

& Agalloco Associates **Sterilization: Principles & Validation**
Aseptic Processing: A Comprehensive Review
June 4-8, 2012 – Vienna, Austria

Take either course or combine them for more comprehensive training

Course Descriptions

The aseptic 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 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.

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 for liquids and gases; Emerging sterilization methods; US and EU Compendia and Regulatory Considerations.

Both courses can be taken in the same week for a discounted fee.

Who Should Attend

These courses are intended for individuals working with sterilization and/or aseptic processing. 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 course will be held at Hotel Savoyen near the center of Vienna, Austria. Vienna Airport is 18 km away, and the can be reached by mass. Room reservations should be made directly with the hotel. The Hotel Savoyen can be reached at +43 (1) 206 33-0 or by e-mail at savoyen@austria-trend.at

Travel Expenses:

Transportation, accommodation and other expenses are the responsibility of the attendee. Contact the Hotel Savoyen directly to book your accommodations. Be sure to mention this course when booking.

& Agalloco Sterilization: Principles & Validation
Associates Aseptic Processing: A Comprehensive Review
June 4-8, 2012 – Vienna, Austria

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.

& Agalloco Associates **Sterilization: Principles & Validation**
Aseptic Processing: A Comprehensive Review
June 4-8, 2012 – Vienna, Austria

Course Schedule

Monday, June 4, 2012
Day 1

8:00 - 8:30 AM
Registration for Sterilization & Combined
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
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

Tuesday, June 5, 2012
Day 2

8:00 - 8:30 AM
Morning Coffee

8:30 - 10:00 AM - Session 5
Sterilization-in-Place
Bulk Liquid Sterilization

10:00 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 6
Dry Heat Sterilization & Depyrogenation
Application of the Half-Cycle Method

Tuesday, June 5, 2012
Day 2 (continued)

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 7
Gas Sterilization
Liquid Sterilization
Vapor Sterilization

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 8
Radiation Sterilization
New Sterilization Methods

5:00 - 6:30 PM
Sterilizing Filtration – Principles*
(Extra session for 5 day attendees)

Wednesday, June 6, 2012
Day 3

8:00 - 8:30 AM
Morning Coffee

8:30 - 10:15 AM - Session 9
Sterilizing Filtration – Principles*

10:15 - 10:30 AM - Break

10:30 - 12:15 AM - Session 10
Sterilizing Filtration – Application & Operation*

12:15 - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 11
US Regulatory & Compensial Expectations

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 12
EU Regulatory & Compensial Expectations

4:45 PM – Sterilization Course Ends

& Agalloco Associates **Sterilization: Principles & Validation**
Aseptic Processing: A Comprehensive Review
June 4-8, 2012 – Vienna, Austria

Wednesday, Jun 6, 2012
Day 1

8:00 - 8:30 AM
Registration – Aseptic Course
Morning Coffee

8:30 – 10:00 AM - Session 1
Welcome / Introductions
History of Aseptic Processing
Comparison of Cleanrooms/RABS/Isolators

10:00 – 10:30 AM - Break

10:30 AM – 12:15 PM - Session 2
Facility / System Qualification

12:15 – 1:15 PM - Lunch

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 3
Sterilizing Filtration – Part 1

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 4
Sterilizing Filtration – Part 2

Thursday, June 7, 2012
Day 2

8:00 - 8:30 AM
Morning Coffee

8:30 - 10:15 AM - Session 5
Process / Equipment Design - 1

10:15 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 6
Process / Equipment Design – 2

12:15 PM - 1:15 PM - Lunch

Thursday, June 7, 2012 (continued)
Day 2

1:15 - 3:00 PM - Session 7
Environmental Monitoring

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 8
Process Simulation

5:00 – 6:30 PM
Sterilizing Filtration – Application & Operation*
(Extra session for 5 day attendees)

Friday, June 8, 2012
Day 3

8:00 - 8:30 AM
Morning Coffee

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 – Aseptic & Combined Course
Ends**

NOTE: Individuals taking the combined courses should attend extra sessions on Tuesday & Thursday from 5:00-6:30 PM

& Agalloco Associates Sterilization: Principles & Validation Aseptic Processing: A Comprehensive Review

June 4-8, 2012 – Vienna, Austria

Registration Form

1. **Personal Information:** Please type or print your name, address and company affiliation

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

2. **Course Fee**
- | | before 01/04/12 | after 01/04/12 |
|-----------------------------------------------------------------------------------------------------------|-----------------|----------------|
| <input type="checkbox"/> Course Sterilization (4-6 June 2012) | € 1'800 | € 2'100 |
| <input type="checkbox"/> Course Aseptic Processing (6-8 June 2012) | € 2'100 | € 2'100 |
| <input type="checkbox"/> Both Courses (4-8 June 2012) | € 3'600 | € 4'000 |
| <input type="checkbox"/> Three or more attendees from same firm receive 10% discount on all registrations | | |

3. **Hotel** The organizers can reserve a hotel room in the Hotel Savoyen. Tariff per Person/Night € 150. A credit card number to guarantee the reservation is mandatory! Please indicate arrivaland departure date.....! Any alterations, cancellations, etc. have to be indicated in time. The organizers do not overtake any costs for rooms that have not been used (no shows).

4. **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. Account holder (beneficiary) is Congress Plus, CH-4058 Basel.
- By Credit Card (4% charge will be added to the registration fee)

Card Number	Validity, MM/YY	CVC Code
-------------	-----------------	----------

5. **Process** Please return the completed form by fax or email to: Congress Plus GmbH, P.O.B. 160, CH-4016 Basel, Fax: +41 61 683 1383, Email: registration@congress-plus.ch. Or [register online here!](#) ****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.