Nelson Labs®
A Sotera Health company

Healthcare Reprocessing Validations

INTRODUCTION

For more than 20 years, Nelson labs Leuven has been performing microbiology, chemistry, and biocompatibility testing. The microbiology lab started as a small part of our overall testing and we conducted mainly sterility, bioburden, endotoxin, and cytotoxicity testing; which are well known in the Pharmaceutical and Medical Device industry. Our facility in Leuven owes its excellent reputation primarily to our high-tech chemistry lab. We are a global leader in the field of Extractables and Leachables testing both for the pharma and the medical device industries. Thanks to our experience in offering highly customized extractables & leachables tests, we decided four years ago to add non-routine projects to our microbiology testing portfolio. Together with the expertise and knowledge from our head office located in Salt Lake City, we added a healthcare reprocessing validation lab at our Belgian facility—performing these validations according to international standards.

The choice to add healthcare reprocessing was very simple as devices intended to be reprocessed in a clinical setting must have cleaning, disinfection, or sterilization instructions provided with the product. These instructions for use (IFUs) will detail the correct way to reprocess the device prior to use to ensure patient safety. Regulatory bodies and healthcare facilities are increasingly concerned about the spread of communicable diseases, including clinically relevant microorganisms, on reprocessed medical devices. Validating these cleaning, disinfection, and sterilization processes is therefore paramount in ensuring patient safety and minimizing healthcare-acquired infections, corrective actions, and recalls. The Leuven lab has been fully ISO 17025 accredited to perform cleaning, disinfection, and steam sterilization validations for reusable medical devices in accordance with MDR requirements since the second half of 2020. Our dedicated team of experts actively serve on the ISO committees regarding reprocessing and have expertise in creating appropriate worst-case testing conditions to help device manufacturers meet regulatory expectations.

In addition to our healthcare reprocessing testing, our team also offers routine microbiology and biocompatibility testing. Our team of experts is ready to help you deliver safe and effective products to the market whenever you need us.

This brochure will give you a short overview of our healthcare reprocessing validations services.

CONSIDERATIONS PRIOR TO PERFORMING A REPROCESSING VALIDATION

Prior to starting a reprocessing validation for a reusable device, it is important to consider two key aspects. The first question you must ask yourself is which reprocessing instructions you would like to validate. The second question you must ask yourself, is which device to use for the reprocessing validation.

1. Which reprocessing instructions would you like to validate?

It is important to note that all reprocessing instructions must be included in the written instructions for use (IFU) document; therefore, all reprocessing instructions provided in the IFU must be validated. Consequently, if you already have an existing IFU, this will be the starting point for your reprocessing validations. When an IFU is not available or may be subject to change, it is helpful to keep a few things in mind. First, the instructions described in the IFU must comply with the applicable national and international standards and guidelines. Second, it is important to consider whether the processing equipment, detergents, disinfectants, etc. are commonly available to the processer. Finally, guidelines and reprocessing instructions may have different requirements based on the markets where you intend to sell your reusable device. There are many things to consider, but Nelson Labs has a global consultancy team that can support you in creating an appropriate IFU.

2. Which device should be used for the reprocessing validation?

Validating the reprocessing processes that occur at healthcare facilities is costly. Fortunately, it may not always be required to perform these validations for all your medical devices. In many instances a family grouping can be used by device manufacturers to select a worst-case device (or devices) that will represent their family groups in the validations. This device (or devices) must be selected based on a written justification which carefully considers the materials and device design of each device to select worst-case representatives. When these worst-case representatives can be successfully validated, all the devices they represent are considered validated as well.

There are three main approaches to evaluating whether a family grouping is appropriate for the medical devices a manufacturer is validating: device use, material type, and device design.

Device Use: If the devices have similar use during surgical procedures, they can be grouped by their function, use, and degree of patient contact. Similarly configured devices or parts used for generally the same purpose and contact comparable amounts of human tissue, blood, mucus, etc. may be grouped together for validation. Additionally, the devices must be reprocessed using the same instructions.

Material Type: If a group of devices are made from the same metals and soft materials, they could qualify for family grouping. Devices are made from materials ranging from metal, to ceramic, to polymers; and sometimes a mix of several materials. Each of these materials holds onto residue differently and, therefore, should be grouped accordingly.

