

Addressing microbial contamination in process equipment

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Microbial contamination problems in the pharmaceutical, biopharmaceutical, medical device, cosmetic, and dietary supplement industries are recognized as a source of risk to the consumer. The presence of objectionable microorganisms in non-sterile products, or any type of microorganism in sterile products, denotes inadequate process controls. The control of microbial contaminants requires the interaction of a multidisciplinary group to identify root causes and to implement corrective actions. This poster assembles information to assist in this investigational process and offers a holistic approach to remediate microbial contamination in process equipment.

Contamination of a product with an objectionable microorganism is a costly and time consuming problem that needs to be addressed quickly and efficiently by a cross-functional team. The cross-functional team should consist of, but not remain limited to, personnel from quality, engineering, operations and microbiology. It is critical to identify the microorganisms early in the investigation and determine whether they are from an intrinsic (of the manufacturing process) or extrinsic (outside of the manufacturing process) source. Based on the probable source, the investigation team can focus its investigation. A careful walk-through of the process can be used to flag areas of microbial risk and identify controls in place or lack of them; understand when the product is at highest risk, and provide solutions to reduce the risk. A holistic approach is commonly performed to address contamination issues and get the manufacturing process running again. As part of the holistic approach, assess the cleanability of the system and make engineering changes to address issues such as coverage, drainability, etc. as needed. Perform a robust high temperature, alkaline cleaning to remove process and microbial residue. If rouge or water scale is present, perform a high temperature acid cleaning to remove the inorganic residue. When possible, use a disinfection/sterilization procedure that is routinely performed on site and ensure critical parameters are achieved during the process. Once the manufacturing process is back up and running, schedule regular meetings to review current microbial control measures and internal plans to quickly and effectively address the next microbial contamination event.

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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