



CATD Webinars

QA Series

How to Prepare for Audit of Aseptic Manufacturing

Part 3 of 3 part series

Registration Fee: £185 for each part

Date: April 6, 2010, 2010 Part 3

Course Duration: 90 min. 2:00pm-3:30pm (each part)

Key Topics & Agenda

The regulatory expectations for aseptic manufacturing processes are both numerous and very demanding for companies to become and remain compliant. The effectiveness of the processes used by companies are evaluated through regulatory audits. This Webinar, which is the third and final of three, is a continuation of the second series and will help attendees learn what the main regulatory areas of focus are during audits. In addition, the webinar will conclude with the "Top 10" most cited deficiencies as found by the FDA and MHRA auditors.

Outline:

1. Continue the review of the areas of focus during audits of aseptic manufacturing processes. These will include environmental monitoring programs, personnel monitoring, and preventative maintenance and calibration programs
2. Review the various "red flags" to avoid during audits. These will help prevent the common pitfalls that many companies find themselves falling into.
3. Learn how to best address any audit observations that your company may receive.
4. Review the "Top 10" areas of regulatory deficiencies as compiled from the FDA and MHRA.

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.

Registration

Please refer to the **register** tab on the CATD website (www.catdglobal.com) or click on the title of the course on the **Webinar 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

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