Choose CMDC Labs Medical Device Testing to help you:

- Understand testing and the regulatory requirements for Cytotoxicity
- Screen raw materials
- Select the right test method for your device according to ISO 10993-5/USP <87> or combination of them both
- Identify cytotoxic effects of potential leachables

Qualitative Evaluation Methods:

- MEM Elution Assay
- Direct Cell Contact Test
- Agarose Overlay
- Agar Diffusion Test
- Colony Formation Assay

Quantitative Evaluation Methods:

- XTT Staining
- MTT Staining
- Neutral Red Uptake (NRU) Staining

International Organization for Standardization ISO 17025 ACCREDITED LABORATORY

CMDC Labs

Cytotoxicity/ Biocompatibility Testing

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What is Cytotoxicity/ Biocompatibility Testing?

The Cytotoxicity Test is designed to evaluate the general toxicity of medical devices and materials. Testing involves extracting devices in a cell culture media and then exposing the extract fluid to mouse fibroblast cells (L929). The cells are allowed to grow in the extract fluid for a specified amount of time before the cells are evaluated using either qualitative or quantitativie methods. The test is performed on all medical devices with patient contact, raw materials, and devices undergoing a cleaning validation or residual manufacturing.

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 Medical Device Testing of laboratory 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

Cytotoxicity is the most common test category utilized in ensuring the safety of medical devices. Used as an important screening tool as well as a significant biological endpoint for submission requirements, these tests assess the cytotoxic potential of a device or material to inhibit cell growth or cause cell death. These in vitro assays can be performed in both qualitative and quantitative methods. The appropriate test method is selected based on the nature of the sample to be evaluated, the potential site of use and the nature of use.

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