

& Agalloco Process Validation 2010: A New Beginning Associates

September, 21-23, 2010 - Princeton, New Jersey

Course Description

This course reviews methodologies for the design and execution of validation studies for development, scale up and commercial preparation of drug products and drug substances. 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 validation activities for drug products and drug substances. Those experienced with validation will refine their knowledge of the subject through interaction with industry's leading expert. Those without a strong background in validation will learn the basics and develop an understanding of the more advanced considerations. The course is intended for personnel working in validation, research & development, pharmaceutical, BPC and biotechnology production, quality assurance and regulatory affairs.

Your Instructors

James Agalloco is President of Agalloco & Associates, a technical service firm to the pharmaceutical and biotechnology industry. Since the formation of Agalloco & Associates in 1991, Jim has assisted more than 100 health care firms in the areas of validation, sterilization, aseptic processing and compliance. He is a frequent author and lecturer on the subject of sterilization, aseptic processing and process validation.

Dr. Steven Ostrove has over 30 years of experience in the Bio-Pharm industry including R&D, scale up, technical service and department management. He is a certified teacher as well as a noted lecturer. He has been an invited speaker and trainer around the world on GMP training and compliance issues. He has extensive experience in project management for projects of all sizes. His project experience ranges from small audits to multi-million dollar facilities.

Margaret M. Szymczak is a Quality Executive with extensive experience in the manufacture of conventional and novel technologies in the Pharmaceutical Industry, and a Program Leader with a proven track record in small molecules, biotechnology, vaccines and product-device combinations. Her background includes Pharmaceutical and Process Development, Quality Assurance/Control and Compliance.

Location

The course will be held at Nassau Inn, located on Palmer Square in the center of Princeton, NJ. A wide selection of fine restaurants and shops are within easy walking distance, and Princeton University is just across the street. Princeton is 45 miles from either Newark or Philadelphia Airport, and also accessible by Amtrak / NJ Transit. There is ample parking nearby. Room reservations should be made directly with the Nassau Inn. The Nassau Inn can be reached at 609.921.7500 or 1.800.8.NASSAU, or on-line at www.nassauinn.com

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Course Schedule

Tuesday, September 21, 2010

Day 1

8:00 - 9:00 AM

Registration
Continental Breakfast

9:00 - 10:30 AM - Session 1

Welcome / Introductions
Introduction to Validation - Agalloco
Prerequisites & Inter-relationships - Agalloco

10:30 - 11:00 AM - Break

11:00 AM - 12:30 PM - Session 2

Addressing FDA's Draft Guidance - Agalloco

12:30 PM - 1:30 PM - Lunch

1:30 - 3:00 PM - Session 3

Development / Quality by Design – Szymczak

3:00 - 3:30 PM - Break

3:30 - 5:00 PM - Session 4

Process Development – Szymczak

5:00 PM - Day 1 Ends

Wednesday, September 23, 2010

Day 2

8:00 - 9:00 AM

Continental Breakfast

9:00 - 10:30 AM - Session 5

BioProcessing – Upstream - Ostrove

10:30 - 11:00 AM - Break

11:00 AM - 12:30 PM - Session 6

BioProcessing – Downstream - Ostrove

12:30 PM - 1:30 PM - Lunch

Wednesday, September 22, 2010 (continued)

Day 2

1:30 - 3:00 PM - Session 7

Chemical Synthesis - Agalloco

3:00 - 3:30 PM - Break

3:30 - 5:00 PM - Session 8

Liquids & Lyophilized Products - Agalloco

5:00 PM - Day 2 Ends

Thursday, September 23, 2010

Day 3

8:00- 8:30 AM

Continental Breakfast

8:30 – 10:00 AM - Session 9

Oral Solid Dosage Forms 1 - Szymczak

10:00 - 10:15 AM - Break

10:15 - 11:45 AM - Session 10

Oral Solid Dosage Forms 2 - Szymczak

11:45 AM - 12:45 PM - Lunch

12:45 - 2:15 PM - Session 11

Other Processes - Agalloco

2:15 - 2:30 PM - Break

2:30 - 4:00 PM - Session 12

Regulation & Compliance Expectations –
Agalloco / Szymczak

4:00 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			Internal Mail Code	
City	State / Province		Zip / Mail Code	Country
Phone			E-mail	

2. Course Fee:

- Early Registration Fee: \$1,900 - **Must be received by no later than August 1, 2010**
- Normal Registration Fee: \$2,100
- Three or more attendees from same firm receive 10% discount on all registrations

3. Please check the appropriate box - **Sorry we do not accept Credit Cards**

- Check Enclosed
- Purchase Order

Purchase Order Number

Company Name

4. Please make a copy of this page, and send the completed form with payment (You will not be registered, unless payment or purchase order number is received with your completed form) to:

Agalloco & Associates
PO Box 899
Belle Mead, NJ 08502-0899

Confirmation: Confirmation of your registration will be sent once payment or PO # has been received.

Vegetarian Meals: Available if requested with registration.

Substitutions: Substitutions are welcome without prior notice up to the day of the course.

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 \$150 service fee.

Travel Expenses: Transportation, accommodations and all other expenses are the responsibility of the attendee.