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Bioburden acceptance criteria in cleaning procedures for processing equipment

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Regulatory agencies require that drug manufacturing processes be designed to ensure that end-products are safe for the user [FDA, Health Canada, PIC/S]. Responsibility lies with the manufacturer to evaluate the hazards of drug preparations per the intended use, the bioburden that the product may contain, and the suitability of testing to ensure a safe product.

Cleaning programs for process equipment should consider microbiological contamination as part of it because it is of concern to patient safety. Nonetheless, the focus of most references and guidelines regarding cleaning of process equipment has been on chemical residues. Some may cover aspects of microbial proliferation in relation to storage conditions.

This presentation discusses the factors that affect microbial control in processing equipment. It also covers an approach to setting microbial limits for cleaning validation considering various scenarios ranging from non-sterile drug products to aseptic manufacturing. In addition, this presentation discusses factors to consider for establishing a clean-hold time.

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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