# & Agalloco Associates

# 2016 TRAINING OFFERINGS

## STERILIZATION: PRINCIPLES AND VALIDATION
## ASEPTIC PROCESSING: A COMPREHENSIVE REVIEW

Take Either Course or Save on Both

## MAY 2-6, 2016, COPENHAGEN, DENMARK

### Course Descriptions

**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 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.

### 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.

## Course Location

### Copenhagen, Denmark

The course will be held at Scandic Palace Hotel in the center of Copenhagen. A variety of restaurants and shops are within easy walking distance. Copenhagen Airport, Kastrup is 12 minutes away by train, and the central train station is only 0.5 Km away. Room reservations should be made directly with the hotel at a discounted rate for attendees. The Scandic Palace Hotel can be reached at +45 33 14 40 50 or on-line at www.scandichotels.com/Hotels/Denmark/Copenhagen/Scandic-Palace-Hotel/

## 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 service fee.

## Confirmation

Electronic confirmation of registration will be sent once payment has been received. Let us know if you need an invoice to initiate payment. This will be sent to you as a PDF by E-mail.

## 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 Scandic Palace is located in the city center and there are over 60 hotels within a 5 km 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*."

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## Sterilization Course Schedule

### *Day 1 - Monday*

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

### *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

### *Day 2 Tuesday (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
Equivalence in 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**

# Aseptic Processing Course Schedule

### *Day 1 - Thursday*

**Aseptic Course Begins**

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

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

❒ Early Registration Fee: € 1,900 ❒ Normal Registration Fee: € 2,200

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

❒ Early Registration Fee: € 1,250 ❒ Normal Registration Fee: € 1,450

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

❒ Early Registration Fee: € 2,950 ❒ Normal Registration Fee: € 3,450

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

3. Payment & Registration - 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 Kantonalbank, 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/1605Courses.html

Please let us know if you need an invoice to initiate payment. This will be sent to you as a PDF by E- mail.

**You will not be registered, unless payment is received.**