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Cleaning challenges in the dietary supplement industry

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In June, 2007 the U.S. Food and Drug Administration issued an industry specific regulation for Dietary Supplements (DS). This regulation states that DS manufacturers "must maintain, clean, and sanitize, as necessary, all equipment, utensils, and other contact surfaces used to manufacture, package, label, or hold components or dietary supplements." Dietary supplement manufacturers in the United States produce thousands of products in tablet, capsule, powder, liquid, and gel forms. The broad diversity of actives, excipients, and product variations makes it difficult for companies to design a cleaning strategy for DS manufacturing operations, hence making it more challenging to comply with new cGMP regulations.

This presentation will review current cleaning issues and challenges encountered by most DS companies. The presentation will cover new trends towards improving cleaning practices with emphasis in the following topics:

- Critical factors affecting the cleaning of dietary supplements
- Grouping strategies and its correlation to solubility, toxicity, and cleanability of a soil
- Acceptable cleanliness criteria

Actual case examples with vitamins and minerals will be used throughout the presentation to demonstrate critical points.

Biography

Elizabeth Rivera is a technical service specialist for the Scientific Division of STERIS Corporation (Mentor, Ohio). Currently, she provides technical assistance in the areas of selection of detergents, disinfectants and sterilization assurance products including the application and use of these in the pharmaceutical, biopharmaceutical, cosmetics, medical devices, dietary supplements and related industries. In addition, she offers conferences on educational technical forums such as IPA, Interphex, ExpoFYBI, ETIF, Expofarma, Executive Conference and more. Also, she has done seminars and webinars sponsored by STERIS and has published articles related to cleaning. She has an undergraduate and graduate degree in Chemical Engineering from the University of Puerto Rico. She has 10 years of experience and travels to places in North America, Latin America and elsewhere to support customers in various aspects of cleaning and decontamination. Previously, she held positions at companies such as BMS and Eli Lilly. She has extensive experience in cleanup of active pharmaceutical programs. She has worked in the preparation, implementation and support of cleaning processes including protocols, validation, qualification of spray devices, master plans, standard operational procedures, training staff, and post-construction cleaning. Other industrial experiences include qualification of equipment, process validation, batch records, investigation of discrepancies, and corrective and preventive actions, according to good manufacturing practices (GMP) for pharmaceutical industries.

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