STERIS®

Cleaning and Microbial Control in Dietary Supplements Manufacturing

Presented by Elaine Kopis Sartain and Paul Lopolito of STERIS Life Sciences

Learn a practical approach to develop a robust, cost-effective cleaning and microbial control program for dietary supplements manufacturing facilities. The focus of this seminar is both processing equipment and manufacturing areas, and includes the current FDA requirements of the dietary supplements industry.

This seminar is designed for professionals in dietary supplements manufacturing who are responsible for high-quality, efficient, cost-effective, and compliant production results including:

Quality Assurance	Regulatory	Plant Managers
Quality Control	Operations	Compliance Officers
Microbiology	Engineering	Sanitation Supervisors

Date and Location: Wednesday, February 16th 2011
Marriott Hotel
18000 Von Karman Avenue
Irvine, CA 92612
Ph: 949-553-0100 FX: 949-798-2321

Registration Fee: $200 per attendee

Register Online: Click Here

Group discounts are available – Please contact:

Linda Peterson
STERIS Corporation
(314) 290-4743
Linda_Peterson@steris.com

Agenda:

7:30 - 8:00	Registration and Continental Breakfast
8:00 – 9:00	Dietary Supplement GMP Requirements for Cleaning & Sanitizing
9:00 – 10:00	Developing a Successful Cleaning Process Selecting Cleaning Agents and Defining Critical Parameters
10:00 – 10:30	Break
10:30 – 11:15	Equipment Design Considerations
11:15 – 12:00	Streamlining Cleaning Procedures through Grouping Strategies
12:00 – 1:00	Lunch
1:00 – 1:45	Preparation of Robust Cleaning SOPs
1:45 – 2:30	Cleaning Validation vs. Verification
2:30 – 3:00	Break
3:00 – 3:45	Addressing Microbial Limits in Process Equipment
3:45 – 4:30	Cleaning and Disinfection Strategies for Non-Product Contact Areas
4:30	Q&A and Adjourn

Certificates of completion will be provided at the end of the course.

STERIS Corporation is the industry leader in bringing cleaning and microbial control solutions to regulated industries. For over 20 years our team of experts has provided non-commercial, technical training, based on real-world experience in addressing the cleaning and microbial control challenges of regulated industries.

Speakers:

Nicki Jacobs

Nicki Jacobs is a Consultant with Jacobs Compliance Services. A graduate of the University of California at Riverside, Nicki Jacobs has been involved in the pharmaceutical, dietary supplement, and food processing industries for more than 30 years. She has held senior management positions in Quality, Accounting, and Regulatory Affairs, in addition to having been directly involved with Customer Service, Formulation, Purchasing, Personnel and Materials Management. Aware of the impact that regulations can exact on Industry, she has been active in regulatory affairs since air quality issues in the 1980's forced the transition from the use of quick-drying organic solvents to aqueous processing materials and technologies. Most recently, she has been a consultant to industry, specializing in GMPs and the other regulations that form the operating environment for Dietary Supplement manufacturers and their suppliers. Jacobs has spoken at numerous industry meetings, including SupplySide West and the IFT Annual Expo, where she presented from the perspective of a Task Force member involved with the Standardized Information on Dietary Ingredients (SIDI™). SIDI™ is an Industry initiative developed by a joint task force from the AHPA, CHPA, CRN, and NPA to support qualifying components and their suppliers. In addition to Industry experience, she has extended education in GMPs, HACCP, SSOPs. Ms Jacobs is a member the American Society for Quality and the Orange County Regulatory Affairs Discussion Group. Jacobs Compliance Services was recently accepted for membership in the Council for Responsible Nutrition.

Paul Lopolito

Paul Lopolito is a Global technical services specialist for the Life Sciences division of STERIS Corporation. He currently provides technical support related to critical environment and process research cleaners, which includes site audits, training presentations and education seminars. Paul has 13 years of industry experience within cGMP/ISO regulated facilities and has held positions as a technical services manager, manufacturing manager and laboratory manager.

Prior to joining STERIS, Paul spent three years as a manufacturing technical services manager at Massachusetts Biological Laboratories (MBL) providing technical support and project management for the vaccine, monoclonal antibody, blood product and filling/packaging groups. Projects included managing cleaning validations (COP/CIP), equipment commissioning and validation, QC assay validation and document management.

Before moving to Massachusetts Biological Laboratories, Paul spent eight years at TEI Biosciences where he held positions of research associate (one year), lab manager (three years) and manufacturing manager (four years). At TEI Biosciences, he participated in product development, pilot scale manufacturing, QC assay development, process and cleaning validations and eventually oversaw the daily manufacturing of implantable biomedical devices.

Paul has specific expertise in managing cross-functional projects related to process cleaning and critical environment operation with direct experience in biopharmaceutical and biomedical device industries. He earned a B.A. in Biological Sciences from Goucher College in Towson, MD.

Elaine Kopis Sartain

Elaine Kopis Sartain is the Sr. Director of Global Marketing and Technical Services for the Life Sciences Division of STERIS Corporation, manufacturer of contamination control and prevention equipment and products. In this position her focus area is microbial control in cleanrooms and other critical environments, and selection and validation of CIP cleaning agents. Elaine is responsible for providing assistance to STERIS customers in selection and application of disinfectants and cleaners and for providing educational seminars and literature to customer groups. Elaine has lectured on microbial control in cleanrooms throughout North America, Europe and Asia, and has numerous published articles on contamination control related topics.

Prior to her current position Elaine held the position of Associate Manager of Quality Control with ConvaTec, a division of Bristol-Myers Squibb, for five years. In this position she was responsible for the daily management of both the Analytical and Microbiological testing laboratories. Prior to moving to Quality Control, Elaine was a Technical Service Chemist for two years in the Calgon Vestal Infection Control Group, a division of Merck & Co., Inc. Before joining Calgon Vestal, Elaine was an Application Engineer with the Nalco Chemical Company.

Elaine is a member of the Association of Official Analytical Chemists, the American Chemical Society, the Institute of Environmental Sciences and Technology, and the Parenteral Drug Association. She has a B.S. degree in Chemistry from Southern Illinois University.

STERIS®

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
www.sterislifesciences.com