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The life cycle approach to cleaning validation

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Following the release of the US FDA 1993 Cleaning Validation guide, the European Union, Health Canada and other countries issued similar guides to provide insight to the industry on how to comply with the regulations of the area (US FDA, 1993; PIC/S, 2009; Health Canada, 2008). These guidance documents place focus on validation, ensuring manufacturing control of the cleaning process. The design phase and post validation monitoring stages are factored into the process, but are not emphasized in the regulatory guides or in the industry practices. In 2008, the US FDA issued the process validation guide focusing on the life cycle approach with three main elements:

Stage 1: Process Design- The commercial manufacturing process is defined during this stage based on knowledge gained through development and scale-up activities. This stage ensures that the variables within the process are identified and critical variable limits are defined

Stage 2: Process Qualification- During this stage, the process design is evaluated to determine if the process is capable of reproducible commercial manufacturing. This stage verifies the process, as designed, produces the expected results

Stage 3: Continuous Process Verification- Ensures that critical variables are monitored and the process remains in a state of control during routine production. These three elements are the building blocks to a harmonized approach to process validation and subsequently, cleaning validation.

This presentation provides an overview of the traditional cleaning validation concepts as it applies to the process life cycle approach The process life cycle model is a significant change in how we view cleaning validation. The process life cycle model provides a better understanding of the design and monitoring of the cleaning process and ensures a more robust cleaning validation program. This model also provides a means of addressing product risk using scientifically based decisions when process deviations and non-conforming results occur during the cleaning process.

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, PDA, ISPE, ETIF, Expofarma, 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.

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