

Course Description

This 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 (fill parts, stoppers, utensils, etc); Terminal Sterilization for products, intermediates and media; Steam sterilization-in-place; Dry heat sterilization and depyrogenation; Gas, Liquid and Vapor sterilization (including isolator decontamination); Radiation sterilization; Filtration sterilization for liquids and gases; Emerging sterilization methods; US and EU Compendia and Regulatory Considerations.

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.

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.

Dr. Klaus Haberer is Chief Scientific Officer of Compliance Advice & Services in Microbiology. Dr. Haberer has almost 40 years of professional experience in industry and academia in the area of microbiology. Prior to founding Compliance in 1999, Klaus was employed by Hoffmann-La Roche, and Hoechst AG (later Marion Roussel). He has served on Ph. Eur's – Expert Group 1 Microbiology since 1986 is a member of PDA's Science Advisory Board. He lectures and publishes frequently in the areas of sterilization, microbiology and aseptic processing.

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.

Location

The course will be held at Hotel Krone Unterstrass near the center of Zurich, Switzerland. A variety of restaurants and shops are within easy walking distance. Zurich International Airport is 20 minutes away, and the central station a short tram ride. Room reservations should be made directly with the hotel. The Hotel Krone Unterstrass can be reached at +41 (0)44 360 56 56 or on-line at www.hotel-krone.ch

Course Schedule

Tuesday, June 14, 2011
Day 1

8:00 - 8:30 AM

Registration
Continental Breakfast

8:30 - 10:00 AM - Session 1

Welcome / Introduction
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

4:45 PM - Day 1 Ends

Wednesday, June 15, 2011
Day 2

8:00 - 8:30 AM

Continental Breakfast

8:30 - 10:15 AM - Session 5

Sterilization-in-Place
Bulk Liquid Sterilization

10:15 - 10:30 AM - Break

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

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

Wednesday, June 15, 2011
Day 2 (continued)

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 - Day 2 Ends

Thursday, June 16, 2011
Day 3

8:00 - 8:30 AM

Continental Breakfast

8:30 - 10:15 AM - Session 9

US Regulatory & Compendial
Expectations

10:15 - 10:30 AM - Break

10:30 - 12:15 AM - Session 10

EU Regulatory & Compendial
Expectations

12:15 - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 11

Gas Sterilization
Liquid Sterilization
Vapor Sterilization

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 12

Radiation Sterilization
New Sterilization Methods

4:45 PM - Course Ends

Registration Form

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

Mr. Ms. Dr. First Name Last Name

Title Company

Work Address

City Zip/Mail Code Country

Phone E-mail

2. **Course Fee**
- Early Registration Fee: € 2'000.— **Must be received by no later than May 1, 2011**
 - Normal Registration Fee: € 2'200.—
 - Three or more attendees from same firm receive 10% discount on all registrations

3. **Payment**
- Payment shall be in Euro. Please check the appropriate box
- By Bank Transfer (net without any charges) to the following account: IBAN (International Bank Account Number) CH66 0077 0016 0649 8494 8, Swift: BKBBCHBB, Basler Kantonalbank, CH-4005 Basel.
 - By Credit Card (4% charge will be added to the registration fee)

Card Number Validity, MM/YY CVC Code

4. **Process**
- Please return the completed form by fax or email to: Congress Plus GmbH, P.O. Box 160, CH-4016 Basel, Fax: +41 61 683 13 83, Email: registration@congress-plus.ch. Or register online here: <https://www.congress-plus.ch/SterilizationCourse0611.htm>
You will not be registered, unless payment is received.

5. **Confirmation**
- Written confirmation of your registration and an invoice will be sent once payment has been received. Please contact us if you need an invoice to arrange for payment.

6. **General Information**
- Substitutions:** Substitutions are welcome without prior notice up to the day of the course.
- Vegetarian Meals:** Available if requested with registration. > > > Tick this box:
- 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 €100 service fee.
- Travel Expenses:** Transportation, accommodation and other expenses are the responsibility of the attendee. Contact the Hotel Krone Unterstrass directly to book your accommodations. Be sure to mention this course when booking.