

FAQs: Validating the Reprocessing of Reusable Medical Devices



What has changed as a result of the proposed guidelines?

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 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. However, the spores are simply a marker placed within a test soil and it is the test soil that should be relevant. 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 seem to be 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. Industry is saying that if additional markers are used in conjunction with microbial markers, a correlation to previous data can be established.

How do I know what artificial soil to use in a cleaning study?

Recently the FDA has been asking for unusual ingredients to be added to standard soil solutions. The main requirement is that the test soil represent the type of organic contamination the device will be exposed to in use. Industry is hoping to establish several types of standard test soils representative of contamination for broad groups of devices, rather than continuing to have individual requests from FDA for special formulations.

In validating re-processing, are the worst-case cleaning parameters expected to be used?

Yes, 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, while the IFU may say to soak the device within one hour of use to prevent excessive drying of organic material, 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?

Although the FDA has mentioned exhaustive extraction, the current expectation is to validate the extraction process. 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. Exhaustive extraction could prove to be elusive, especially if no guidance is given as to what exhaustive means.

Will destructive testing be required to validate adequate cleaning?

The FDA is suggesting that 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. Due to the cost of some devices, this is getting resistance from manufacturers. Build-up from multiple cleanings is the concern. However, if devices are adequately cleaned, there should be no build-up – so there is much discussion around the hospital cleaning practices. Nonetheless, our experience has been that if the lab 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?

Probably not. 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, it is evident that the FDA will be expecting 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?

Most likely. Hospitals/users are saying IFUs need to be easy to understand and possibly standardized. The FDA is listening. Proposed guidelines ask manufacturers to validate the usability/understandability of their instructions, and 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 by all.

Is use of FDA-cleared equipment required in the lab's validation?

No, the use is not required for labs since the FDA recommendation is targeted for health care facilities. 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 proved 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 the extensive validations and calibrations typically performed in the laboratory setting and therefore results should be more accurate and reproducible.

What is the process for getting validation studies completed?

Because the FDA has not set a standard for validation and has asked for a variety of markers, we 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.

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.

WuXi AppTec has many years of experience and unmatched expertise regarding reusable devices, with key technical staff who serve on the pertinent regulatory committees/working groups. For more information on the reprocessing of reusable medical devices, contact an Account Manager at +1 (651) 675-2000 or +1 (888) 794-0077. www.wuxiapptec.com • www.comboproducts.com