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The Fundamentals of Biological Testing Measures for Medical Devices

Due to its inherent nature, the biological safety of a medical device is fundamental to ensuring patient and device user safety over time. All medical device manufacturers are required to comprehensively investigate their devices to meet certain expectations by official authorities prior to receiving market approval. If you are a manufacturer, authorized representative, importer, or distributor of medical devices within the European Union (EU) or United States (US), you must comply with either the EU's Medical Device Regulation of 2017 (MDR) or In Vitro Diagnostic Regulation (IVDR), or the US Food and Drug Administration's standards such as a 510(K) or premarket approval (PMA), each dependent on the type and nature of a given device. It's important to note that with the delay of the EU's Medical Device Regulation (MDR), the Amending Regulation defers the application of the MDR until May 26th, 2021, however TÜV SÜD still encourages all manufacturers to continue to pursue meeting the new requirements now in preparation for the future change.

Importance of Biological Testing

Medical devices and materials are subjected to a thorough biological evaluation process and biocompatibility testing to ensure the final product is proven to be safe for a patient. This testing will assess interaction of device with tissue, cells, intact skin, or body fluids over a period of time in order to determine the device's biocompatibility and any potential biological risks.

Biocompatibility of medical devices is a complex and ever-evolving subject based around the internationally recognized standard, ISO 10993. Specific testing protocols will be dependent on the chemical characteristics of a device's materials, as well as the nature, degree, frequency, and the amount of time the device will be in direct and indirect contact with a human body. Tests can include:

- In Vitro Cytotoxicity
- Irritation
- Sensitization
- Systemic Toxicity
- Genotoxicity
- Carcinogenicity
- Hemocompatibility
- Implantation
- Reproductive and Developmental Toxicity

Understanding ISO 10933-1

Prior to 1987, there were no universally recognized standards for device biological safety testing. Today, ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" is the most common standard for biological testing and biocompatibility assessing, as it offers a framework for a consistent biological evaluation. This standard specifies the general principles governing the biological evaluation within a risk management process, the general categorization of medical devices based on their usage, evaluation of existing data from relevant sources, and the overall assessment of the biological safety of the medical device. As a general rule, all biocompatibility testing should be performed in compliance with ISO 17025 and Good Laboratory Practice (GLP) regulations.

Determining Which Testing is Required

It's important to develop the right testing strategy in order to meet the biological safety expectation for the device. In order to confirm that a given device is fit for its intended medical use, the first step in the evaluation process is to gather physical and chemical information on the medical device or component which the process of the chemical characterization of the device and taking into consideration the impact of the manufacturing process on the final device components. Once the manufacturer has strong evidence for the physical and chemical properties of the device, a toxicological assessment related to each of the detected substances should be performed. Depending on the results various Biological Endpoints should be considered, which is another critical step during the biocompatibility evaluation. Device manufacturers generally work with experienced toxicologists and clinical investigators to determine how to meet the requirements of the materials biocompatibility matrix.

As the manufacturer, you should evaluate and provide a rationale for the biocompatibility the final medical device. To facilitate this evaluation, manufacturers typically record safety data of every component, material and manufacturing process, i.e. processing aids, and residues from cleaning agents, used within a medical device and may conduct testing on the finished device. In consideration of biocompatibility, the manufacturer may assemble supplier data on candidate materials, administer analytical and in vitro testing of materials, and confirm biocompatibility via additional testing of a finished device.

How Notified Bodies Play Their Part

A Notified Body is an organization designated by an European Union country to assess the conformity of medical devices before being placed on the market. These bodies will carry out all necessary tasks related to conformity assessment procedures when a third party is required.

Involvement of notified bodies in conformity assessment procedures where the conformity assessment procedure requires the involvement of a notified body (for higher risk classes than self-declared class I devices), the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned.

About TÜV SÜD

Founded in 1866 and headquartered in Munich, Germany, TÜV SÜD is one of the world's leading Notified Bodies for the assessment of medical devices. With more than 24,500 employees located across over 1,000 locations, TÜV SÜD is a trusted partner of choice for safety, security, and sustainability solutions. For more information on how TÜV SÜD can help you, visit our website.

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TÜV SÜD is a global provider of auditing and certification services. Our in-depth knowledge of regulatory compliance around the world and our highly experienced auditors provide you with a fast, efficient service. We focus on helping you become more consistent, efficient and compliant – which means you bring products to market faster, avoid liabilities and boost profits.

Related services

TÜV SÜD provides the following related services:

- Medical Device Testing
- IEC 60601-1 Testing
- Cybersecurity Testing
- Wireless Testing
- Chemical or Biological Testing

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