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 alternative 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.