Non-Clinical Pharmacology & Toxicology Program

Scientific and Regulatory Services

Understanding the regulatory requirements for non-clinical studies can be a challenge for any company seeking early drug safety data development or chemical registration within the US, UK or EU. Conducting studies that are not in compliance with established regulatory guidelines or performing unnecessary studies can be costly and wasteful. ***toXcel***, LLC has expertise in toxicology and pharmacology to assist companies in strategically developing non-clinical study programs that will meet regulatory requirements in a timely and cost-effective manner.

toXcel offers the following services:

- Strategic advice on developing and implementing pharmacology and drug safety programs, including cost estimates and proposed schedules for laboratory studies
- Review and gap analysis of currently existing pharmacology and toxicology programs
- Literature searches for relevant scientific information for your product
- Determine alternative test methods where appropriate
- Develop data waiver justifications in lieu of actual study when applicable
- Plan safety pharmacology/toxicology studies within required timeframes
- Select appropriate CROs with the necessary skills and equipment
- Design non-clinical pharmacology and toxicology study protocols according to regulatory guidelines
- Manage and monitor non-clinical pharmacology and toxicology studies
- GLP compliance monitoring
- Review and evaluate draft study reports
- Develop study strategies to elucidate mode of action where required
- Provide guidance and representation in interactions with regulatory agencies
- Assess data valuation for the due diligence process

Let ***toXcel*** be your partner in establishing your non-clinical pharmacology and toxicology studies programs.

For further discussion on how ***toXcel*** can help meet your scientific and regulatory objective, please don't hesitate to contact us.

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