Device Design: Medical devices of similar size and challenge features may be grouped together as a family. The considerations that are employed in this type of grouping include the number of components, design challenges for cleaning, and surface area.

Family grouping for steam sterilization validation requires different considerations compared to family groupings for cleaning. Additionally, whereas family grouping for cleaning/disinfection validations will mostly consider worst-case devices, family groupings for steam sterilization may include the selection of a worst-case tray configuration (if appropriate). Family grouping for steam sterilization validations have some additional considerations when compared to cleaning. Steam validations should also incorporate steam penetration resistance, weight, and packaging.

Nelson Labs experts can perform a written worst-case device determination and justification in order to help you select your worst-case device(s) according to the applicable guidelines.

GUIDANCE FOR CLEANING, DISINFECTION, AND STERILIZATION VALIDATIONS

What you need to know for your cleaning Validation

A cleaning validation is necessary to assure that once the device has been used, soil as well as detergent residuals are reduced to acceptable levels after cleaning using the recommended cleaning procedure. The validation should follow requirements outlined in AAMI TIR12, AAMI TIR30, ISO 17664, and the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." Every cleaning validation will consist of contamination, cleaning, and post-reprocessing effectiveness evaluations. Contamination should use a relevant test soil that should be applied using simulated-use testing practices to simulate real-life clinical usage. The ensuing evaluation of the cleaning procedure should quantitatively assess relevant markers. Nelson Labs will assist you in selecting the correct soil, soiling procedures, validation procedures, and test soil markers in accordance with applicable guidelines.

Automated or Manual cleaning?
Cleaning can be done automatically in a washer/disinfector or it can be done manually. A validated automated cleaning process should be created if the reusable device can withstand such conditions. Additionally, a manual cleaning process can be considered. If the device cannot withstand automated cleaning, the users should be alerted to this issue and a validated manual cleaning process should be available.

Setup of a cleaning validation

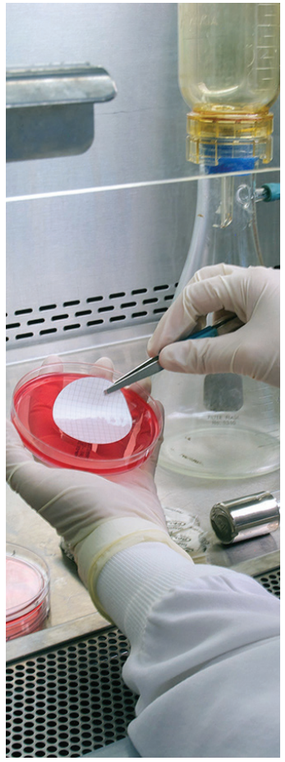
Contamination: The devices are soiled using the appropriate test soil which will allow the evaluation of clinically relevant markers such as protein, hemoglobin, carbohydrates, and total organic carbon (TOC). The device's intended use and wait time between patient use and cleaning are considered in determining the soiling method. The devices are often sprayed, handled with soiled gloves, and immersed in the test soil—or all three. All movable parts may be actuated to simulate clinical use and then left in contact with the test soil for an appropriate time. The devices are then removed from the soil and allowed to set for an appropriate time to simulate the wait time between patient use and processing.

Simulated use: Cleaning validation studies should incorporate multiple full use cycles to assess the accumulation of soil that may happen over time. To this end, six (6) cycles of soiling, cleaning, and disinfection or sterilization (or both) are performed. A visual inspection ensures that no visually detectable test soil builds up over repeated reprocessing cycles.

Cleaning processes: Multiple test replicates will be cleaned according to the cleaning procedure provided by the manufacturer. If applicable, a worst-case interpretation of these instructions will be used for the validation. Nelson Labs can assist you in selecting this worst-case interpretation. Manual cleaning might involve immersing devices in detergent prepared according to the detergent manufacturer's recommendations. A soft-bristled brush may be used to aid in soil removal, paying particular attention to crevices and hard-to-clean areas. Some devices may need to be subjected to a mechanical step that may include ultrasonic cleaning in an enzymatic detergent. Automated cleaning may involve such a manual cleaning step as well prior to processing in a washer/disinfector. Nelson Labs can perform manual cleaning as well as automated cleaning validations; we have an EN ISO 15883-1/-2 compliant washer disinfector commonly used in healthcare facilities.

