SHOULD I TEST DEVICE MATERIALS, OR ONLY A COMPOSITE OF THE FINISHED DEVICE?

Manufacturers should gather safety data on every component and material used in a device. In addition, testing should be conducted on the finished device as specified by ISO 10993-1. Generally, the best approach is to:

- Assemble vendor data on candidate materials
- Conduct analytical and vitro screening of materials
- Conduct confirmatory testing on a composite sample from the finished device

There is a risk in testing the finished device without developing data on component materials. If an adverse result occurs, it can be difficult to track down the component that is causing the problem. This may end delaying a regulatory submission due to having to repeat testing on the individual components.

Screening device materials minimizes this risk. The initial chemical characterization should detect leachable materials that could compromise device safety. Inexpensive non-animal studies (such as cytotoxicity and hemocompatibility tests) provide an additional screen for material safety. Material screening tests also help insure that the chance of a redesign to the device due to biocompatibility test failures will be minimized. Many manufacturers assemble data on a library of qualified materials used in their products.

For all biocompatibility studies, test samples should be sterilized using the same method as will be used for the finished device.

CMDC Labs

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Biocompatibility

Biocompatibility

Biocompatibility testing is a critical part of the regulatory approval process for medical devices as even the best designed products can produce unintended complications if the materials used cause a biological reaction in the patient. Well characterized materials widely used in the industry can produce unexpected reactions if processed in a way that leads to contamination, degradation, or leaching of toxic compounds into a patient.

CMDC Labs is ISO 17025 accredited and has expertise in a wide range of products and manufacturing processes to help assess the biological risks of a new device design or process change, and develop an appropriate testing program for assessing the safety of your products.

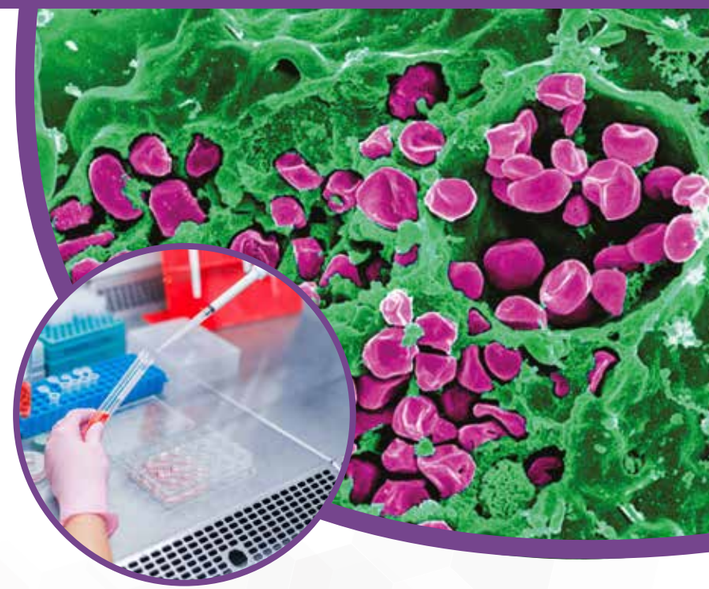
From chemical characterization of degradation products and extractables and leachables testing, to toxicological risk assessments and biological evaluations, our veterinarians, chemists, and toxicologists can facilitate the appropriate testing to best support your international regulatory submissions.

Choose CMDC Labs Medical Device Testing to help you:

- Evaluate the biocompatibility of your new device
- Assess the impact of a design change or new manufacturing process on your device's safety
- Evaluate new raw material suppliers
- Consider effects of sterilization techniques or long-term material stability
- Generate toxicology reports
- Establish biological evaluation plans

Applicable Standards

- ISO 10993
- ISO 18562
- US FDA Guidance Document on ISO 10993-1 (Sep 2016)
- MDR Regulation (EU) 2017/745 of the European Parliament and the Council of 05 April 2017 on Medical Devices



Why Perform Biocompatibility Testing?

Biocompatibility testing for medical devices is a critical step in the process of developing and approving products intended for use in or on the human body. The primary objective of this testing is to ensure the safety of patients by evaluating how the body responds to a device and its constituent materials. Biocompatible devices are engineered to perform their intended functions without eliciting an inappropriate host response, be it inflammation, allergic reaction, infection, or any form of toxicity. Without rigorous biocompatibility testing, there is a heightened risk that medical devices could cause adverse reactions in patients, leading not only to medical complications but also to potential legal consequences for manufacturers.

The significance of biocompatibility extends beyond immediate patient safety as well. A device that is not biocompatible can compromise the integrity and efficacy of medical treatments. For example, if an implanted device such as a pacemaker or hip replacement were to cause an inflammatory response, the device may fail to function as intended, leading to worsened health outcomes or the need for additional surgeries. Testing also provides valuable data on how devices interact with biological systems over time, informing long-term safety profiles and guiding post-market surveillance. In essence, biocompatibility testing is a cornerstone in building the scientific evidence that underpins patient safety, regulatory approval, and the long-term success of medical devices in healthcare.

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