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Mitigating the environmental impact of cleaning processes in GMP regulated facilities

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Cleaning procedures are required in cGMP industries for maintaining safe and optimally performing manufacturing equipment and facilities. The use of cleaning products to effectively remove process residues, dust, allergens, and infectious agents may be crucial to prevent product contamination that could adversely affect patient safety. But the use of cleaning products may also present health and environmental concerns. They may contain chemicals associated with skin irritation and corrosion, inhalation risks, and other human and animal health problems.

Additionally, some cleaning products are environmentally hazardous, containing ingredients that must undergo significant treatment (e.g. pH adjustment) before they can be safely discharged. Since the use of some products creates potential handling, storage, and disposal issues for users, these use factors are increasingly becoming components of the selection criteria when new or current cleaning processes are being evaluated.

This presentation addresses common issues regarding cleaning products and procedures used by GMP industry users, and offers assistance in the selection of cleaning chemistries to ease major environmental and health concerns. The focus is given to relevant issues in minimizing pollution, reducing waste, managing personnel hazards, and complying with local regulations.

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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