Positive device recovery: One device that will be soiled but not cleaned will be extracted multiple times to obtain an extraction efficiency. This information gives an idea of how well the marker(s) are recovered using the extraction method selected and will be used as a correction factor when performing residuals testing.

Residual testing: After the devices are cleaned, they are visually inspected to make sure that there is no visible soil remaining on the devices. Subsequently, the devices are extracted using a validated method to quantitatively assess the amount of test soil markers that remain on the devices following cleaning. The amount of residuals left on the device must fall within acceptable limits in accordance with applicable guidelines.



What you need to consider for your Disinfection validation

Disinfection validations are used to validate device manufacturers' disinfection instructions. Validations may be performed to support high-level disinfection, intermediate-level disinfection, and low-level disinfection processes depending on the intended use or Spaulding Classification (noncritical, semi-critical, or critical) of the device. Nelson Labs can assist you in determining the appropriate disinfection level.

Thermal disinfection

Thermal disinfection is defined in the ISO15883-1:2006 standard as "disinfection achieved by the action of moist heat". This can be performed by exposing devices to hot water, steam, or a combination of the two. Thermal disinfection can be a part of the automated cleaning program set in washer/disinfectors. In this case temperatures ranging from 82°C to 95°C will typically be used, with the time depending on the model of the washer/disinfector. When it is not part of an automated cleaning program, thermal disinfection can occur through boiling test items or through pasteurization. The latter typically uses water at temperatures of 65°C to 77°C for a contact time of at least 30 minutes.

Automated thermal disinfection validations can be performed in two different ways, the A0 approach or the microbiological challenge approach. For the automated thermal disinfection processes European regulatory agencies expect, A0 data as indicated in ISO15883-1:2006. US FDA on the other hand will expect microbiological challenge studies, but validation is only needed if the thermal disinfection step is the final reprocessing step. Non-automated thermal disinfection processes are validated using microbiological challenge studies.

Chemical disinfection

For disinfection validations, devices are inoculated in the worst-case location(s) of the device that present the biggest challenge(s) to the disinfection process. These sites are inoculated with an appropriate concentration and type of organism(s) depending on the required disinfection level. The organisms are allowed to dwell on the test replicates after which the devices are disinfected and extracted to determine the organism counts present after disinfection. One positive device control is not disinfected between inoculation and extraction. The number of organism(s) on the positive device is compared to that of the disinfected devices to establish appropriate log reduction(s) for the process. Additionally, neutralization efficiency testing is performed to support the validity of the bioload reduction results.

What is important in a Steam Sterilization Validation?

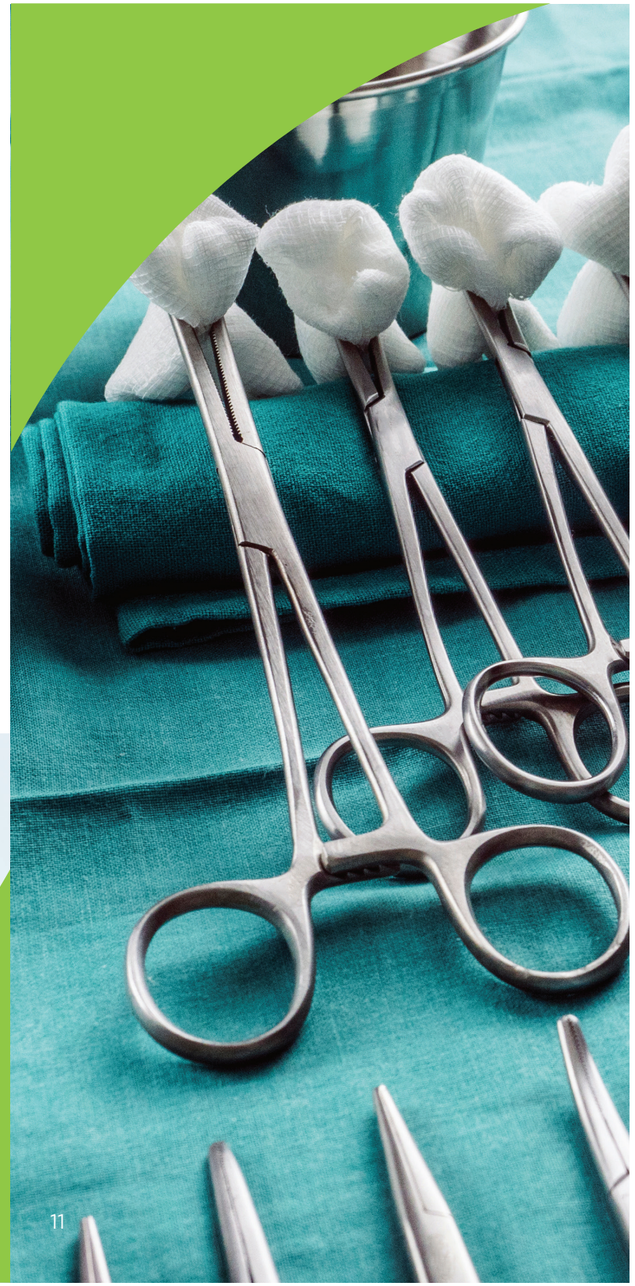
Steam Sterilization Validation testing confirms the appropriate Sterility Assurance Level (SAL), dry time, and temperature profile of the intended steam sterilization cycle parameters for a medical device. Based on the data obtained through testing, the manufacturer will be able to provide healthcare facilities with validated sterilization parameters.

