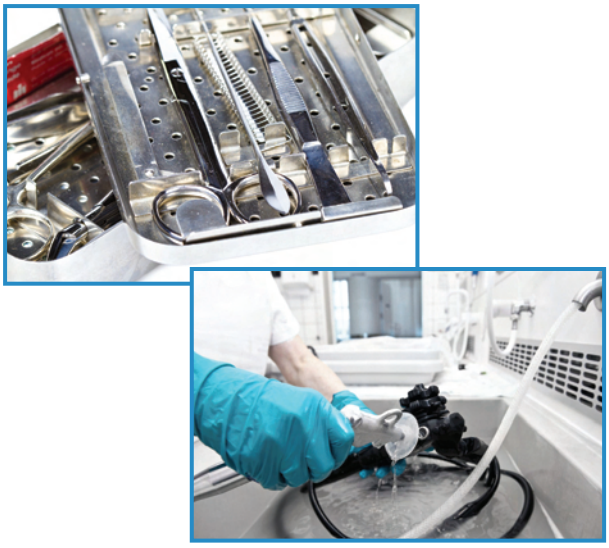
reprocessing validation

As outlined in the FDA Reviewer Guidance: "Labeling Reusable Devices for Reprocessing in a Health Care Facility," the FDA expects manufacturers to validate all applicable cleaning, disinfection, sterilization and dry-time instructions for reusable devices.

To assist manufacturers in meeting these regulatory requirements, WuXi AppTec offers a comprehensive program for evaluation and validation of cleaning and sterilization processes. Testing follows guidelines from AAMI TIR No. 12 and AAMI TIR 30 ("Designing, Testing & Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers").



WuXi AppTec is able to perform the full spectrum of cleaning, disinfecting, and/or sterilizing processes – whether manual, ultrasonic or automated – allowing faster turnaround times and better sample control. On-site equipment includes a STERIS Reliance Genfore Washer/Disinfector that offers a variety of options to meet specific needs.

validation services

Protocol Development

A custom protocol is written for each study, tailored specifically to the device and the manufacturer's instructions for reuse. WuXi 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, this study tests those processes using simulated soil inoculated with an appropriate marker.

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}.

Dry Time Validations

Manufacturers must provide heath care facilities with an effective dry time to be used in conjunction with the required steam sterilization cycle. Drying cycles are tested to prove the cycle works according to the given parameters.r.

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.

Talk to us and find out how our reprocessing validation services can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com

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FAQs

reusable medical device reprocessing validations

What has changed as a result of proposed FDA guidelines regarding the reprocessing of reusable medical devices?
The single biggest change is the concept that multiple markers may be required to properly demonstrate cleaning efficacy. These now can include not only microbial markers but also markers that are components of potential soil materials that may be left behind after cleaning.

Proposed guidelines say that spore log reduction is not recommended in measuring cleaning efficacy. So what is the best approach?
The FDA has stated that spore log reduction is not relevant to show cleaning efficacy. The best approach is to test several markers, such as TOC, hemoglobin and protein, either with or without the addition of a microbial marker. These non-microbial markers are the common ones being requested by the FDA. However, the FDA has not specified which of these to use or what the accepted endpoint should be.

How do I know what artificial soil to use in a cleaning study?
To meet the current requirements, the test soil should represent the type of contamination the device will be exposed to in use.

In validating reprocessing, are the worst-case cleaning parameters expected to be used?
The expectation has always been that worst-case parameters should be used. However, it appears the FDA may expect the manufacturer to go beyond "reasonable" expectations. For example, the IFU may say to soak the device within one hour of use to prevent drying of organic material, but in actual practice it may not happen. In that case, the manufacturer may be expected to use excessive drying (beyond what the IFU says) in the cleaning study.

Do I need exhaustive extraction in my cleaning study?
The current expectation is to validate the extraction process. One way to validate that process is exhaustive extraction. No criteria have been given for an endpoint for exhaustive extraction; therefore, if the lab can quantitate the extraction efficiency, it should be sufficient for providing definitive results.

Will destructive testing be required to validate adequate cleaning?
Cutting, forced disassembly or other destructive manipulations may be required to access certain areas of a device to prove that adequate cleaning has taken place. Build-up from multiple cleanings is the concern. However, if devices are adequately cleaned, there should be no build-up. Our experience has been that, if the laboratory can validate their extraction procedure so that the recovery is quantitated, destructive testing should not be required.

Will the FDA accept reprocessing instructions in a 510(k) from a predicate device?
Because the FDA is questioning the applicability of test parameters that were used on predicate devices, they may ask that devices currently on the market repeat the cleaning studies using the proposed guidelines. For any new devices, the FDA expects the manufacturer to use the proposed guidelines versus any older criteria or protocols.

Are there changes expected for the instructions for use (IFU) provided by the manufacturer?
Proposed guidelines ask manufacturers to validate that their instructions are usable and understandable. This will require a type of human factors test, where a group of users must follow the instructions in cleaning a device. The ability of the users to successfully execute the cleaning procedure will determine if the instructions are understandable.

Is use of FDA-cleared equipment required in the lab's validation?
As the FDA intends validation testing to simulate and challenge actual use conditions, the use of sterilizers and accessories that have a 510(k) helps achieve this aim. As long as the lab's equipment is proven to be equivalent to or better than FDA-cleared equipment, it should be acceptable. In general, lab equipment will have tighter tolerances and closer specifications because of extensive validations and calibrations typically performed in the laboratory setting and therefore results should be more accurate and reproducible.

Will turnaround times change as new testing is implemented?
Several factors can affect turnaround times. Due to the detailed nature of the protocol, the review process to satisfy FDA expectations may take longer. And, while the tests themselves will not take longer than before, the breadth of studies – and, therefore, the time needed to perform them – may expand.

What is the process for getting validation studies completed?
WuXi AppTec will develop a customized test plan with you to address the risks specific to your device and its use. The process starts with detailed discussions with our technical staff to develop the validation plan. Once the plan is finalized, the proposal is developed and the project is performed in our Atlanta laboratories

WuXi AppTec has many years of experience and unmatched expertise regarding reusable devices, with key staff who serve on the pertinent standards committees / working groups. We can provide knowledgeable guidance in the design of testing plans that meet FDA expectations.

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To learn more about our reprocessing validations for reusable devices, contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com