# & Agalloco Associates

# 2014 TRAINING OFFERINGS

## STERILIZATION: PRINCIPLES AND VALIDATION
## ASEPTIC PROCESSING: A COMPREHENSIVE REVIEW
Take Either Course or Save on Both

## PROCESS VALIDATION: 2014

## MARCH 24-28, 2014, IRVINE, CALIFORNIA
## APRIL 7-11, 2014, PRINCETON, NEW JERSEY
## JUNE 23-27, 2014, ZURICH, SWITZERLAND

### Course Descriptions – Schedule at each venue is identical

**Sterilization: Principles and Validation** – Monday - Wednesday
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; Compendial and Regulatory Considerations.

**Aseptic Processing: A Comprehensive Review** – Thursday-Friday
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 includes 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.

**Process Validation: 2014** – Monday-Thursday
This critically acclaimed process validation course was first presented in the 1980's and introduced a generation of scientists & engineers to validation practices. We have been updated the classic offering to be consistent with the expectations of FDA and EMA Process Validation guidance documents and draw upon the instructors' wealth of experience with process validation. It addresses design / execution and maintenance of activities supporting both drug substance and drug product production processes utilizing a life-cycle approach and incorporating DOE, QbD and risk based considerations.

### Who Should Attend
These courses are intended for individuals working with sterilization, aseptic processing or process validation. Experienced individuals will refine their knowledge through interaction with industry experts. Those without a strong background will learn the basics and develop an understanding of the more advanced considerations. The courses are appropriate for personnel working in QA/QC, regulatory affairs, R&D, production, engineering, process development, validation, and microbiology.

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## Course Locations

### Irvine, California

The Beckman Center is conveniently located less than 3 miles from John Wayne International Airport. There are no on-site accommodations. Irvine, CA offers a range of accommodations within minutes of the Beckman Center. Orange County offers a variety of restaurants and other nearby amenities. Additional information can be contacted at (949) 721-2200 or on-line at http://www.thebeckmancenter.org/

### Princeton, New Jersey

The courses will be held at the Chauncey Conference Center, 1½ miles from Princeton, NJ. Princeton is midway between the Newark, NJ and Philadelphia, PA airports. The hotel provides free shuttle service to/from Princeton. Room reservations should be made directly with the hotel. The Chauncey Conference center can be reached at (609) 921-3600 or on line at http://www.acc-chaunceyconferencecenter.com.

### Zurich, Switzerland

The course will be held at Hotel Krone Unterstrass near the center of Zurich, Switzerland. A variety of restaurants and shops are within walking distance. Zurich International Airport is 20 minutes away by taxi, and the central station is a only 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

## Discounts

Early registration must be received not less than 45 days prior to the start of the course in the form of full payment or purchase order. Group discounts are offered on each registration when 3 or more registrants from the same company attend the same course. Early registration and group discounts will be combined for greater savings.

## Cancellations

Course fees are fully refundable, if written notice is received 7 days prior to the start of each course. Within 7 days, your fee will be refunded less a $250 (€ 200 for Zurich) service fee.

## Confirmation

Electronic confirmation of registration will be sent once payment has been received.

## Substitutions

Substitutions are welcome without prior notice

## Accommodations

Transportation, accommodation and other expenses are the responsibility of the attendee. We do not book accommodations for attendees. The Basel & Princeton venues have on-site hotel rooms. The Beekman Center is located in Irvine, CA and there are over 30 hotels within a 5 mile radius to choose from.

## Vegetarian Meals

Available if requested with registration.

## Faculty

**James Agalloco** is President of Agalloco & Associates, which provides a range of technical services to the pharmaceutical and biotechnology industry. Since the formation of A&A in 1991, Jim has assisted more than 200 pharmaceutical, biotechnology, medical device, equipment manufacturers and bulk pharmaceutical firms in a range of validation, sterilization, aseptic processing and compliance areas. Jim has more than 40 years of industrial experience. He was previously employed at Bristol-Myers Squibb, Pfizer and Merck. He has a BE and MS in Chemical Engineering and an MBA in Pharmaceutical Studies.

