TCG Lifesciences | Chembiotek

Representative IND-enabling Package

At TCG Lifesciences, we specialise in providing GLP-compliant toxicology and safety pharmacology studies tailored for small molecule drug candidates. Our IND-enabling packages are designed to meet global regulatory requirements (FDA, EMA, ICH) and support a seamless transition into first-in-human clinical trials.

Our IND-Enabling Study Package Includes:

- **General Toxicology (GLP)**
  - Single-dose (acute) toxicity studies
  - Repeat-dose toxicity studies (7, 14, 28, and 90-day) in rodents and non-rodents (via partners)
  - Dose Range Finding (DRF) studies
  - Recovery group assessments
  - Clinical observations, body weight, and food consumption monitoring
  - Clinical pathology evaluations (haematology, clinical chemistry, urinalysis)
  - Gross necropsy, organ weights, and comprehensive histopathology

- **Toxicokinetic (TK) & Systemic Exposure Analysis**
  - Parallel TK sampling during repeat-dose studies
  - Bioanalytical method development and LC-MS/MS sample analysis
  - Exposure-response assessment to determine NOAEL

- **Safety Pharmacology (ICH S7A Core Battery)**
  - Central Nervous System (CNS): Functional Observation Battery (FOB) / Modified Irwin Test
  - Cardiovascular: ECG, heart rate, and blood pressure monitoring (via telemetry in non-rodents through partners)
  - Respiratory: Respiratory rate, tidal volume, and minute volume (via whole-body plethysmography)

- **Genetic Toxicology**
  - Bacterial reverse mutation assay (Ames test)
  - *In vitro* mammalian chromosomal aberration test
  - *In vivo* micronucleus test in rodents

- **Additional IND-Enabling Support**
  - Maximum Tolerated Dose (MTD) studies
  - Species selection guidance and study design consultation
  - Access to reproductive and developmental toxicology studies (as required)
  - Regulatory-compliant reporting suitable for IND/CTA submissions

We can customise the list as per collaborator requirements.

More Information
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