Cambridge Polymer Group

How Safe Is Your Med Device?

ISO 10993-18:20 Extractables & Leachables Studies

Recent changes in ISO 10993-18:2020 have increased the emphasis on conducting a chemical risk assessment prior to biological testing. Accurate chemical risk assessment of medical devices in the form of extractables and leachables analysis has become a critical component of bringing your product to market. If done correctly, E&L studies can save time, money and minimize risk to you and to the patient.

When Do You Need a Chemical Risk Assessment?

•According to ISO 10993-1:2018, chemical risk assessment is the first step in performing a biocompatibility assessment.

•As part of FDA submissions such as Investigational Device Exemption (IDE), 510(K) Premarket Notification, Premarket Approval (PMA).

•The EU MDR has similar requirements for chemical risk assessment.

•To evaluate a new material of composition or contact material as being chemically equivalent to an "old" material.

•As a guideline for internal Quality Control.

E&L Testing Methods

Common techniques used for chemical characterization include:

•**HS-GC-MS** for highly volatile organic compounds

•**GC-MS** for semivolatile organic compounds (SVOC)

•**UHPLC-UV-ELSD-QTOF-MS** for nontargeted nonvolatile organic compounds (NVOC)

•**LC-MS** for targeted nonvolatile organic compounds (NVOC)

•**ICP-MS** for inorganic/elemental impurities

•**IC** for inorganic ions

Why Choose CPG for Your Chemical Risk Assessment?

Expertise. We are materials experts and understand the design, composition and end-use of your device. We understand the additives, production by-products and solvent/polymer interactions that will be crucial for analyzing your device.

Turnaround Time. Our turnaround times are typically 6 weeks for chemical assessment, with another 2-3 weeks at our toxicology partner.

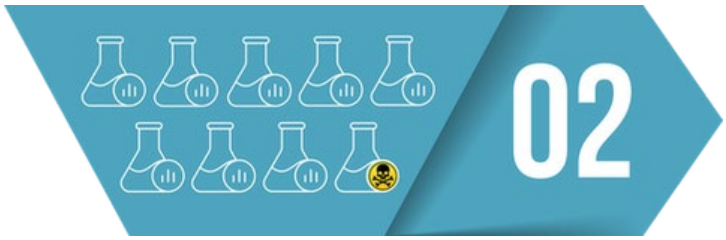
Collaboration. We work with you as an integral part of your team to make sure you understand your results in the context of your end-use. We communicate with you at every step of your ISO 10993-18:20 study.

Chemical Risk Assessment Workflow

Information Gathering

Materials of Construction
Manufacturing Process

All available data is collected on the medical device's materials of construction, additive packages, surface treatments/coatings, manufacturing processing aids, and processing conditions. The collected information is used to justify whether additional chemical characterization testing (extractables) is necessary. The data also provides critical context for guiding analytical method selection.



Extractables

Define AET + Extraction + Test Methods
ID/Quantify Compounds Above AET
Toxicological Risk Assessment

For devices of greater risk or more uncertainty in materials/manufacturing, an extractable study is likely to be required, at minimum. **If the extractable results flag compounds at concentrations presenting a potential toxicological concern**, leachable studies may be necessary to more accurately estimate the actual patient exposure.

Leachables

Targeted Analysis on Compounds
Flagged in Extractables Testing

If some chemicals are found to present a potential toxicological risk, a targeted leachable study may be necessary in order to evaluate the actual concentration of the compound when the device is subjected to simulated end use conditions. Only compounds flagged as potentially above toxicological threshold need be evaluated in the leachable study.

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