Processing/Reprocessing Validations for Medical Devices
The Most Experienced Validation Experts in the Industry

For over 20 years NAMSA has offered expert and thorough manual cleaning efficacy validation studies as well as manual disinfection efficacy validation studies. NAMSA is now pleased to offer automated cleaning efficacy validation studies and automated disinfection efficacy validation studies using our new, state-of-the-art washer-disinfector. Our experts ensure that the highest quality, newest technology, and latest regulatory expectations are incorporated into our processing/reprocessing validation studies. We accomplish this through our multiple channels of contact with the FDA and through active participation in organizations responsible for the development of applicable standards.

OVERVIEW OF CLEANING EFFICACY VALIDATION AND DISINFECTION EFFICACY VALIDATION

In order for manufacturers to market reusable medical devices, the FDA requires specific, detailed validated processing/reprocessing procedures be provided by the manufacturer to the end user. Two important components of those processing/reprocessing procedures are cleaning procedures and disinfection procedures.

These components need to be properly validated as described in guidance AAMI TIR12, AAMI TIR30, and ANSI/AAMI ST 58, as well as the FDA 2011 draft guidance on Processing/Reprocessing Medical Devices in Health Care Settings (see Resources section for full citation). Validation Methods and Labeling, Document issued on May 2, 2011, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, and Office of Device Evaluations.

By offering validation studies for these important and increasingly popular automated methods, NAMSA continues to expand our ability to provide our clients the opportunity to partner with an experienced “one-stop shop” for all of their reusable medical device testing and validation needs.

MANUFACTURER RESPONSIBILITIES

The FDA places responsibility for developing and validating methods for effective processing/reprocessing of a medical device on the manufacturer of that device. The manufacturer is expected to validate that the device can be cleaned and disinfected, or sterilized adequately to allow the device to be used and/or reused. As outlined by the FDA, the manufacturer must test and validate any labeling claims of fitness for reuse that are provided in the instructions for the handling, cleaning, disinfection, packaging, and sterilization of medical devices in a health care facility.

In addition to providing other guidance and information, AAMI TIR30, AAMI TIR12, and the FDA 2011 draft guidance addresses the issues related to manufacturer validation testing for cleaning and disinfecting medical devices.

LABORATORY PROCEDURE

An important part of this process is testing the effectiveness of the proposed cleaning and disinfecting instructions the manufacturer must supply in their device Instructions for Use (IFU). Because cleaning and disinfection are defined as different processes with different expected endpoints, each process must be validated independently.

To validate the cleaning procedure in the product IFU, it must be demonstrated, through testing, that the procedure can consistently achieve levels of residual soil on the device, as measured by specific soil markers, that are compatible with its intended use. In order to accomplish this in the laboratory, the device is contaminated with a clinically relevant soil under conditions that simulate use and cleaned using the worst-case application of the cleaning
procedures found in the manufacturer’s IFU. During the post-cleaning stage, the device is extracted in the appropriate matrix (saline, sterile water), and analyzed by the appropriate method to determine the remaining residual level of the specified soil marker(s).

To validate the disinfection procedure (where applicable) in the product IFU, it must be demonstrated, through testing, that the procedure can consistently achieve the specified levels of reduction in the population(s) of the challenge organism(s) that is compatible with its intended use. In order to accomplish this in the laboratory, the device is inoculated with the specified, clinically relevant challenge organism(s) and disinfected using the worst-case application of the disinfection procedures found in the manufacturer’s IFU. During the post-disinfection stage, the device is neutralized by the validated neutralization method and extracted and recovered by the validated extraction and recovery method to determine the surviving population of the challenge organism(s). The comparison of these recovered populations to the positive control population for the challenge organism(s) determines the level of disinfection achieved by the procedure.

As the FDA and other regulatory bodies continue to increase the scrutiny of processing/reprocessing instructions for medical devices, it becomes even more critical that these procedures are validated in a thorough and robust manner. NAMSA’s experienced experts have aided clients in successfully releasing hundreds of products into the market. We look forward to assisting you.

Instructions for Use Development/Refinement
• Expert consultants to review and provide direction to meet FDA expectations.

Feasibility Testing and Test Method Development
• Evaluation of cleaning, disinfection, and/or sterilization methods including appropriateness of test soil and/or residual marker analysis

Human Factors
• Laboratory evaluation and feedback on execution of processing/reprocessing procedures (disassembly/assembly, ease of reprocessing)
• In vivo and cadaver studies: opportunities for user evaluation/training

Protocol Development
• Expert consultants to develop and administer protocols and studies, including the FDA 2011 draft guidance on Processing/Reprocessing Medical Devices in Health Care Settings, AAMI TIR12, AAMI TIR30, ISO 17665, ANSI/AAMI ST81, ANSI/AAMI ST79, and/or ISO 17664
• Use of appropriate test soil(s), clinically relevant challenge organism(s) and “worst-case” conditions

Testing
• Cleaning efficacy (automated and/or manual cleaning)
• Test soil preparation and soiling that simulates actual use
• Soil accumulation evaluation
• Residual marker analysis including, but not limited to:
  • Protein
  • Hemoglobin
  • Carbohydrates
  • Total Organic Carbon (TOC)
• Residual cleaning agent analysis
• Disinfection efficacy (High Level, Intermediate Level, Low Level)
• Bioburden recovery efficacy
• Validation of microbial recovery (neutralization validation)
• Product inoculation, disinfection, and microbial recovery/enumeration
• Sterilization efficacy
• Product inoculation, bioindicator (BI) placement and sterility testing
• Sterilization in vessels validated to meet current FDA expectations, using FDA-cleared accessories and FDA-cleared parameters
• Dry time validations
• Life cycle testing

Study Support and Reporting
• All laboratory raw data are available to be reviewed by Quality Assurance

RESOURCES:
The MRO® Approach
Regulatory strategy, testing services and clinical research all support the medical product development process. These services must be available when needed, either individually or collectively depending on the stage of the product development process. With NAMSA’s MRO® approach to testing and consulting, you maintain project control while gaining the benefit of on-demand external support—whether it’s to extend your in-house capabilities or access specialized expertise at exactly the right time.

We’ve assisted numerous companies from around the world in bringing their great ideas to the patients who need them. We know you’re passionate about developing and producing safe, effective and compliant medical products for global markets so we’ve designed our services, trained our people and maintained our facilities to get you there.

You deserve the best knowledge, integrated services and flawless execution in your chosen partner. NAMSA’s ready.

OUR SERVICES
Regulatory and Quality Systems Consulting
Research and Development Support
Non-Clinical Testing
Clinical Research
Post-Market Support