NON-CLINICAL PHARMACOLOGY & TOXICOLOGY PROGRAM

Scientific and Regulatory Services

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

toXcel offers the following assistance:

- Review and gap analysis of currently existing pharmacology and toxicology programs
- Strategic advice on developing and implementing pharmacology and drug safety programs, including cost estimates for laboratory studies
- Literature searches for relevant scientific information for your product
- Develop data waiver justifications in lieu of actual study when appropriate
- Plan safety pharmacology/toxicology studies within required timeframes
- Determine alterative test methods where appropriate
- Selection of appropriate CROs with the necessary skills and equipment
- Design non-clinical pharmacology and toxicology study protocols according to regulatory guidelines
- Develop study strategies to elucidate mode of action
- Management and monitoring of non-clinical pharmacology and toxicology studies
- GLP auditing
- Review and evaluate draft study reports
- Guidance and representation in interactions with regulatory agencies
- 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 contact Alan Katz at 703-754-0248 extension 111 or by email at Alan.Katz@toxcel.com.

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