Medical Matters - Services

Content

1 Services

With core expertise in toxicology, biocompatibility, quality assurance and regulatory affairs, we help manufacturers of medical devices in the development, approval, and production of biologically safe products. Our support covers the initiation, strategic planning, execution and documentation of biological safety assessments (BSA), coordination of chemical analytical and pre-clinical testing, as well as documentation and evaluation of outcomes in toxicological risk assessments. In accordance with regulatory standards our assessments take a scientifically sound, risk-based approach that can be embedded in quality management systems and covers the complete life cycle of devices.

1.1 Regulatory support

Our services include integration of the biological safety process in the wider quality management system along with procedure and template development. In addition, we perform gap assessments against latest regulations for established processes.

We may also support you in your regulatory body correspondence. Writing responses and developing gap fixes for received deficiency reports in any stage of a submission is one of our core competencies. We may further support you in developing an approval strategy for the biological safety part of your submission.

1.2 Biological safety assessments

We support you in biological safety evaluations of medical devices in compliance with the systematic approach outlined in ISO 10993, and relevant FDA and European guidelines, to help bring your device to market and ensure regulatory compliance over its entire lifecycle.

Document types such as the biological evaluation plan (BEP) and biological evaluation report (BER) are essential steps in the medical device development process. They ensure that all available data is considered and if testing is found necessary, that the test strategy is documented, scientifically sound and any outcomes are evaluated in compliance with regulatory guidelines. To cover the complete lifecycle, we further offer biological safety impact assessments (BSI) for changes, deviations or any other events with a potential effect on the biological safety profile of legally marketed devices.

BEPs and BERs are typically established for newly developed products or products undergoing an initial evaluation. Beyond that, our services include the preparation of biocompatibility dossiers (BCD) especially suitable for regulatory submissions. These documents are typically established on product family level and include all biocompatibility data, including impact assessments, generated over a products lifecycle. They allow to be updated continuously and can be reviewed periodically for emerging biological risks and regulatory compliance. They are therefore the ideal document type to document the biological safety of a product family over its lifecycle.

1.3 Chemical characterization

Our services include chemical characterization of materials and final finished devices according to the principles outlined in ISO 10993-18. Material characterizations may include an evaluation of their suitability for their intended purpose.

Chemical characterization may include the estimation of substances released by the medical device during clinical use by means of chemical analytical testing. However, chemical analysis is preceded by comparison of subject devices to clinically established (i.e., predicate) devices, including a comparison of the hypothetical worst-case chemical release profile of the subject devices with that of the predicate devices to determine the need for further chemical analytical testing. Only if found necessary is subsequent extractable and/or leachable testing conducted.

1.4 Toxicological risk assessments

As one of our core competencies we establish full toxicological risk assessment reports for extractables and leachables (E&L) found in your chemical analytical testing, including, if warranted a pre-screening and risk categorization of detected compounds. Documentation may either be in a standalone document or, for maximum coherence and reviewer friendliness, integrated in the corresponding biological safety assessment.

To provide the highest standard of chemical hazard and risk assessments, we compile toxicological profiles per compound and/or classes of compounds under consideration of all relevant endpoints. Relevant endpoints are evaluated contingent on the intended use of devices and route-specific exposure limits are established leveraging available literature and in silico Quantitative Structure Activity Relationship (QSAR) software tools.

1.5 Toxicological profiles

We may further establish stand-alone toxicological profiles for any chemical constituent or particulates on or in your device. Acceptable limits derived in such profiles may be used in product monitoring activities, as cleanliness acceptance criteria, in biological safety assessments of potential contaminants and detected manufacturing aid residues and in toxicological risk assessments of extractables and leachables (E&L) or any other analytical outcomes such as particulates.

1.6 Hazardous substances

Based on material standards, material characterization, formulation data and/or chemical analytical testing data, it may be determined whether a hazardous substance as defined in MDR 2017/745 section 10.4.1 or any other regulation is present in a final finished device. If composition data is available, we offer to screen it against the latest version of hazardous substance lists as they are defined in MDR 2017/745 section 10.4.1.

If a carcinogenic, mutagenic, or reproductive toxicant (CMR) of category 1A or 1B and/or an endocrine disruptor as defined in the MDR regulation (MDR 2017/745) with potentially greater than 0.1% w/w has been identified on a final device in the course of a biological safety assessment or hazardous substance assessment, further justification, including an analysis of alternatives and a detailed risk assessment are necessary. Our services include the documentation for the presence/absence of such substances and if applicable establishment of a more detailed hazardous substance assessment, including further justification for the presence of the substance, an analysis of alternatives and a detailed risk assessment.

Similarly, if substances from other REACH lists, the California Proposition 65 list or any other regulatory hazardous substance list are identified as present during a biological safety assessment, we might support you with a more in-depth assessment.

1.7 Data science & management

With a profound background in statistics, epidemiology, as well as various fields of science and manufacturing processes, we can support you in the analysis, graphical visualization and interpretation of a wide range of your data, independent of its type. We may support you in identifying appropriate statistical methods, study designs and the analysis of cross sectional-, time-series- as well as panel-data.

We may further support you in management of your leachable & extractable data based on risk management principles described in ISO 14971.

1.8 Training courses

We offer tailor-made training courses in any field of our expertise including biocompatibility evaluation, toxicological risk assessment and data handling, analysis and visualization with Excel, Minitab and R, respectively.

2 Contact

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