



Aseptic Processing of Sterile Drug Products

Strategies for Ensuring Regulatory Compliance

Registration Fee: £865

Date: April 15-16, 2010

Course Duration: Two Day 9am-5pm

Course Objective

Sterile drug products, produced by aseptic processing are a high priority in the FDA's current risk-based inspectional program. Meanwhile, the agency's guidance to cGMP compliance for sterile drug products produced by aseptic processing has recently been revised. Staying up-to-date has never been more critical. This comprehensive course covers everything you need to know about aseptic processing. Specific topics include aseptic filling simulations, environmental monitoring techniques, how to define alert and action levels, how to prepare for a regulatory audit and much more. Participants return to their jobs armed with the skills and knowledge necessary to implement programs needed to help establish a state of control with their manufacturing process.

Key Topics

Improve Your Ability To:

- Be familiar with current regulatory requirements, guidance documents and industry practices relating to the manufacture of aseptically produced sterile products.
- Establish a quality system that will set strategies for how to become and remain compliant.
- Understand regulatory expectations for environmental monitoring programs and how to establish an effective program.
- Understand sterilization issues, common terminology and regulatory deficiencies cited with the various methods
- Develop an effective media fill program and discuss issues regarding manipulations
- Understand the major areas of focus during regulatory audits of aseptic processing facilities.



Faculty

Mr. Kenneth J. Christie

COO of Consulting Services
VTS Consultants, Inc.

Kenneth Christie has over 25 years of experience in the areas of Manufacturing of Sterile Products, Quality Assurance, and Validation Management. Prior to becoming the Vice President of Consulting Services for VTS, Mr. Christie spent thirteen years with the Parke-Davis Sterile Products Division of Warner-Lambert where he served as Manager of the Validation Department for eight years. His main responsibilities were management of all validation activities associated with the plant's equipment, utilities, computer control systems, and third party biotechnology companies. Mr. Christie also managed contracted validation personnel and defended all corporate validation practices to regulatory agencies such as the FDA, CBER, CDER, and the United Kingdom's MHRA Division.

Mr. Christie also spent seven years working for Wyeth Laboratories Sterile Biological Vaccines Division of American Home Products as a Manufacturing Supervisor. Mr. Christie is an active speaker and/or trainer for several professional organizations. On the international arena, he has provided pre-FDA audit inspections for foreign firms, along with authoring articles on the challenges of aseptic processing. In his current position, Mr. Christie is a trainer of numerous GxP related topics, provides regulatory consulting and commissioning services and helps develop the corporate business plans.

Mr. Christie possesses a B.S. degree in Biology with a Chemistry minor and holds an Executive Masters Degree in Business Administration from Michigan State University.

CERTIFICATE OF ATTENDANCE AND COURSE MATERIAL

- All participants will receive a certificate of attendance upon completion of the course.
- The participants will be receiving specially prepared course manual

Location

Park Inn– Central London

Just a stone's throw from the **British Museum** and within walking distance to **Covent Garden & Oxford Street**, the Park Inn is nestled between London's financial district and the West End.

Conveniently located within the heart of **historic Bloomsbury**, the Park Inn is situated between Russell Square and Holborn tube stations and is within easy reach of Kings Cross and Euston Train stations.

Address:

92 Southampton Row, London, England, WC1B 4BH



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Registration

Please refer to the **register** tab on the CATD website (www.catdglobal.com) or click on the title of the course on the conferences/meeting or home page to register on line.

If you have any problem registering please do not hesitate to contact us at info@catdglobal.com or call us at + 44 (0) 20 8485 1234 or fax us at + 44 (0) 20 8485 1234

***Registration Fee Includes:**

Presentation Materials, Luncheon, and Refreshment

***Please indicate any special Dietary requirements when registering for the course**

Contact for More Information

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