MEDICAL DEVICES

Combining toxicological expertise with regulatory know-how to give you a head start in development

MAKE THE RIGHT DECISIONS IN THE R&D PHASE

When you are in the early phase of development of medical devices, the most vital decision to make is the right choice of material. Consequently, careful consideration must be given to selection of materials and chemical constituents with regard to toxicity.

We can help you to optimise your choice of material, enabling a cost-efficient development as well as minimised negative effects on human health.

OPTIMISE SAFETY

The first step is to assess the toxicity of materials and chemical constituents. With our extensive knowledge of toxicity of chemicals, we provide safety assessments of materials and chemical constituents such as additives, residual monomers and metabolites. Moreover, we investigate impurities and degradation substances in order to optimise the safety aspects of your products.

Based on decades of experience working with medical device manufacturers, suppliers of materials as well as regulatory bodies, DHI offers expert consultancy in this area.

UP-TO-DATE KNOWLEDGE AND INTERPRETATION OF REGULATIONS

Just because a material contained in a medical device has the right technical properties, it does not mean that it complies with the regulatory demands.

Moreover, established materials might require reconsideration in a new context. Therefore, it is essential to be familiar and stay up-to-date with the relevant regulations and consider them as early as possible in the development phase. Safety is a key issue in the new Medical Device Directive (MDR) which will come into force in 2019. With the help of our regulatory experts, we help to clarify which standards and regulatory demands apply to specific raw materials and products in various markets.

Choosing toxicologically safe materials and chemical constituents is a pivotal factor when developing medical devices.

CLIENT

Developers, manufacturers and distributors of medical devices and similar, related articles

CHALLENGE

The right choice of material in the early phases is crucial for optimising the development of medical devices and minimising the risk of costly mistakes

SOLUTION

- With our in-depth knowledge of toxicology, we are a strong partner in the development phase.
- We help you select the right materials based on toxicological data gathered from targeted data searches or QSAR evaluations.
- In addition, we ensure documentation on regulatory compliance.
- We also offer third party evaluation and validation of risk assessments.

VALUE

- Cost- and time-efficient development of medical devices
- Professional partners, also for your own experts
- Expert compilation of data and documentation on biosafety, including dossiers
- Efficient data retrieval
- Targeted strategies for biological testing
- Documentation on and compliance with regulatory standards and requirements

FITTING ALL SUBJECT CATEGORIES

The Medical Device Directive covers a very broad range of products, from bandages and surgical instruments to pacemakers and implants. Within the EU classification, medical devices are divided into four categories: I, IIa, IIb and III. As a result, different medical devices might be subject to different approval procedures. DHI guides you through the regulatory pitfalls and ensures that your product complies with both EU and US Food and Drug Administration (FDA) requirements.

EFFICIENT DATA SEARCH AND INFORMATION RETRIEVAL

Electronic databases offer inexhaustible sources of toxicological data, but it requires specialist knowledge to perform a targeted and efficient data search. We help you to develop structure-based search strategies, including retrieval and assessment of toxicological data. Amongst others, our data searches include chemical constituents, such as processing aids, residues and additives.

MIGRATION ESTIMATES

Repeated laboratory testing is time consuming and expensive, particularly for medical implants in contact with body fluids and tissues. The application of numerical diffusion models has become an accepted method of estimating migration into various media in the food contact material legislation. DHI can apply such estimates to medical devices to replace laboratory migration testing.

Combining our toxicological expertise with mathematical matrix models, we estimate migration of substances from one- or multilayer materials made of polymers, such as LDPE, LLDPE, HDPE, PP (homo), PP (random), PP (rubber), PS, HIPS, PET, PEN or PA.

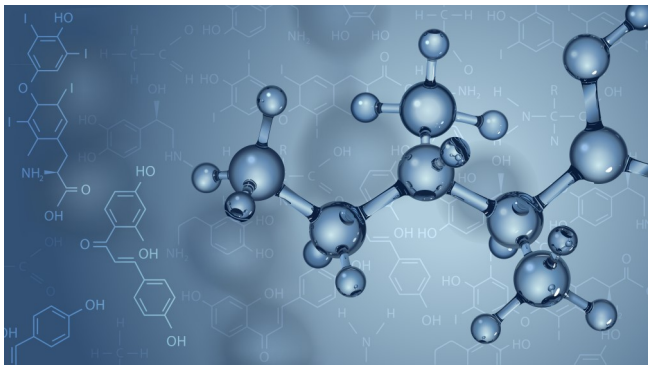
If needed we also offer to plan and monitor leachables studies performed at contract laboratories.

BENEFIT FROM IN SILICO TOOLS LIKE QSAR ANALYSIS TO PREDICT TOXICOLOGICAL ENDPOINTS

Laboratory testing may be avoided by using QSAR models to predict chemical behaviours directly from chemical structure and simulating adverse effects in cells, tissues and lab animals.

Consequently, QSAR models are a fast and cheap way to generate data and fill data gaps. With QSAR analyses, we can predict a large variety of toxicological and ecotoxicological endpoints. We apply QSAR models for risk assessments, regulatory decisions, and for the optimisation of existing products.

In addition to QSAR, we are also experienced in using data from other non-animal test methods such as read-across, grouping of chemicals and in vitro tests.



We are skilled users of QSAR models and of data from read-across, grouping of chemicals and in vitro tests and apply these tools to perform risk assessments and optimisation of products.

BIOCOMPATIBILITY, BIBLIOGRAPHIC DOCUMENTATION AND ISO STANDARDISATION

With a targeted test strategy you can reduce your total testing needs. If testing of a product is required for assessing contained materials or substances, DHI provides consultancy on the relevant as well as supplementary testing in accordance with ISO standard 10993 and ISO 18562.

We moreover advise on safety assessments of all types of medical devices, such as:

- Classification of medical devices based on method and period of application
- Evaluation of the need for supplementary biological tests before notification to the authorities
- Biocompatibility assessment according to relevant legislation in your national or international markets

Supplementing or substituting biological tests, we furthermore perform specific data mining for bibliographic documentation.

EXPOSURE SCENARIOS AND RISK ASSESSMENT

Besides biological evaluations of individual substances, we assist you in setting up the relevant exposure scenarios for your medical devices. Based on these evaluations and exposure scenarios, we carry out a risk assessment of your product. The results are subsequently evaluated in accordance with the present legislation.

Contact: info@dhigroup.com
For more information, visit: www.tox.dhigroup.com