of the sterilization methods will be provided. Regulatory expectations for compliance and submission applicable in the US and rest of the world will be included.

Who Should Attend

This course is intended for individuals requiring an in-depth knowledge using sterilization processes. Those experienced with sterilization technology can refine their knowledge of the subject through comprehensive treatment of the subject matter. Those without a background will learn the fundamentals of sterilization processes, before progressing into details of the sterilizing methods. The course is appropriate for personnel working in production, R&D, QA/QC, engineering, validation, microbiology, and regulatory affairs. Examples of applications for pharmaceuticals, biologics and medical devices will be utilized.

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 and Sterility Assurance 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 as on USP Parenteral Products-Industrial 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

Course Schedule

Wednesday, September 28, 2011

Day 1

8:00 - 9:00 AM

Registration
Continental Breakfast

9:00 - 10:30 AM - Session 1

Welcome / Introduction
Prerequisites for Sterilization Validation
Microbiology of Sterilization

10:30 - 11:00 AM - Break

11:00 AM - 12:30 PM - Session 2

Steam Sterilization Fundamentals
Designing for Sterilization

12:30 PM - 1:30 PM - Lunch

1:30 - 3:00 PM - Session 3

Parts Sterilization

3:00 - 3:30 PM - Break

3:30 - 5:00 PM - Session 4

Terminal Sterilization by Moist Heat

5:00 PM - Day 1 Ends

Thursday, September 29, 2011

Day 2

8:00 - 9:00 AM

Continental Breakfast

9:00 - 10:30 AM - Session 5

Dry Heat Sterilization & Depyrogenation

10:30 - 11:00 AM - Break

11:00 AM - 12:30 PM - Session 6

Sterilization-in-Place
Bulk Liquid Sterilization

Thursday, September 29, 2011 (continued)

Day 2

12:30 PM - 1:30 PM - Lunch

1:30 - 3:00 PM - Session 7

Sterilizing Filtration – Part 1

3:00 - 3:30 PM - Break

3:30 - 5:00 PM - Session 8

Sterilizing Filtration – Part 2

5:00 PM - Day 2 Ends

Friday, September 30, 2011

Day 3

8:00 - 8:30 AM

Continental Breakfast

8:30 - 10:00 AM - Session 9

Gas Sterilization
Liquid Sterilization
Vapor Sterilization

10:00 - 10:15 AM - Break

10:15 - 11:45 AM - Session 10

Radiation Sterilization

11:45 - 12:45 PM - Lunch

12:45 - 2:15 PM - Session 11

Equivalence in Sterilization
Application of the Half-Cycle Method
Emerging Sterilization Methods

2:15 - 2:30 PM - Break

2:30 - 4:00 PM - Session 12

Regulatory Expectations for Sterilization

4:00 PM - Course Ends

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 August 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 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 Nassau Inn directly to book your accommodations.