

NEUROPHARMACOLOGY & NEUROTOXICITY TESTING

Scientific and Regulatory Services

The U.S. EPA Office of Chemical Safety and Pollution Prevention (OCSPP) has established neurotoxicity and developmental neurotoxicity test guidelines for use in the testing of pesticides and toxic substances, and the development of test data for submission to the Agency; similar tests are required for high tonnage substances under REACH in the EU. The U.S. FDA and EU include Safety Core Battery Tests in the S7A Safety Pharmacology Studies for Human Pharmaceuticals. The European Medicine Agency, OECD, ICH and other international organizations have set forth general policies and recommendations for drug and chemical safety assessments.

The scientists at **toXcel** can assist in determining which studies are appropriate to meet the regulatory objectives for your product. **toXcel** can be your source for conducting a cost comparison for study placement, protocol design, study monitoring, and third party review of all data submitted to either agency. **toXcel** coordinates submission of documents and materials to EPA, ECHA, or FDA and can track their progress during Agency review. Scientists at toXcel will act on your behalf to provide written responses to EPA, ECHA, or FDA comments regarding neurotoxicity studies and outcomes.

toXcel is an experienced and reliable source of non-clinical, scientific, and regulatory support for your company.

Areas of Scientific Expertise include:

- Neurotoxicology
- Developmental Neurotoxicology
- Ocular Toxicology
- General Toxicology (Acute, Subchronic, Chronic, Mutagenicity, and other special studies)
- In vivo study design and study monitoring
- In vitro study design and study monitoring
- Review of draft reports
- Risk assessment
- Mechanistic and Mode-of –Action Testing
- Drug Safety Profiles

For further discussion on how **toXcel** can meet your specific needs, please contact Alan Katz at 703-754-0248 extension 111 or by email at Alan.Katz@toxcel.com.

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