Nelson Labs®
A Sotera Health company

# Biological Safety Evaluation

Using a risk-based approach to safety

**Safeguarding Global Health™**
– with every test we complete.

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## The days of the "check box" approach to biocompatibility are over.

Instead, manufacturers of modern-day, complex devices need to assess the biocompatibility of their medical device materials and processes by taking a holistic risk-based approach to their biological safety evaluations.

Our experts have broken out the biological safety evaluation process into three distinct phases that can be used to accommodate a medical device in any stage of the product lifecycle.

**This process is comprehensive and available today:**

**STEP 1: IDENTIFY RISK**
**Biological Evaluation Plan (BEP)**

**STEP 2: MITIGATE RISK THROUGH TESTING**
**Biological Evaluation**

**STEP 3: EVALUATE THE RESULTS**
**Biological Evaluation Report (BER)**

Medical device manufacturers benefit from the **outside perspective** of the experts at Nelson Labs through the **biological evaluation process.**

+1 (801) 290-7522 | www.**nelsonlabs**.com | advisoryservices@nelsonlabs.com

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**STEP 1: IDENTIFY RISK**
**Biological Evaluation Plan (BEP)**

**Create a Biological Evaluation Plan (BEP);** consider the device materials, intended use, and existing data to prescribe a risk-based approach to the evaluation of device safety. Risks are identified considering patient contact and duration, materials, processing and their potential to cause harm.

## What should be included in a BEP?

### Physical / Material Information
- Suppliers
- Patient contact
- Specification sheets
- Testing information on raw materials

### Device Description & Categorization
(based on ISO 10993-1)
- Clinical use
- Duration of exposure (including cumulative)
- Include pictures

### Special Test Sample Preparations
- Master product
- Absorption capacity
- Parts to include or exclude
- Cut/don't cut

### Outline ApplicableTesting & Risk Assessments
- Tests to perform based on risk to patient
- Conversation of areas where there is no risk (important if FDA asks for consideration in a particular area that does not apply to your specific device.)

## Standards

ISO 10993-1:2018: "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process."

US FDA guidance document "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process.'"

MDR Regulation (EU) 2017/45 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

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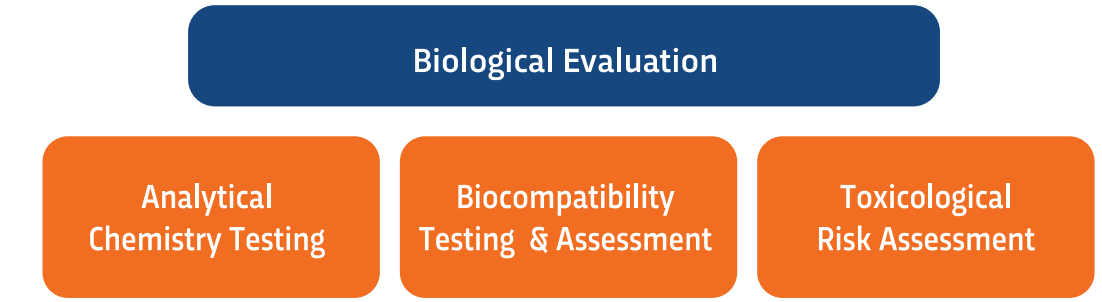
## STEP 2: MITIGATE RISK THROUGH TESTING
## Biological Evaluation

**Execute the Biological Evaluation:** based on the risks identified in the BEP, perform a combination of analytical chemistry testing, biocompatibility testing and assessment, and/or toxicological risk assessment.




### Biological Evaluation

| | |
|---|---|
| **Analytical Chemistry Testing** *ISO 10993-18* | Identifies and quantifies what chemicals are leaching from the device that might interact with the patient. Utilizing the Nelson Labs Unique Compound Screener Database helps avoid unidentified compounds. |
| **Biocompatability Testing & Assessment** *ISO 10993 Series* | A combination of written evaluations and biological testing to address risks or knowledge gaps regarding device biocompatibility. |
| **Toxicological Risk Assessment** *ISO 10993-17* | Evaluates the results of chemistry testing considering the risks of the device and nature of patient contact to determine safety. |

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## STEP 3: EVALUATE THE RESULTS
## Biological Evaluation Report (BER)

**Biological Evaluation Report (BER);** written by Nelson Labs' experts, this information is a summary of all the evidence gathered to support the biological safety of the device and acts as a conclusion statement to the entire project.

**Anatomy of a BER:**

**A.** Summary of the device, its intended use, and the strategy used to evaluate the potential biological risks associated with the device

**B.** Review of the outcome
- Biocompatibility tests
- Chemistry testing w/tox assessment
- Risks addressed purely by material and literature review

**C.** Discussion and explanation of unexpected results or material/processing changes conclusion
- If there are tests which did not pass, a discussion of the relationship between the failure and actual safety of a device;
- An assessment of the impact raw materials/manufacturing changes might have on the device (when a part of the device/manufacturing process changes from what was tested to the device that is being submitted).

**D.** Overall conclusion on device biological safety
- Conclusion statement that the device has been evaluated and complies with ISO 10993 standards
- Signed by an expert with the appropriate education and experience to make the final conclusion based on all data and evidence provided (as required in ISO 10993-1).

## Unique Compound Screener Database

Nelson Labs exclusively owns the most expansive library of 5000 medical device compounds in the world - including approximately 2000 specific non-volatiles. This tool reduces the reliance on animal testing, saving manufacturers time and money when utilized during the Biological Safety Evaluation.

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