

## Take either course or combine them for comprehensive training

### Course Descriptions

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; Compendia and Regulatory Considerations.

The aseptic course will provide comprehensive coverage of aseptic processing reviewing basic principles, technology choices, process design, environmental monitoring, and process simulation. The course will include sessions on aseptic processing risk assessment, contemporary regulatory expectations and future technologies process. The course materials and recommendations are wholly compatible with the regulatory expectations of 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. 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 Radisson Blu, Steinentorstrasse 25, CH-4001 Basel in the center of Basel, Switzerland.

A variety of restaurants and shops are within easy walking distance. Basel's Euroairport (BSL) is approximately 30 minutes away, and the central station a short tram ride. Room reservations should be made directly with the hotel.

The Hotel Radisson Blue can be reached at +41 (0)61 227 27 27 or on-line at [www.radissonblu.com/Hotel-basel](http://www.radissonblu.com/Hotel-basel)

### Travel Expenses

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

## 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.

**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 has been a member of several USP's Expert Committee since 2005, a member of Pharmaceutical Technology's Editorial Advisory Board, and PDA's Science Advisory Board.

**Gautam Maitra** is Head of Regulatory and External Affairs at AC Immune SA. Guatam holds a Fil. Lic. in Chemistry from Stockholm University. Gautam also served as the European Director of one of the Parenteral Drug Association where he developed strong relationships with major health authorities: FDA, EMA, BfArM, ANSM, MPA, MHRA, Swissmedic etc. and other bodies: ICH, EFPIA, WHO, PIC/S. He has been an invited attendee to the annual USP European Stakeholder Forums. He has also been a member of the Bio-Manufacturing Working Group of the EFPIA/EBE in Brussels and a member of the PDA Task Force for early Phase Clinical Trials material. He serves on the Board of Directors of the Regulatory Affairs Professional Society (2013-15) and the President of the RAPS Swiss Affiliate. He is the President of the Geneva-based Swiss India Business Forum.

## **Sterilization Course Schedule**

### *Monday, May 13, 2013 - 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, May 14 2013 - 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, May 14, 2013 - 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

### *Wednesday, May 15, 2013 - 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 & Compendial Expectations

**3:00 - 3:15 PM - Break**

**3:15 - 4:45 PM - Session 12**

EU Regulatory & Compendial Expectations

**4:45 PM – Sterilization Course Ends**

## **Aseptic Processing Course Schedule**

### *Thursday, May 16, 2013 - Day 4*

#### **Aseptic Course Begins**

#### **8:00 - 8:30 AM**

Registration – Aseptic Course  
Morning Coffee

#### **8:30 – 10:00 AM - Session 1**

History of Aseptic Processing  
Comparison of Cleanrooms/RABS/Isolators

#### **10:00 – 10:30 AM - Break**

#### **10:30 AM – 12:15 PM - Session 2**

Sterility by Design

#### **12:15 AM – 1:15 PM - Lunch**

#### **1:15 - 3:00 PM - Session 3**

Facility / System Qualification

#### **3:00 - 3:15 PM - Break**

#### **3:15 – 5:00 PM - Session 4**

Environmental Monitoring

#### **5:00 PM – Day 4 Ends**

### *Friday, May 17, 2013 - Day 5*

#### **7:30 - 8:00 AM**

Morning Coffee

#### **8:00 - 9:45 AM - Session 5**

Aseptic Processing Risk Assessment

#### **9:45 - 10:00 AM - Break**

#### **10:00 – 11:45 AM - Session 6**

Process Simulation

#### **11:45 AM - 12:45 PM - Lunch**

#### **12:45 – 2:30 PM - Session 7**

Aseptic Processing Regulation & Compliance

#### **2:30 - 2:45 PM - Break**

#### **2:45 - 4:15 PM - Session 8**

Future Directions in Aseptic Processing

#### **4:15 PM – Aseptic Course Ends**

**Registration Form**

1. Please print your name, address and company affiliation (use separate page for each attendee)

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

2. **Sterilization Course Fee**  
 Early Registration Fee: € 1'800  
 Normal Registration Fee: € 2'100

- Aseptic Processing Course Fee**  
 Early Registration Fee: € 1'200  
 Normal Registration Fee: € 1'400

- Combined Course Fee**  
 Early Registration Fee: € 2'800  
 Normal Registration Fee: € 3'300

- Three or more attendees from same firm receive 10% discount on all registrations

3. **Payment – Must be received by no later than April 15, 2013.** 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 No.) CH6600770016064984948, Swift: BKBBCHBB, Basler Kantonal-bank, 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, CH-4002 Basel, Fax: +41 61 683 13 83, Email: [registration@congress-plus.ch](mailto:registration@congress-plus.ch). Or register online at: <https://www.congress-plus.ch/1305-CourseWeekBasel.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.

7. **Hotel booking**

The organizers can reserve a hotel room in the [Hotel Radisson Blu, Basel](#). Please indicate in the fields below and mention in "remarks" if the credit card is only for hotel purposes.

Arrival Date: \_\_\_\_\_ Departure Date: \_\_\_\_\_ Special requests: \_\_\_\_\_

Single Room at CHF (Swiss Francs) 279 + City Tax per person/night. Prices are by night and include breakfast. 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).