



Toxicology & Regulatory

- Drafting of the biological evaluation plan (BEP).
- Drafting of material toxicological profiles.
- Literature review of the history of use of raw materials.
- Equivalence study of materials in case of shortage or multisourcing.
- Cleaning residue analysis.
- Gap Analysis: old vs. new versions of the ISO 10993 Series.
- Toxicological support for chemical characterization (*ISO 10993-18*).
- Drafting of the toxicological risk assessment (TRA) (*ISO 10993-17*).
- Drafting of the biological risk assessment (BRA) (*ISO 10993-1*).
- Assistance with non-conformities in biocompatibility.

Ecotoxicology

An evolving regulatory landscape and a growing push toward environmental stewardship in healthcare calls for a shift to more **sustainable manufacturing**. Future-proof your success: contact us about our eco-toxicology add-ons to explore how we can provide an **eco-toxicological Impact assessment** tailored to your needs.

EXAMPLES OF PRODUCTS EVALUATED:

Orthopedic surgery equipment, OTC Gels, Ointments and Sprays, Wound and Skin Care, Aesthetic Treatments, Injector with therapeutic solutions, External prosthesis, Implant, Suture thread, Needleless blood collection device, etc.

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Our R&D approvals:

