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Mitigating the environmental impact of cleaning processes in GMP regulated facilities

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Abstract

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 Life Sciences Division of STERIS Corporation (Mentor, Ohio). Currently, she provides technical support in the areas of formulated detergents, disinfectants for critical environments, and sterility assurance products. Her primary focus is on the proper selection of detergents, disinfectants, and sterilization assurance products including the technical support in implementing or using these in the pharmaceutical, biopharmaceutical, cosmetics, medical devices, dietary supplements, and others related. In addition, she lectures at technical educational forums, such as IPA, Interphex, ExpoFYBI, and Executive Conference. She has published articles related to cleaning. She earned a Bachelor and Graduate degree in Chemical Engineering from the University of Puerto Rico.