Drug Safety and Metabolism

Experience – from discovery to full development: Ricerca has the know-how

Ricerca Biosciences provides drug safety and metabolism services to guide new therapies from discovery to full development support. Our extensive profile of IND enabling pivotal studies support swift progression of your lead compounds into the clinic – streamlining your development process. We provide the resources of a highly skilled, client-focused staff with extensive academic, scientific and pharmaceutical industry experience.

Core services

IND-enabling studies
- Regulatory/general toxicity
  - Maximum tolerated dose
- Dose range-finding – 5-14 days
- Repeat dose GLP – 4-13 weeks
- Rodents, dogs, NHP, minipig
  - Complete toxicokinetics/pharmacokinetics support with LC/MS/MS
- Safety pharmacology: ICH core battery & supplemental safety pharmacology studies
  - CNS, respiratory; renal, GI
- Full clinical and anatomic pathology, ophthalmology, ECG

Nonclinical registration
- Chronic toxicity – 6-9 months
- Investigative toxicology
- Carcinogenicity studies

Safety Pharmacology

Our safety pharmacology studies are designed to determine potential hazards and assist in the prediction of adverse effects. Because pharmacological responses may be unique, we work with you to design customized, detailed protocols for your studies.

- CNS, respiratory
- Functional Observational Battery (FOB) and motor activity
- Supplemental safety pharmacology studies
  - GI, Renal

Ricerca Biosciences employees have one goal in mind – to meet your next milestone on time with quality

Specialties

Even after 40 years, we are always on the cutting edge of the evolving preclinical safety and metabolism field. Beyond the basics, we are adept at specialized and novel approaches.

- General toxicity
- Non-human primate
- Minipig (Gottingen)
- Safety pharmacology – respiratory and CNS
- Discovery PK
- Bioanalytical support

Core strengths

- Over 40 years of experience
- Scientific and regulatory expertise
- Direct access to scientists
- Rapid initiation and turnaround time
- Compliance with GLP regulations
- Low staff turnover
- AAALAC accreditation
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Metabolism studies
Ricerca’s Drug Metabolism and Pharmacokinetics (DMPK) specialists provide world-class expertise in selecting a testing strategy specific to your development stage and provide high-quality data necessary for intelligent decision making.

In vivo metabolism
- Full PK/PD modeling
- Metabolite ID & profiling
- ADME mass balance, tissue distribution
- Radiochemistry synthesis support

Pharmacokinetics (PK) & Toxicokinetics (TK)
- Bioavailability
- Formulation selection
- Bioequivalence (BE)
- TK support for single and multiple dose toxicology studies

Expertise with major therapeutic areas
- Cardiovascular
- CNS
- Gastrointestinal
- Immunology/inflammation
- Anti-infectives
- Metabolic/endocrine
- Oncology (cytotoxic and cytostatic)
- Pain

Commitment to animal welfare
Ricerca Biosciences is committed to the enhancement of animal health and welfare. We honor an organizational commitment toward the ethical and humane use of laboratory animals, paying particular attention to the housing conditions and environmental enrichment of our animal species.

Species tested
- Cat
- Dog
- Ferret
- Guinea pig
- Hamster
- Minipig
- Mouse
- Non-human primate
- Rabbit
- Rat

Full support services
- Histology/pathology
- Quality assurance
- Analytical chemistry for dose formulation analysis
- Bioanalytical chemistry

Routes of administration
- Dermal
- Dietary admixture
- Intratracheal
- Intramuscular
- Intracocular
- Intravenous (bolus, infusion)
- Oral gavage
- Rectal
- Subcutaneous
- Subdural
- Vaginal
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Other Ricerca services

Chemistry

- Process chemistry
- Process development and engineering
- Analytical chemistry
- Medicinal chemistry
- Custom synthesis
- Radiosynthesis
- Custom development and validation of analytical methods for bulk pharmaceuticals, impurities and metabolites
- Physical characterization (particle size, surface area, pore volume, tensile/compression testing, etc.)
- Stability testing
- GLP characterization of test and control articles