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Accelerating Scientific Discovery

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Designing an effective cleaning procedure for medical devices using laboratory studies

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Designing an effective cleaning procedure is a critical part of a medical device site operation. The presentation will discuss laboratory studies that lead to the design of a successful cleaning procedure to be incorporated in the medical device manufacturing process. The presentation will review critical parameters, cleanliness acceptance criteria, and quality attributes to ensure that medical devices are successfully cleaned. Actual case examples will be used throughout the presentation to demonstrate critical points. The following topics will be covered in this presentation:

- Residues typically associated with the manufacturing of medical devices
- Critical factors affecting the cleaning of medical devices
- Laboratory evaluation: Why and how?
- Cleanliness criteria based upon sampling method and pre-established limits
- Successful case stories

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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