DHI SOLUTION

PHARMACEUTICAL PRODUCTS FASTER TO MARKET

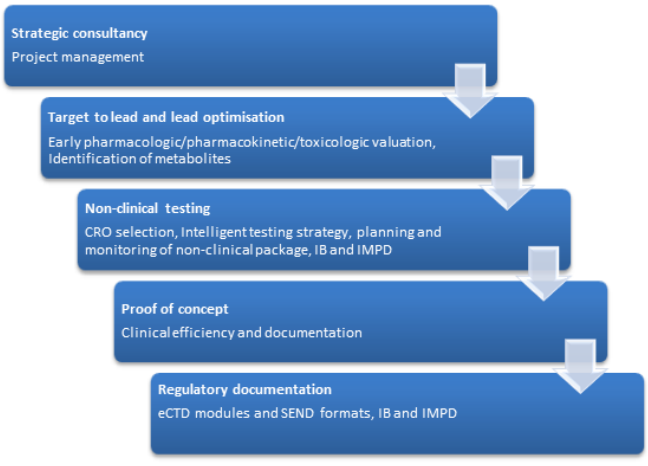
Professional assistance in toxicology, ecotoxicity testing and documentation

FROM STRATEGIC DEVELOPMENT TO PRECLINICAL TESTING

The development of new medicine is in itself a tremendous challenge. Doing it according to the national and international regulations is adding to the task.

Making the right strategic decisions in the early phases is crucial for optimising the development of pharmaceuticals and minimising the risk of making costly mistakes. Changing existing pharmaceutical products or materials in the production line also requires in-depth knowledge of toxicology and the documentation requirements.

With our expertise in toxicology we are a strong partner in the development phase. We help you select the right drug candidate based on exhaustive toxicological profiles, targeted data searches and QSAR analyses. Furthermore, we can assist with proficient project management and elaboration of testing strategies. Last but not least - we can relieve you of the regulatory paperwork.



Our strategic consultancy based on extensive scientific and regulatory knowledge and experience will help you to meet the regulatory requirements for placing a product on the market according to EMA (European Medicines Agency) or FDA (Food & Drug Administration, US).

Our services cover several phases of drug development, from development strategy to non-clinical assistance or required testing of pharmaceuticals. We are particularly targeting developers and producers of pharmaceuticals who are in the early stages of drug development or want to change an existing product, as well as producers in

SUMMARY

CLIENT

Developers and producers of pharmaceuticals

CHALLENGE

Optimising the development or transformation of pharmaceuticals while adhering to the regulations and minimising the risk of costly mistakes

SOLUTION

We possess the necessary expertise and experience to support you in the development phase as well as in project management and the set-up of testing strategies. Moreover, we can take care of the paperwork.

VALUE

- Cost- and time-efficient development of pharmaceuticals
- QSAR analyses for efficient data generation
- Compliance with regulatory requirements, e.g. from EMA and FDA
- Environmental risk assessments complying with the requirements of EMA
- Elaboration of toxicological profiles (incl. pharmacological and pharmacokinetical properties of lead compounds)
- Planning of testing strategies, contact to CROs and study monitoring
- Expert compilation of data and documentation, incl. preparation of IMPD or IB

the final phases of development needing assistance with toxicological evaluation or preclinical testing and the mandatory environmental risk assessment.

BENEFIT FROM QSAR ANALYSES TO PREDICT TOXICOLOGICAL ENDPOINTS

With QSAR models it is possible to predict chemical behaviours related to the chemical structure and simulating adverse effects in cells, tissues, and lab animals. Consequently, QSAR modelling is a fast and cheap way to generate data and fill data gaps. With QSAR analyses we can predict a large variety of toxicological end points, including skin irritation and sensitisation, carcinogenicity, mutagenicity, genotoxicity and reproductive toxicity as well as ecotoxicological endpoints. We apply QSAR models for risk assessments, regulatory decisions, and for optimisation of formulations.

We offer a one-stop-shopping solution, from innovation to clinical proof of concept. Thereby, you will reduce the time and cost in profiling your potential drug candidate. Dependent on your specific needs, our services can be chosen independent of each other or be subsequent steps on the way to clinical phase 2 trials.

LEAD OPTIMISATION AND DISCOVERY SUPPORT

Before an identified lead compound is ready for toxicological tests according to the ICH guideline, it needs to be put to a thorough test. Besides determining the pharmacological and pharmacokinetical properties, this also includes a toxicological profile of the lead compound. In addition, it may be relevant to identify metabolites and possible residues from the chemical synthesis of lead structures, such as small molecules.

NON-CLINICAL SUPPORT

When entering the preclinical phase, a testing strategy must be prepared based on the pharmacological/toxicological profile of the lead compound. In close collaboration with our clients, we design an optimal non-clinical test package and help you select a contract laboratory (CRO). We are happy to take lead in the contact to CRO's, monitoring of tests and evaluating test protocols and study reports.

REGULATORY DOCUMENTATION

When your proof of concept for clinical efficiency has been substantiated, the regulatory documentation necessary for early marketing of your drug candidate must be prepared. This requires profound knowledge of dossiers and regulatory affairs, and DHI can assist you in preparing both non-clinical eCTD modules and SEND formats as well as Investigator's brochure (IB) and the Investigational Medicinal Product Dossier (IMPD).

ECOTOXICOLOGICAL TESTING AND ENVIRONMENTAL RISK ASSESSMENTS

The marketing of a medical product for human use in Europe requires an environmental risk assessment according to the EMA.

DHI's environmental laboratories carry out standardised and specialised tests on biodegradability, toxicity and bioaccumulation of chemical substances, products and complex mixtures.

Based on your information on use patterns, typical doses, metabolism and excretion, we carry out Phase I assessments and support recommendations for Phase II. In a data gap analysis we assess whether the available data fulfil the requirement or further testing is needed. A strategy for bridging data gaps can be developed to ensure cost efficiency. A test program is developed and quotations from the CRO are evaluated. Finally the expert report for the dossier is prepared.

In our GLP(Good Laboratory Practice)-certified laboratory we offer long-term toxicity tests on fish, daphnia and algae. These tests are among the base set of tests proposed for determination of the predicted no effect concentration (PNECwater) of a substance, for which adverse effects are not expected to occur.

ACCREDITATION AND GLP COMPLIANCE

All tests carried out in the environmental laboratories at DHI are accredited by DANAK, the Danish Accreditation and Metrology Fund. Furthermore, the laboratory performs all ecotoxicological tests recommended by EMA on physical-chemical fate and effects studies in compliance with the OECD Principles of GLP.

DHI is certified according to DS/EN ISO 9001:2008 for "Consulting, software, research & development and laboratory testing, analysis & products within the area of water, environment & health".

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