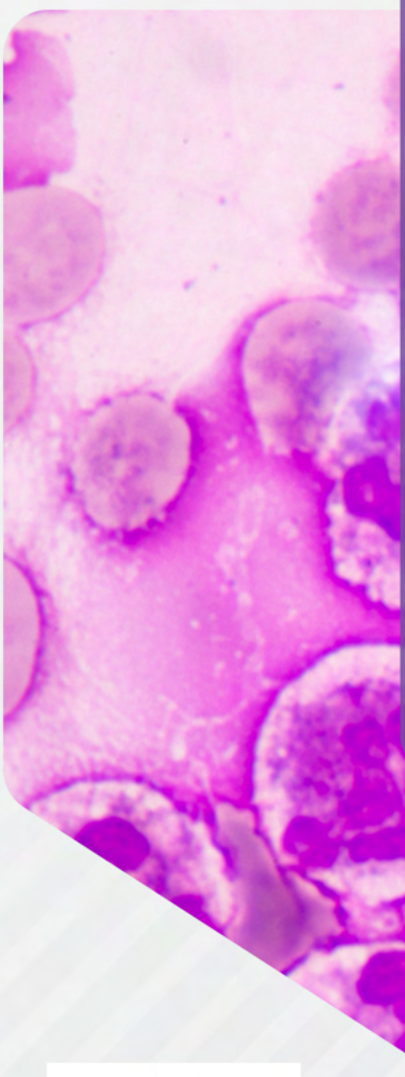
CMDC Labs



ACUTE SYSTEMIC TOXICITY & SUBCHRONIC TOXICITY

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SYSTEMIC ACUTE TOXICITY

The Acute Systemic Toxicity test identifies leachables that cause systemic (as opposed to local) harmful effects by analyzing extracts produced followling exposure to the device or device material. Mice are injected with test material extracts and a negative control blank (intravenously or intraperitoneally, depending on the extracting media). At four additional time periods after the injection, hazardous symptoms in the mice are monitored. This test is advised for all blood contact devices, according to the Materials Biocompatibility Matrix. It might be suitable for any other apparatus that makes tissue comntact.

The Material Mediated Pyrogen Test determines whether a substance has the capacity to raise a person's body temperature after being injected into their blood.

The Bacterial Endotoxin Test (LAL)is an in vitro QC method utilized in the manufacturing of pharmaceuticals and biomedical products to evaluate pyrogenicity for purposes of lot release. Each device or substance must have it validated. However, the rabbit pyrogen test is the favored method for determining biocompatibility.

SUBCHRONIC TOXICITY

When an animal is exposed to test materials and/or extracts over a period of up to 10% of its lifetime, tests for subchronic toxicity are conducted to identify any potential negative effects (e.g. up to 90 days in rats). When choosing an animal model for subchronic toxicity, it is important to take into account the actual use circumstances of a medical device. Case-by-case analysis is used to select the best animal models.

Two commonly used subchronic testing methods are provided by CMDC Labs and are suitable for a variety of devices. Both experiments use mice. One administers a device extract or device component by intraperitoneal infusion. The other delivers medication intravenously. In order to evaluate the subchronic toxicity of devices and device materials, implant experiments are frequently conducted for a variety of time periods.

Subchronic tests are required for all permanent devices and should be considered for those with prolonged contact with internal tissues.

MAKING THE UNKNOWN KNOWN...