Tailored Toxicology Solutions with unique expertise in **Medical Devices**

ToxHub supports Medical Device safety by offering expert toxicological assessments, ensuring compliance and enhancing device safety. Our services include:

- Biological Evaluation Plan and Biological Evaluation Report within a risk management process, in accordance with ISO 14971, 10993 and MDR;
- Clinical evaluation Plan and Report (CEP and CER) according to MDCG, MEDDEV and SSCP;
- Gap analysis according to ISO standards and MDR;
- Justification for the classification of substance-based MDs according to rule 21 of MDR;
- Pharmacological appraisal for functional ingredients: principal intended action by pharmacological, immunological or metabolic means, and rationale for the qualification of the product as a device;
- Toxicological assessment of MD components according to ISO 10993 and MDR;
- Interpretation of results obtained in biocompatibility assessments in accordance with ISO 10993-1;
- Toxicological Risk Assessment of extractables and leachables according to ISO 10993-17;
- Regulatory compliance.

Toxicological risk assessment is of paramount importance for Medical Devices under the Medical Device Regulation (MDR):

– The MDR is a comprehensive regulatory framework adopted by the European Union to ensure the safety, performance, and effectiveness of medical devices sold within its member states;

– Evaluating the safety of medical devices and determining their suitability for clinical use is a crucial component of the overall process;

– It helps manufacturers identify potential hazards, select appropriate materials, and implement risk mitigation strategies, all of which contribute to the overall safety and effectiveness of medical devices used in the European market.

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Eight key reasons why toxicological risk assessment is vital for Medical Devices under the MDR:

- Patient Safety
- Compliance with MDR Requirements
- Early Hazard Identification
- Material Selection
- Post-Market Surveillance
- Minimizing Non-Conformities
- Risk Management and Mitigation
- Strengthening Confidence

Why collaborate with ToxHub?

- Tailored toxicology advisory services
- Expert advice during product development
- Unique expertise in both toxicology and pharmacology
- Support through the entire regulatory process
- Assistance in responding to regulatory bodies
- Effective and compliant scientific-based documentation
- Two-way feedback process, keeping a close dialogue with clients

To further discuss how our consultancy services can benefit your organization, contact our expert team.

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