Jim is a past President of the Parenteral Drug Association and served as an Officer or Director from 1982 to 1993. He is a current member of USP's Microbiology Expert Committee. He serves on the Editorial Advisory Boards of *Pharmaceutical Technology* and *Pharmaceutical Manufacturing*. Jim participates on the Scientific Advisory Boards of: Laureate Bioservices; MEDInstill; and VanRX.

He has authored or co-authored more than 40 book chapters, over 110 papers and has lectured extensively on process validation, aseptic processing, and sterilization, domestically. He is co-editor of "*Validation of Pharmaceutical Processes*", 3rd edition and "*Advanced Aseptic Processing Technology."*

**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. Russ has over 45 years of experience in the pharmaceutical and related industries, including pharmaceutical manufacturing and quality control, medical devices, nutritional products, and consumer products.

Prior to establishing TWG, Russ was employed by PDA, Bristol-Myers Squibb, Sterling Drug and Winthrop Laboratories. He is a member of several USP's Expert Committees, a member of Pharmaceutical Technology's Editorial Advisory Board, and PDA's Science Advisory Board. He is a member of ASTM E55 and serves as Vice-chair of E55.03 General Pharmaceutical Standards. He is the author and co-author of more than 50 papers and book chapters and is co-author of "*Contamination Control in Healthcare Product Manufacturing*."

**Phil DeSantis** is a pharmaceutical consultant, specializing in Pharmaceutical Engineering and Compliance. Phil retired in 2011 as Senior Director, Engineering Compliance for Global Engineering Service at Merck (formerly Schering-Plough) located in Whitehouse Station, NJ. His responsibilities included development, implementation and support of standards and practices for all facility and equipment-related capital projects and site operations. He served as Global Subject Matter Expert for Facilities and Equipment and on the Global Validation Review Board and Quality Systems and Standards Committee.

Phil is a chemical engineer, having received a BSChE from the University of Pennsylvania and an MSChE from New Jersey Institute of Technology. He has over forty-four years of pharmaceutical industry experience. Prior to Schering-Plough, Phil held executive positions for Fluor Corporation and Raytheon Engineers & Constructors, where he led groups providing validation and compliance consulting services to pharmaceutical and biotech clients. Prior to that, he served in technical positions in several major pharmaceutical firms, including Squibb, Ortho Pharmaceutical Corporation and an earlier period at Merck. He is on the PDA Scientific Advisory Board and is active in ISPE. He has been as a frequent lecturer for both organizations. He has published or contributed to several articles and books in the area of validation and pharmaceutical engineering. In addition, Phil has lectured on "Steam and Dry Heat Sterilization" as part of the FDA's field investigator training program.

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## Sterilization Course Schedule

**Instructors - Agalloco / DeSantis / Madsen**

### *Day 1 - Monday*

**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

### *Day 2 - Tuesday*

**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

### *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

### *Day 3 - Wednesday*

**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**

Agalloco & Associates, PO Box 899, Belle Mead, NJ 08502-0899 jagalloco@aol.com

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## Aseptic Processing Course Schedule

**Instructors - Agalloco / DeSantis / Madsen**

### *Day 1 - Thursday*

**Aseptic Course Begins**

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

**8:30 – 10:00 AM - Session 1**
History of Aseptic Processing
Aseptic Processing Technologies

**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 1 Ends**

### *Day 2 - Friday*

**7:30 - 8:00 AM**
Morning Coffee

**8:00 - 9:45 AM - Session 5**
Interventions / Process Simulation

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

**10:00 – 11:45 AM - Session 6**
Aseptic Processing Risk Assessment

**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**

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## Process Validation Course Schedule

