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From the Blog

Reprocessing and Cleaning Validation for Medical Devices

April 6th 2026

In healthcare manufacturing and clinical environments, contamination control is a fundamental regulatory and patient safety obligation. Medical devices may be exposed to biological contaminants through clinical use, or to chemical and particulate residues generated during manufacturing. Both reprocessing validation and cleaning validation are therefore required disciplines, each governed by distinct regulatory frameworks, yet sharing a common objective: demonstrating that contamination is effectively and reproducibly reduced to levels that do not compromise device safety, functionality, or intended performance.

Defining the Scope: Reprocessing vs. Cleaning Validation
Although the terms 'reprocessing' and 'cleaning validation' are sometimes used interchangeably, they address distinct stages of the device lifecycle and involve different regulatory obligations.

Reprocessing Validation
Reprocessing refers to the complete set of validated operations applied to a used medical device to render it safe for reuse. Per ISO 17664 and applicable EU MDR 2017/745 requirements, reprocessing encompasses cleaning, disinfection, inspection, packaging, and sterilization, as applicable. Manufacturers of reusable devices are required to provide validated reprocessing instructions, demonstrating that each cycle maintains device safety and performance without degradation.

The FDA, under 21 CFR Part 820 and associated guidance documents, further requires that reprocessors of single-use devices (SUDs) submit a 510(k) premarket notification demonstrating that reprocessing does not compromise the device's safety profile or labelled performance.

Process Methodology: A Structured Approach
Both reprocessing and cleaning validation follow structured, risk-based methodologies consistent with current regulatory and scientific expectations.

Protocol Development and Risk Assessment
Validation begins with a documented risk assessment identifying the contamination sources, critical quality attributes, and worst-case scenarios applicable to the device. A protocol is then developed, defining the scope, acceptance criteria, sampling strategy, analytical methods, and equipment qualification requirements.

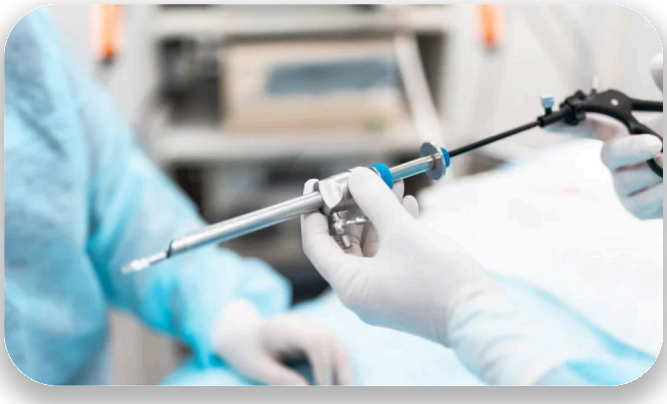
Test Soil Selection
Representative test soils simulate the contamination expected under intended use conditions. For clinical reprocessing, standard test soils per ISO 15883 or ASTM standards (e.g., blood-based soils, protein surrogates) are commonly employed. For manufacturing cleaning validation, soils reflect the specific residues associated with the production process, mould release agents, lubricants, adhesives, or API residues in combination product environments.

Analytical Methods
Quantification of residual contamination requires validated analytical techniques appropriate to the target residue and substrate:

- Total Organic Carbon (TOC) analysis for non-specific organic residue quantification
- UV spectrophotometry or HPLC for chemical-specific residue detection
- Limulus Amebocyte Lysate (LAL) or for endotoxin
- Bioburden testing per ISO 11737-1 for microbial contamination
- Residual assays

Method validation, including specificity, linearity, recovery efficiency, and limit of detection, is required prior to use in validation studies.

Acceptance Criteria
Acceptance limits must be scientifically justified, typically based on toxicological risk assessments (e.g., Permitted Daily Exposure calculations per EMA guidelines), visually clean criteria, or microbiological thresholds.



Cleaning Validation
Cleaning validation, in contrast, is principally a manufacturing quality assurance requirement. It provides documented evidence that a defined cleaning process consistently reduces residues, including process chemicals, bioburden, particulates, and cross-contamination from prior products, to levels that are toxicologically or microbiologically acceptable. Regulatory expectations are defined under ISO 15883 (washer-disinfectors), AAMI TIR12, and AAMI ST98, as well as ICH Q7 and CGMP regulations where pharmaceutical or combination products are concerned.

The shared principle across both disciplines is process reproducibility: a validated process must demonstrate consistent performance across repeated cycles and under worst-case conditions.

Technical Challenges in Contamination Control
Cleaning and reprocessing validation are inherently complex, driven by the diversity of device geometries, material compositions, and contamination types encountered across the medical device sector.

Residue Complexity
Residues requiring removal may include blood, proteins, lipids, nucleic acids, chemical processing agents, endotoxins, and particulate matter. Each presents different solubility and adhesion characteristics depending on the substrate material, stainless steel, polymer, titanium, or porous ceramics, requiring tailored cleaning chemistries and validated parameters.

Device Geometry
Narrow lumens, blind-ended channels, porous sintered surfaces, and multi-component assemblies significantly complicate residue access and removal. Cleaning process design must account for the most inaccessible locations, with validation specifically demonstrating removal efficacy at worst-case sites.

