



## Laboratory Testing & Consulting Services

### CLEANING VALIDATION OF REUSABLE DEVICES

LexaMed assists medical device manufacturers in the design, testing and labeling of devices intended for reuse and reprocessing in health care facilities by establishing cost-effective cleaning validation programs to meet FDA requirements. LexaMed's team of professionals has extensive knowledge and experience in designing and conducting these programs. We are available to assist at each phase of the process and are considered industry leaders in this field.

When a medical device is labeled as "reusable", manufacturers of these devices must provide complete written instructions for the cleaning of the products to support the label claim. Manufacturers are obligated under the Food and Drug Administration (FDA) labeling regulations (21 CFR 801) to have the suitability of these processes validated.



### CLEANING VALIDATION PROGRAM FOR DEVICES LABELED FOR RE-USE

Cleaning a device is a critical step in reprocessing it after patient use. Cleaning which is ineffective in removing foreign material from the inside and outside of a device can interfere with efficacy of subsequent disinfection and/or sterilization processes. In conjunction with water and detergents, cleaning can be done using manual processes such as wiping, brushing, flushing and soaking or cleaning can be done with mechanical means such as ultrasonic cleaners and washer-decontaminators.

Testing of the cleaning process must be conducted to verify its effectiveness. The testing conducted by LexaMed complies with AAMI TIR 12 and AAMI TIR 30 and involves the use of a suitable artificial test soil and a quantitative test method for detecting residual test soil after cleaning. The basic study design is as follows and can be modified depending on the device and client's specific needs.

- *Devices are contaminated with an organic test soil material that contains clinically relevant soil components to be quantified for validation testing (e.g. protein, hemoglobin, carbohydrate).*

- *Contaminated devices are cleaned using either the manufacturer's recommended cleaning process or a process determined during the course of the study. The process may involve a manual or automated cleaning method or both, if required.*
- *Following cleaning, the devices are visually inspected for residual soil followed by extraction and quantitative analysis using a validated method to determine the level of residuals remaining. .*
- *The final step is an evaluation to determine if the cleaning process effectively removed the detergent residuals to a safe non-toxic level.*
- *Based on test results, a conclusion is made as to the effectiveness of the cleaning procedure*

For more information on these programs or any other LexaMed offerings, contact Jan Koenker at 419-693-5307 or email at [jkoenker@lexamed.net](mailto:jkoenker@lexamed.net).

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