Steam Sterilization Sterility Assurance Level testing validates the recommended gravity or pre-vacuum steam sterilization parameters for the medical device. Nelson Labs validates individual devices, implants, trays, kits, or other reusable devices. Typically, a Sterility Assurance Level (SAL) of 10-6 is validated using the biological indicator overkill method. Validations can be performed using the partial cycle or full cycle approach. Along with the SAL validation, dry time validation testing, and internal temperature mapping are required to validate steam sterilization cycle parameters. Dry time testing ensures that after the sterilization cycle, the packaging and the device(s) are not wet given that residual moisture is detrimental as it may compromise the sterile properties of the packaged device. Temperature mapping profiles the temperature inside the containment device as well as the chamber during steam sterilization and demonstrates the heating properties of the device.

THE MOST CHALLENGING REUSABLE DEVICES: FLEXIBLE ENDOSCOPES

Flexible endoscopes present a particular challenge to reprocessing and are of particular concern for the spread of communicable diseases. They, therefore, have complex reprocessing instructions, being processed in specialized automated endoscope reprocessor (AER) equipment that must be validated according to unique validation criteria.

Nelson Labs offers full cleaning, disinfection, and sterilization validation services for endoscopes and other diagnostic scopes for clinical use. In addition, AERs should be validated for their intended use for each unique scope type and configuration. Our experts have extensive experience with scope cleaning, disinfection, and sterilization validations working with scope and AER manufacturers as well as US FDA.



END-OF-LIFE TESTING

In addition to validating the reprocessing instructions to assure that cleaning, disinfection, and sterilization of reusable devices meet expectations, medical device manufacturers must determine the number of reprocessing cycles or provide other indications to determine the end of life. When the IFU indicates that devices can be reprocessed for a certain amount of cycles, this must be validated using simulated use testing that mimic clinical conditions and the full processing steps. Repeated soiling may be included, after which the specified number of cleaning, disinfection, or sterilization exposure cycles are run to assess end-of-life functionality and ensure safe operation not only at the beginning but also at the end of a device's life cycle. The number of samples is determined by the customer based on their post-exposure functionality test requirements.

BIOCOMPATIBILITY TESTING FOR REUSABLE DEVICES

The focus of reprocessing validations centers on validating the reprocessing efficacy with regards to infection control and not on assessing the biocompatibility of the reusable medical device. However, the reprocessing of reusable devices is intricately linked with their biocompatibility. Chemicals or processing conditions may affect the biocompatibility of the used materials. Detergents and disinfectants may attack materials, the devices are repeatedly exposed to high temperatures, and whereas devices may physically withstand these reprocessing cycles this does not mean that a device will remain biocompatible after repeated processing. Consequently, and especially with the advent of the new era of MDR, reprocessing must be included in the biocompatibility evaluation of devices to ascertain patient safety of the device at the beginning, middle, and end of a device's life cycle—which is also stated in ISO 10993-1.

