康龙化成 PHARMARON

Laboratory Services

Non-GLP Toxicity Studies

After discovery, the next stage in the development pipeline involves generating safety data to progress into First-in-Human studies. Although regulatory agencies require GLP studies for an IND submission, these are preceded by exploratory non-GLP toxicity studies to determine risks, dosing and other important aspects of *in vivo* GLP testing.

Capabilities

- Facilities in US and China
- AAALAC-accredited facilities
- Accelerated turnaround times
- Extensive experience with worldwide regulatory agencies, e.g., FDA, EMA, OECD, China NMPA
- Program-specific designs
- SEND datasets generated in-house
- Stock colonies for dogs and non-human primates

Services

Efficient Generation of Robust Non-GLP Data to Accelerate Your IND Program

***In Vivo* Pharmacokinetic/Pharmacodynamic Studies**

- Exposure and biomarker data, and methods referenced for safety assessment program planning

Vehicle Formulation Screening for Toxicology Studies

Maximum Tolerated Dose/Maximum Feasible Dose Studies

- Rodent and non-rodent species
- Clinical observations, body weights, TK Analysis

Dose Range Finding Studies

- Rodent and Non-rodent species
- Clinical observations, body weights, TK Analysis, clinical pathology
- Histopathology

Genetic toxicology assays and ion channel assays

- To mitigate liabilities early in the drug development process

Bioanalytical support

- Qualified methods in place to facilitate future validation work

Integrated and comprehensive services for all stages of drug development

康龙化成 PHARMARON

bd@pharmaron.com

Laboratory Services

Chemistry, Manufacturing and Control

Clinical Development

Biologics & CGT

Pharmaron is a global life science service provider that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products