Worst-Case Condition Definition
Regulatory expectations require that cleaning validation be performed under worst-case conditions, maximum soil load, minimum cleaning cycle parameters, and maximum device complexity. This ensures that routine operating windows remain within validated limits. For reprocessing, this additionally encompasses the maximum number of reprocessing cycles declared in the instructions for use (IFU), with functional performance confirmed at end-of-life.

Process Reproducibility
Validation protocols must demonstrate statistical reproducibility across a minimum of three consecutive cycles (typically), with acceptance criteria met at

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Integration with Laboratory and Sterilization Services
Laboratory Services Integration
Validation studies require access to accredited laboratory services capable of performing the full suite of analytical methods described above. At Medistri, laboratory services are integrated within the same quality management system as sterilization operations, enabling coordinated study execution, data traceability, and consolidated technical documentation. This reduces the risk of inter-laboratory variability and simplifies regulatory audit management.

Sterilization Validation Linkage
Cleaning is a prerequisite for effective sterilization. Residual soil loads, particularly proteins and organic films, can reduce the efficacy of ethylene sterilization processes. Cleaning validation must therefore establish that residue levels prior to sterilization are within the bounds assumed during sterilization process validation and bioburden control strategy.
Medistri provides contract sterilization services across multiple modalities, including EO and steam, enabling manufacturers to manage the cleaning-to-sterilization workflow within a single validated supply chain. This is particularly relevant for manufacturers seeking to streamline technology transfer, reduce lead times, and maintain a single audit relationship for both cleaning validation support and terminal sterilization.

Practical Considerations for Manufacturers
Manufacturers initiating or expanding cleaning and reprocessing validation programmes should consider the following operational factors:

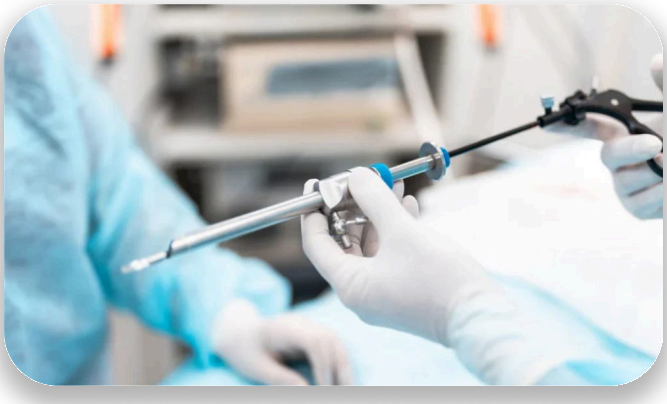
- Early engagement: Validation planning should begin during design and development, not at commercialisation. Device geometry decisions made during design directly affect cleanability and validation complexity.
- IFU development: Reprocessing instructions must be validated before being published. Post-market changes to reprocessing instructions may require re-validation and, in some cases, regulatory notification or submission.
- Change control: Modifications to cleaning agents, process parameters, equipment, or device materials may require partial or full re-validation. A documented change control procedure aligned with ISO 13485 is essential.
- Data integrity: All validation data must be generated, reviewed, and retained in accordance with applicable data integrity requirements, including 21 CFR Part 11 for electronic records in FDA-regulated environments.
- Post-market surveillance: Cleaning and reprocessing validation is not a one-time activity. Field data, complaint trends, and post-market clinical follow-up (PMCF) may trigger re-evaluation of validated processes.

As regulatory scrutiny of reprocessing and manufacturing cleanliness continues to intensify, manufacturers benefit from working with contract service partners that can provide integrated laboratory testing, sterilization services, and regulatory expertise within a single, audited quality system.

Medistri's dual-site infrastructure in Switzerland and Hungary is designed to support precisely this need — enabling manufacturers to execute compliant, efficient validation programmes that meet the requirements of ISO, MDR, and FDA frameworks while maintaining the supply chain resilience required in today's regulated environment.

To learn more about Medistri's Validation Services, please visit our website here or contact us at contact@medistri.com.

– The Medistri Team



each iteration. Variability in water quality, temperature control, detergent concentration, and mechanical action must be characterised and controlled within defined tolerances.

Regulatory Framework and Standards Alignment
Cleaning and reprocessing validation activities must be integrated within the manufacturer's Quality Management System and are subject to regulatory oversight across multiple jurisdictions.

Key Regulatory References:
EU MDR 2017/745 — Annex I GSPR, reusable device requirements
FDA 21 CFR Part 820 — Quality System Regulation
ISO 17664 — Processing of health care products: reusable medical devices
ISO 15883 — Washer-disinfectors: requirements and test methods
AAMI ST98 — Cleaning validation for medical devices
ICH Q7 — GMP guide for active pharmaceutical ingredients
ISO 11737-1 — Bioburden determination
ISO 14971 — Risk management for medical devices

EU MDR 2017/745
Under EU MDR, manufacturers of reusable devices are required to demonstrate, as part of the clinical and technical documentation, that reprocessing does not adversely affect device performance and that validated IFUs are provided. Notified Body review of reprocessing validation data is mandatory for Class IIa devices and above.

FDA Requirements
The FDA's guidance on reprocessing of single-use devices requires submission of reprocessing validation data to demonstrate microbial and chemical safety. The Agency's 2015 guidance on reprocessing and subsequent updates reinforce expectations for validated protocols, worst-case testing, and functional performance confirmation.