

& Agalloco Aseptic Processing: A Comprehensive Review Associates October 24-26, 2011 – Zurich. Switzerland

Course Description

This 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.

Who Should Attend

This course is intended for individuals involved with or considering the use of aseptic processing. Those experienced with aseptic processing will refine their knowledge of the subject 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, production, engineering, validation, and microbiology.

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

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Associates October 24-26, 2011 – Zurich. Switzerland

Course Schedule

Monday, October 24, 2011

Day 1

12:00 - 12:30 PM

Registration / Welcome Refreshments

12:30 – 2:00 PM - Session 1

Welcome / Introductions

History of Aseptic Processing

Comparison of Cleanrooms/RABS/Isolators

2:00 - 2:15 PM - Break

2:15 PM - 3:45 PM - Session 2

Facility / System Qualification

3:45 – 4:00 PM - Break

4:00 - 5:30 PM - Session 3

Process / Equipment Design

5:45 PM – 6:45 – Reception

Tuesday, October 25, 2011

Day 2

8:00 - 8:30 AM

Morning Coffee

8:30 - 10:15 AM - Session 4

Environmental Monitoring

10:15 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 5

Process Simulation

12:15 PM - 1:15 PM - Lunch

Tuesday, October 25, 2011 (continued)

Day 2

1:15 - 3:00 PM - Session 6

Sterilizing Filtration – Part 1

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 7

Sterilizing Filtration – Part 2

4:45 PM - Day 2 Ends

Wednesday, October 26, 2011

Day 3

8:00 - 8:30 AM

Morning Coffee

8:30 - 10:15 AM - Session 8

Aseptic Processing Risk Assessment

10:15 - 10:30 AM - Break

10:30 AM - 12:15 PM - Session 9

Future Directions in Aseptic Processing

12:15 PM - 1:15 PM - Lunch

1:15 - 3:00 PM - Session 10

Aseptic Processing Regulation & Compliance -1

3:00 - 3:15 PM - Break

3:15 - 4:45 PM - Session 11

Aseptic Processing Regulation & Compliance -2

4:45 PM - Course Ends

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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		
City	Zip/Mail Code	Country
Phone	E-mail	

2. **Course Fee**

- Early Registration Fee: € 1'800 – **Must be received by no later than Aug 19, 2011**
- Normal Registration Fee: € 2'100
- 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
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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/AsepticCourse1011.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.