CMDC Labs

INTRODUCTION TO BIOCOMPATIBILITY

MAKING THE UNKNOWN KNOWN...

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WHAT IS DEVICE BIOCOMPATIBILITY?

The term "biocompatibility" describes how a medical device interacts with a patient's tissues and physiological systems while being used to treat them. One aspect of a device's overall safety review is an assessment of biocompatibility. Analytical chemistry, in vitro experiments, and animal models are used to examine the biocompatibility of devices. A device's biocompatibility is influenced by a number of factors, including:

*Chemical and physical nature of its component materials

*Types of patient tissue that will be exposed to the device

*Duration of that exposure

Of course, ensuring patient safety is the main goal of a device biocompatibility examination. When establishing a biocompatibility testing program, manufacturers should take business regulatory objectives and compliance concerns into account. Analyzing a device's biocompatibility is invariably a risk assessment process. There is no device or device component that is risk-free. Device creators strive to reduce risk while enhancing value to patients.

WHAT ARE THE FDA AND EU/ISO REQUIREMENTS FOR BIOCOMPATIBILITY TESTING?

The ISO Standard 10993, Biological Evaluation of Medical Devices, is the best place to start when learning about biocompatibility standards. The Guidance on Selection of Tests is covered in Part 1 of the standard, along with criteria for animal welfare, while particular test protocols and other testing-related topics are covered in Parts 3 through 19 of the standard. In Europe and Asia, testing methods that adhere to the ISO 10993 family of documents are allowed. The tripartite Guidance was replaced by a Blue Book Memorandum G95-1 that the FDA released in 1995. (the previous biocompatibility testing standard). FDA has largely implemented the ISO directive, despite the fact that in some instances, FDA's testing standards go above and beyond those of ISO.

When compared to the USP processes formerly utilized for FDA submissions, the specific ISO test techniques differ slightly. Companies that intend to register their products in both Europe and the United States should adhere to ISO test processes as they tend to be more severe. Since extra testing might be required, it is important to confirm FDA regulations. Japanese sample preparation and testing protocols differ slightly from USP and ISO tests.

CMDC Labs highly recommends discussing your proposed biocompatibility testing plan with an FDA reviewer before initiating testing

DO I NEED BIOCOMPATIBILITY DATA?

Nearly all devices that have considerable tissue interaction usually need biocompatibility data of some form. To establish whether your device requires biocompatibility testing, consult the ISO Materials Biocompatibility Matrix, a flowchart from ISO 10993-1. A majority of the time, businesses organize their own biocompatibility investigations. If you require some or all of the following categories of biocompatibility data, you might be able to reduce the amount of testing you need to do on a particular device.

Data from earlier submissions - If data from an earlier submission is available, take into account the following information as you apply it to your present device. If there are significant changes in any of these areas, confirmatory testing will be required:

*Materials selection
*Manufacturing processes
*Chemical composition of materials
*Nature of patient contact
*Sterilization method

Supplier Data - If vendor data is used, producers should get copies of the original study reports. A majority of the time, manufacturers will wish to perform at least some confirmatory testing themselves (e.g. cytotoxicity and hemocompatibility studies).

Analytical information - Manufacturers may utilize analytical information to show that a device has a low overall risk or a low risk of having a specific biological consequence. Some instructions on this procedure are provided in Section 18 of ISO Standard 10993, Chemical Characterization of Materials.

Clinical data - The ISO 10993-1 test selection matrix's biological impacts categories can be satisfied using clinical data in specific cases. The information may come from the device in question's clinical trials or from clinical experience with comparable or identical predicate devices.

HOW DO I DETERMINE WHICH TESTS I NEED?

Confirmation of the device's suitability for its intended purpose forms the basis of the ISO Standard. Device component chemical characterization is the first stage in this process. Probably the most important step in a biocompatibility assessment is in vitro biological testing. Devices are categorized using the ISO materials biocompatibility matrix according to the kind and length of body interaction. A list of possible biological impacts is also provided. Certain consequences must be taken into account and addressed in the regulatory filing for each category of device. For any medical device, ISO 10993-1 does not specify a particular battery of testing. Instead, it offers a foundation for creating a program for biocompatibility testing.

To discover how best to meet the standards of the materials biocompatibility matrix, device designers should often engage with an experienced device toxicologist and their clinical investigators. There should be documentation of the reasoning behind the testing plan for each category of biological effects. This is particularly true if a manufacturer opts not to do testing for an effect that the matrix for their particular product category specifies.

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

Every part and material used in a medical device should have safety information collected by the manufacturer. Additionally, ISO 10993-1 guidelines need to be strictly followed when performing testing on the finished item. In general, the best course of action is to: compile vendor data on potential materials

Analytical and in vitro material screening to confirm final product performance should be performed on a composite sample taken from the final product. Testing the final product without gathering information on the component ingredients carries a certain amount of risk. It may be challenging to identify the element that is the cause of a negative outcome. If you repeat the testing on each component individually, you can end up delaying your regulatory submission.

CMDC Labs is fully equipped for all your biocompatibility testing needs.

Device material screening mitigates risk. Leachable compounds that might jeopardize the safety of the device should be identified during the initial chemical characterization. The cost-effectiveness of non-animal research, such cytotoxicity and hemocompatibility tests, adds another layer of material safety screening.

Additionally, preliminary material screening, evaluation and compatibility tests ensure that you won't have to alter your product design as a result of biocompatibility test failures. Many manufacturers compile information on a list of approved materials that they utilize in their goods. Some test methods are not suitable for testing composite materials. Due to physical constraints, each device component must be tested separately using agar overlay, direct contact cytotoxicity tests, and implant investigations.

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