

Reprocessing Validation for Reusable Medical Devices

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 instructions for use (IFUs), including cleaning, disinfection, cycle parameters, and aeration times, if applicable.

WuXi AppTec offers a comprehensive program for evaluation of cleaning, disinfection 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."

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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► PROTOCOL DEVELOPMENT

A custom protocol is written for each study, tailored specifically to the device and the manufacturer's instructions for use (IFU). In developing these protocols, WuXi AppTec's scientific staff assists clients in assessing their cleaning processes and determining the appropriate biomarkers to use in cleaning efficacy studies.

► CLEANING EFFICACY STUDIES

Manufacturers must verify the efficacy of their recommended cleaning processes. Following the manufacturer's cleaning instructions, these studies test the cleaning process using a challenge consisting of simulated soil to represent contamination in use. The cleaning process is then assessed for removal of chemical, physical or biomarkers such as protein, carbohydrate, hemoglobin, total organic carbon (TOC) and microorganisms.

► STERILIZATION EFFICACY STUDIES

Manufacturers must provide health care facilities with detailed sterilization instructions for their particular medical device. Sterilization parameters are tested to determine their capability in producing a sterility assurance level of (typically) 10⁻⁶. Studies are available for evaluating the following sterilization processes:

- Steam – Pre-vacuum and/or Gravity (121-123°C and 132-135°C)
- Ethylene Oxide (EO)
- CO₂ / H₂O₂ / VHP, etc.

► 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.

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

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

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