

# **& Agalloco Associates**

## **Sterilization: Processes & Validation**

September 22-23, 2009 - Princeton, NJ

### **Course Description**

This course covers the entire range of sterilization processes utilized in the pharmaceutical, biotechnology and medical device industries. It begins with a review of the microbiology of sterilization, and how that relates to sterilization process selection, cycle development, operation and validation.

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 Instructor**

James Agalloco is President of Agalloco & Associates, a technical service firm to the pharmaceutical and biotechnology industry. Since the formation of Agalloco & Associates in 1991, Jim has assisted more than 100 health care firms in a wide range of validation, automation and compliance areas. Jim has over 35 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 received his BS in Chemical Engineering from Pratt Institute in 1968 and his MS, also in Chemical Engineering from Polytechnic Institute of New York in 1979. He received his MBA in Pharmaceutical Studies from Fairleigh Dickinson University in 1983. 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.

### **Location**

The course will be held at Nassau Inn, located at 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 accessible by Amtrak / NJ Transit. There is ample parking nearby. Rooms are available at a rate of \$189 plus tax for attendees provided reservations are made prior to 8/22/09. The Nassau Inn can be reached at 609.921.7500 or 1.800.8.NASSAU, or on-line at [www.nassauinn.com](http://www.nassauinn.com)

**Course Schedule**

**Tuesday, September 22, 2009**

**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  
Terminal Sterilization

**12:30 PM - 1:30 PM - Lunch**

**1:30 - 3:00 PM - Session 3**

Parts Sterilization  
Validation of Steam Sterilization  
Steam Sterilization-in-Place

**3:00 - 3:30 PM - Break**

**3:30 - 5:00 PM - Session 4**

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

**5:00 PM - Day 1 Ends**

**Wednesday, September 23, 2009**

**Day 2**

**8:00 - 9:00 AM**

Registration  
Continental Breakfast

**9:00 - 10:30 AM - Session 5**

Gas Sterilization  
Liquid Sterilization  
Vapor Sterilization

**10:30 - 11:00 AM - Break**

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

Isolator Decontamination  
Radiation Sterilization

**12:30 PM - 1:30 PM - Lunch**

**1:30 - 3:00 PM - Session 7**

Sterilization by Filtration

**3:00 - 3:30 PM - Break**

**3:30 - 5:00 PM - Session 8**

Emerging Sterilization Methods  
Regulatory Expectations for Sterilization

**5:00 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: \$1,000 - Must be received by no later than 8/15/2009
  - Normal Registration Fee: \$1,200
  - Three of more attendees from same firm receive 10% discount on all registrations

3. Please check the appropriate box
- Check Enclosed       Purchase Order

PO Number	Firm Name
Name of Attendee(s)	

**Sorry we do not accept charge cards**

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.

**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.