knoell

worldwide registration

THINK GLOBALLY – ACT LOCALLY

BIOLOGICAL SAFETY OF MEDICAL DEVICES

Do you need support registering your medical devices to comply with biological safety requirements? knoell's global team of experts has extensive experience with all types of medical devices. We provide you with access to our in-house subject matter experts in areas such as analytical chemistry, toxicology, endocrine disruptors, CMRs, QSAR, nanomaterials etc. Take advantage of our wide range of services! Let's talk about it!

- **Compilation of a biological evaluation plan**
  Regulatory compliance requires a robust, methodical biological evaluation plan, in accordance with the relevant regulatory guidelines and standards, and the applicable regional medical device regulations. We tailor your individual biological evaluation plan to be compliant with ISO 10993 (as well as ISO 18562 or ISO 7405, as required), and to meet the expectations of regional regulatory bodies (e.g. EU-notified bodies, MHRA or US FDA), specific to your medical device and your marketing plans. The biological evaluation plan includes a material characterization and data gap analysis, biological evaluation strategy develpment, and recommendations for chemical/analytical and toxicological/biological testing.

- **Study concept management and study monitoring**
  Conducting an analytical (extractable and leachable (E/L)) or biocompatibility study requires adherence to current standards to reliably fulfil regulatory requirements. As study monitors, we assist you in conducting your study from the request for quotation at contract research organisations (CROs) to the final study report; thus ensuring that your study will be performed according to the highest standards and as specifically as required for your medical device. We liaise directly with the laboratory to provide support throughout the full study period, and to ensure timely input from our toxicologists whenever required.

- **Toxicological risk assessment of extractable/leachable substances**
  The toxicological risk assessment and establishment of allowable limits for raw materials, or E/Ls detected during chemical characterization is performed following the process described in ISO 10993-17. Based on existing toxicological data on the substances, and taking the medical device's specific exposure conditions into account, we characterise the toxicological risk associated with the medical device's use. If required, alternative assessment approaches, e.g. in silico modelling (Quantitative Structure Activity Relationship-QSAR), grouping, or read-across are used. The toxicological risk assessment of E/Ls is regarded in the context of the overall biological response to the final product, providing a powerful tool to avoid unnecessary animal testing.

- **Compilation of a biological evaluation report**
  The biological evaluation report summarizes all data and findings gathered during the biological evaluation. Integrating all relevant information, from material and chemical characterization and toxicological risk assessment, it provides an overall conclusion on the biological safety of your device.

- **Zoonosis risk assessment for materials of animal origin**
  For medical devices utilizing materials of animal origin, a zoonosis risk assessment in accordance with the ISO 22442 series is required within the risk management process. The risk of zoonotic pathogen transmission to humans and subsequent infection due to the medical device use is evaluated. Information on starting material, pathogen burden, production process, and susceptibility of pathogens to inactivation through the production process is compiled and assessed. In cases of a non-acceptable residual risk, further investigation is triggered and risk mitigation measures proposed.

- **Training**
  Do you need help for your teams to gain more insights into biocompatibility and biological evaluation processes of your medical devices? We provide in-house training tailored to your specific requirements and concerns.

knoell: your go-to partner for registration – worldwide

Think globally, act locally. Our strength is being where it matters.

Contact us at **meddev@knoell.com**

www.knoell.com

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