

Pharmacology and Toxicology

We offer a variety of services in the areas of toxicology and pharmacology to assist companies in the preclinical and clinical development of pharmaceuticals and medical devices and for evaluation of in-licensing and out-licensing opportunities. Areas of expertise include safety assessment of small molecules and biopharmaceuticals, drug metabolism and pharmacokinetics, and biocompatibility analysis for medical devices. These capabilities are supported by a strong in-house (bio)analytical base and formulation capacity.

We cover a comprehensive range of important development activities, including:

- Protocol development
- Study placement, monitoring, and management
- Report writing and full review of the preclinical program
- Design and execution of complete preclinical development programs

Our technical expertise includes:

- Toxicology, including mechanistic studies
- Absorption, Distribution, Metabolism and Excretion (ADME)
- Pharmacology
- Pharmacokinetics
- Pharmacodynamics



Regulatory Support of FDA filings for Drugs and Medical Devices

We design comprehensive regulatory strategies for preclinical and early clinical development and provide assistance in interactions with FDA and preparing IND filing.

We have a strong record of accomplishments in:

- Preparation of summary documents for regulatory submissions
- Investigator Brochure creation
- IND preparation and review
- Preparation for FDA meetings

Our medical devices services include:

- Review and gap analysis of nonclinical and clinical data
- Biocompatibility evaluation (ISO 10993 and G95-1) and report writing
- Preparation of documentation for regulatory submissions (510k, PMA)





Pharmacology, Toxicology and Regulatory Services for Drugs and Medical Devices



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