**Instructors - Agalloco / DeSantis**

### *Day 1 - Monday*

**8:00 - 8:30 AM**
Registration / Coffee

**8:30 – 10:00 AM - Session 1**
Introduction to Validation / Prerequisites

**10:00 – 10:30 AM - Break**

**10:30 AM – 12:15 PM - Session 2**
Addressing FDA& EMA Guidance 1

**12:15 AM – 1:15 PM - Lunch**

**1:15 - 3:00 PM - Session 3**
Pre-formulation / Pharmaceutical Development

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

**3:15 – 5:00 PM - Session 4**
Stage 1 Activities

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

### *Day 2 - Tuesday*

**8:00 - 8:30 AM**
Morning Coffee

**8:30 – 10:00 AM - Session 5**
Facility / System Qualification

**10:00 – 10:30 AM - Break**

**10:30 AM – 12:15 PM - Session 6**
BioProcessing

**12:15 AM – 1:15 PM - Lunch**

**1:15 - 3:00 PM - Session 7**
Chemical Synthesis

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

**3:15 – 5:00 PM - Session 8**
Liquids & Lyophilized Products

**5:00 PM – Day 4 Ends**

### *Day 3 - Wednesday*

**8:00 - 8:30 AM**
Morning Coffee

**8:30 – 10:00 AM - Session 9**
Stage 2 Activities – Part 1

**10:00 – 10:30 AM - Break**

**10:30 AM – 12:15 PM - Session 10**
Stage 2 Activities – Part 2

**12:15 AM – 1:15 PM - Lunch**

**1:15 - 3:00 PM - Session 11**
Oral Solid Dosage Forms - 1

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

**3:15 – 5:00 PM - Session 12**
Oral Solid Dosage Forms – 2

**5:00 PM - Day 3 Ends**

### *Day 4 - Thursday*

**8:00 - 8:30 AM**
Morning Coffee

**8:30 – 10:00 AM - Session 13**
Stage 3 Activities

**10:00 – 10:30 AM - Break**

**10:30 AM – 12:15 PM - Session 14**
Best Practices in Validation

**12:15 AM – 1:15 PM - Lunch**

**1:15 - 3:00 PM - Session 15**
Addressing FDA & EMA Guidance 2

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

**3:15 – 5:00 PM - Session 16**
Regulation & Compliance Expectations

**5:00 PM – Course Ends**

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## Registration Form

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

Mr. □ Ms. □ Dr. □ First Name Last Name

Title Company

Work Address

Country Zip/Mail Code City

Phone E-mail

Course Attending Location

2. **Sterilization Course Fee** – Monday-Wednesday

❒ CA / NJ Early Registration Fee: $ 2,400 ❒ CA/NJ Normal Registration Fee: $ 2,700
❒ Zurich Early Registration Fee: € 1,800 ❒ Zurich Normal Registration Fee: € 2,100

**Aseptic Processing Course Fee** – Thursday-Friday

❒ CA / NJ Registration Fee: $ 1,600 ❒ CA / NJ Registration Fee: $ 1,800
❒ Zurich Early Registration Fee: € 1,200 ❒ Zurich Normal Registration Fee: € 1,400

**Combined Sterilization & Aseptic Processing Course Fee** – Monday-Friday

❒ CA / NJ Registration Fee: $ 3,600 ❒ CA / NJ Registration Fee: $ 4,000
❒ Zurich Early Registration Fee: € 2,800 ❒ Zurich Normal Registration Fee: € 3,300

**Process Validation Course Fee** – Monday-Thursday

❒ CA / NJ Registration Fee: $ 3,200 ❒ CA / NJ Registration Fee: $ 3,600
❒ Zurich Early Registration Fee: € 2,400 ❒ Zurich Normal Registration Fee: € 2,800

**Early Registration – Payment or PO # must be received no later than 45 days before the start of each course. Three or more attendees from same firm receive 10% discount on all registration**s.

3. Payment & Registration for Zurich Only - 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 : _____

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. Or register online at: https://www.congress-plus.ch/1406Courses.html You will not be registered, unless payment is received.

4. Payment & Registration for CA & NJ courses only - 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:

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