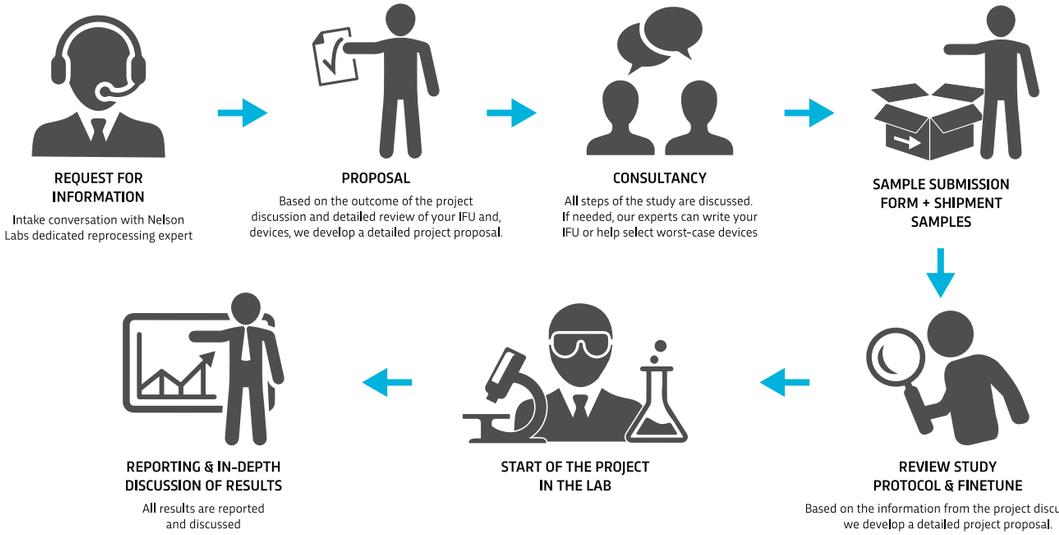
This sounds simple in theory, but in reality, assessing the biocompatibility of reusable devices can become quite complex. Our advice would be to address biocompatibility prior to the start of the reprocessing validations. Biocompatibility testing may be combined with performing reprocessing validations, e.g. in the case of assessing biocompatibility at end of life, but this will not always be the case.

Nelson Labs offers a full range of services to meet the requirements of ISO 10993 for Extractables & Leachables, Biocompatibility, and Toxicological Risk Assessments of medical devices. Biocompatibility testing is very common in the medical device industry. Our Technical Advisory group can provide a full-service experience and guide you through all the biocompatibility challenges for reusable medical devices.

A TEAM OF EXPERTS YOU CAN COUNT ON

Our team of dedicated experts are ready to help you deliver the lifesaving medical devices of tomorrow. Thanks to our thorough understanding of the different guidelines and standards, we can assist you in defining an adequate test plan that matches your product criteria and launch plans.

With 7 simple collaboration steps, we can guide you flawlessly through your project:



ACCREDITATIONS

Nelson Labs Europe is ISO 17025 (BELAC) accredited. To offer the highest level of quality data, Nelson Labs Europe is also GLP licensed (2010) and GMP licensed (FAGG/AFMPS, Federal Agency for Medicinal and Health Products) for the release of medicinal products. Nelson Labs Europe is FDA registered and has been successfully audited by the FDA for GMP programs.

NELSON LABS OFFERS

Complete Confidence
Your test is done right every time. Our track record and reputation for quality and reliability sets us apart.

Industry-leading Experts
We understand your business and the challenges you face. Thanks to our active monitoring of the regulatory landscape and working with industry groups we give a full perspective on critical topics and changes.

Exceptional Service
95% of all first-time customers partner with Nelson Labs for future testing. We serve our customers from a world-wide network of labs and facilities.

End-to-end Solutions
We are the only comprehensive provider of mission-critical services. Our experts can guide you along the entire product development life cycle.

Nelson Labs®
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Safeguarding Global Health®
with every test we complete

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About Nelson Labs

Nelson Labs a global leader in microbiological and analytical chemistry testing and advisory services for the medical device and pharmaceutical industries. Nelson Labs serves over 3,800 customers across 14 facilities in the North America, Asia and Europe. We have a comprehensive array of over 800 laboratory tests supporting our customers from initial product development and sterilization validation, through regulatory approval and ongoing product testing for sterility, safety and quality assurance. We are regarded as a best-in-class partner with a strong track record of collaborating with customers to solve complex issues. Learn more about Nelson Labs at www.nelsonlabs.com

Safeguarding Global Health® - with every test we complete.

If you would like to learn more about our medical device cleaning validations, please contact us at infoEurope@nelsonlabs.com or call us at +32 (0)16 400.484.

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