**Toxicological Risk Assessment of Medical Devices**

Medical devices can consist of diverse materials: polymers, metals, ceramics, composites, etc. Manufacturing process, packaging, and sterilization may introduce additional chemical substances into the final product. Any chemical or material that may leach or be released from a medical device into the patient must be considered a potential health risk and assessed toxicologically.

The standards ISO 10993-1 and -18 recommend to perform a complete chemical characterization and toxicological assessment of all medical device’s chemical constituents and extractables and leachables (E&L) prior to any biological testing (Fig., Steps 1-3).

E&L are a group of substances that include sterilization and process residues, additives, degradation products, plasticizers, monomers, etc. A complete E&L profile is essential for the safety assessment of medical devices. Therefore, E&L’s identification requires a broad range of analytical methods such as ICP-, LC-, and GC-MS.

The RMS Foundation can advise customers on performing chemical characterization and offers toxicological risk assessments provided by toxicologists according to ISO 10993-17. A toxicological risk assessment report documents the determination of the allowable limits for the substances identified. The report also states whether the identified E&L pose an acceptable or unacceptable risk to patient health. Finally, a recommendation is given whether further biological testing is necessary.

Our offers for toxicological risk assessment of medical devices:

- **Toxicological risk assessment of a hypothetical worst-case chemical release according to ISO 10993-17**
- **Toxicological risk assessment of extractables and leachables (E&L) according to ISO 10993-17**
- **Systematic literature reviews to collect toxicological data according to ISO 10993-1, Annex C**

Other services:

- Analysis of the chemical composition, degradation products, and residuals of medical devices
- Analysis of inorganic E&L

Discuss your questions with us! We are happy to advise you.

**Contact for toxicological risk assessment according to ISO 10993-17:**

Dr. Marc Bohner  
Phone +41 32 644 20 40  
marc.bohner@rms-foundation.ch

More information as well as our service catalogue can be found on our website.

RMS Foundation has been certified according to ISO 9001 and is an ISO/IEC 17025 (type C) accredited laboratory.

Subscribe to our mailing list and read more RMS newsletters covering other topics.