

Validation of Cleaning and Sterilization Processes for Reusable Medical Devices



AppTec is a unique single source for comprehensive GLP/GMP-compliant testing, contract research and development, and specialized cGMP manufacturing services for biopharmaceuticals, medical devices, cellular therapeutics, and tissue-based products. We provide our clients the highest level of state-of-the-art science, regulatory expertise and individualized customer service.

When reusable medical devices are cleaned and sterilized in a health care facility, manufacturers are responsible for providing their customers with complete and comprehensive written instructions for handling, cleaning, disinfection and sterilization. The FDA expects manufacturers to validate all reuse instructions including cleaning and disinfection procedures, cycle parameters, and aeration times, if applicable.

AppTec offers a comprehensive program for evaluation of cleaning and sterilization processes for reusable medical devices. Testing is based on guidelines outlined in AAMI T.I.R. No. 12¹ and T.I.R. No. 30.² This program assists the manufacturer in meeting the requirements of the FDA Reviewer Guidance: "Labeling Reusable Devices for Reprocessing in a Health Care Facility."

PROTOCOL DEVELOPMENT

A custom protocol is written for each study, tailored specifically to the device and the manufacturer's instructions for reuse. AppTec's scientific staff assists clients in assessing cleaning processes and developing protocols.

CLEANING EFFICACY STUDIES

Manufacturers must verify the efficacy of their recommended cleaning processes. Following the manufacturer's cleaning instructions, these studies test those processes using a microbial marker of simulated soil inoculated with bacterial spores and/or other appropriate organisms. Additionally, the cleaning can be assessed for removal of chemical, physical or other markers such as protein, carbohydrate, and total organic carbon (TOC).

STERILIZATION EFFICACY STUDIES

Manufacturers must provide health care facilities with detailed sterilization instructions for their particular medical device. Sterilization parameters are tested to determine capability of producing a sterility assurance level of at least 10^{-6} . Studies are available for evaluating the following sterilization processes:

- Ethylene Oxide (EO)
- CO₂ / H₂O₂ / VHP, etc.
- Liquid Chemical (Steris System 1[®], glutaraldehyde, etc.)
- Steam – Pre-vacuum and/or Gravity (121-123°C and 132-135°C)

SUPPORT FOR FUNCTIONALITY STUDIES

These studies involve exposure to multiple cleaning and or sterilization cycles as part of the functionality studies required to determine the useful life of a device.

¹ AAMI Technical Information Report No. 12: "Designing, Testing & Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers."

² AAMI Technical Information Report No. 30: "A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices."



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