CONTENT BRIEF

# Why Medical Device Success Begins with Proper Biocompatibility Evaluation

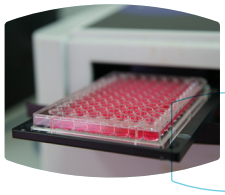
When developing a new medical device, safety is a critical driver of success. Depending on the application, a device's biocompatibility is a crucial criterion in determining the safety of a medical device. In evaluating biocompatibility, manufacturers need to address several regulatory and compliance standards before the device is submitted to the appropriate governing regulatory agency. In this overview, we examine key testing standards and data used in the biocompatibility assessment process.

## BIOCOMPATIBILITY TESTING STANDARDS AND DATA

ISO 10993 and USP Class VI provide a series of standards to evaluate a medical device's risk profile, based on the nature of body contact and the duration of contact. ISO 10993 is the standard for evaluating the biocompatibility of devices that come into direct or indirect contact with the human body. This standard uses a risk-based approach. Risk is defined in ISO 14971 as, "the combination of the probability of occurrence of harm and the severity of that harm." A risk-based approach weighs the likelihood and consequences of a particular risk and adapts the original equipment manufacturers' (OEM) quality management activities accordingly. In addition to device-specific factors like intended use, the device risk assessment will be driven in part by the materials from which the device is constructed. A material supplier may be able to provide biocompatibility test results of materials used in the device, which may simplify the testing required on the device. Additionally, there are standards available which guide the biological evaluation of medical devices and their constituent materials.

**If you would like to learn more about assessing biocompatibility through a risk-based framework, check out our blog post, "More than Materials: A Risk-Based Framework for Biocompatibility Assessment."**

While both ISO 10993 and USP Class VI standards are designed to provide guidance on biocompatibility evaluations, these evaluations come from different perspectives. ISO 10993 guidance is intended to be considered in the context of the finished medical device, while USP Class VI guidance is intended to apply to plastic materials which are intended for use in medical device and pharmaceutical applications. Generally, USP Class VI criteria covers only a portion



of the testing described by ISO 10993. Depending on the device's intended use and risk assessment, all or portions of the testing in ISO 10993 are recommended for a specific application. Below is a chart of some of the biocompatibility endpoint testing described by ISO 10993 and USP Class VI:

| BIOCOMPATIBILITY EVALUATION CRITERIA | WHAT DOES THIS EVALUATE | DESCRIBED BY | |
|---|---|---|---|
| | | ISO 10993 | USP VI |
| **Cytotoxicity** | Potential toxicity to living cells | X | |
| **Sensitization** | Potential to cause a sensitizing effect upon repeated exposure | X | |
| **Irritation** | Potential to cause a localized inflammatory response | X | X |
| **Acute Systemic Toxicity** | Potential to cause short-term toxic effects | X | X |
| **Material Mediated Pyrogen** | Potential to cause fever | X | |
| **Subacute Toxicity** | Potential to cause medium-term toxic effects | X | |
| **Subchronic Toxicity** | Potential to cause long-term toxic effects | X | |
| **Genotoxicity** | Potential to damage genetic information/ cause mutations | X | |
| **Implantation** | Potential to cause local effects after contact with tissue | X | X |
| **Hemocompatibility** | Potential for interaction with blood | X | |
| **Chronic Toxicity** | Potential to cause very long-term toxic effects | X | |
| **Carcinogenicity** | Potential to cause cancer/tumors | X | |
| **Reproductive/ Developmental Toxicity** | Potential to impact reproductive function, embryonic development | X | |

Note: Although biocompatibility data for the material may be provided for several biological evaluation criteria, the data must be considered in the context of the entire device.

## BIOCOMPATIBILITY

The ability of a material to interact with a host without generating a response that would negatively impact its performance.

## BIOSTABILITY

The ability of a material to maintain its key performance characteristics throughout the lifetime of the medical device in which it is used.

When an OEM is selecting the materials from which to construct a medical device, material biocompatibility testing provides guidance on the selection of appropriate materials. A material that has been evaluated for biocompatibility, either through USP Class VI or ISO 10993 methods, enhances the OEM's confidence that the material will not negatively impact the overall device biocompatibility. The knowledge that a material does not have inherent undesired biological interactions mitigates the risk of a device failing biocompatibility testing. For example, material-only testing may also help with the interpretation of the results from the device's biocompatibility test, where multiple materials and components are evaluated at one time in the finished device configuration.

Ultimately, it is the responsibility of the OEM to demonstrate to regulatory agencies that their device has an appropriate level of biocompatibility. However, OEM efforts to gain regulatory approval may be aided by collaborations and partnerships with material suppliers who can provide biocompatibility and other supporting data on their materials. Additionally, material suppliers may support communication with regulatory agencies though registration of a device master file.

## EVALUATE BIOCOMPATIBILITY WITH GREATER CONFIDENCE

Lubrizol is equipped with decades of knowledge and experience to guide OEMs through the biocompatibility evaluation and regulatory processes to help ensure the material success of their next medical device.

**To learn more about biocompatibility's importance in the material selection process and how it impacts device performance, watch this VIDEO. If you would like to discuss how our team of medical polymers experts can help you better evaluate biocompatibility, contact us HERE.**

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22-2156