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YOUR EXPERTS IN

PHARMACOKINETICS

ADDED VALUE THROUGH EXPERIENCE

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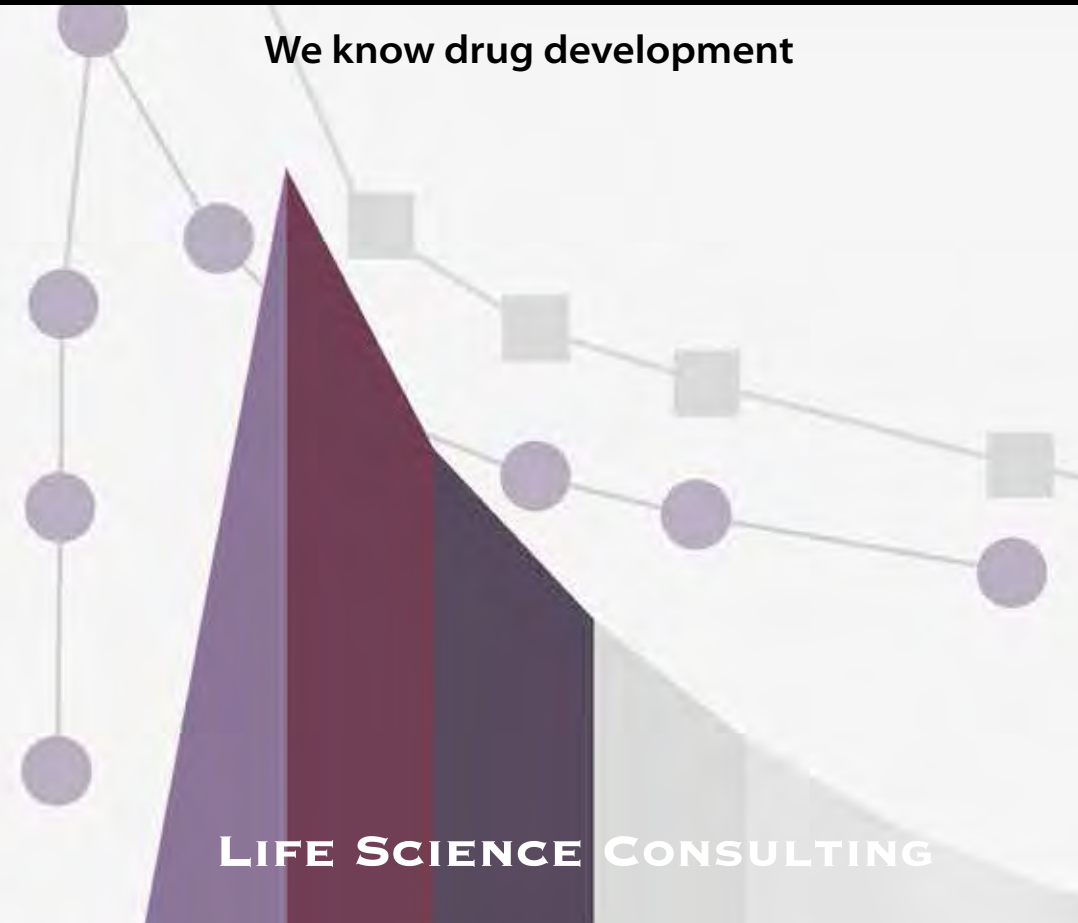
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We know drug development



LIFE SCIENCE CONSULTING

Flexible and tailored support to drug development projects

Pharmacokinetics



Toxicokinetics (GLP)



PKPD



Modelling & Simulation



ADME



Regulatory Documents



R&D Project Management

Extensive experience from big pharma and biotech companies with small molecules, peptides, proteins and monoclonal antibodies.

At PKxpert we use state of the art methodology and the validated software **Phoenix WinNonlin** to design, evaluate and report both nonclinical and clinical pharmacokinetic studies in a time efficient way.

Toxicokinetics (TK) are an integral part in the safety assessment of drug candidates. At PKxpert we perform TK evaluations in compliance with **GLP** regulations in order to meet the highest quality standards.

What doses should be used in the first human trial? What is the right administration frequency? What is the optimal infusion length for your product? Through **Modelling & Simulation** of the pharmacokinetics and pharmacodynamics we help you to identify the best design for your studies.

ADME (Absorption, Distribution, Metabolism, and Excretion) studies in animals and man are a mandatory part of the regulatory documentation of new drugs in development. We help you to identify the necessary studies, find the optimal design and support you in the outsourcing process.

Drug development is a lengthy and costly process that is highly regulated. Providing the right **documentation** to regulatory authorities is crucial for a timely and successful approval process. The team at PKxpert has experience from numerous approval processes and can help you to compile the right documentation.

Drug Development is complex. Many different disciplines and competences need to work jointly, solve problems, and find solutions in order to be successful. If you need an experienced **project leader** that can manage complex processes or support a **due diligence** process, **talk to us**.