Neurotoxicity & Neuropharmacology

Scientific and Regulatory Services

The potential for substances to cause neurotoxicity in the adult, or in the developing central nervous system of the fetus, are addressed in legislation for both pharmaceuticals and chemicals.

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 UK and EU.

For pharmaceuticals the U.S. FDA, UK, and EU include Safety Core Battery Tests as set forth in the ICH S7A Safety Pharmacology Studies for Human Pharmaceuticals and examination of the fetus and newborn in Developmental studies are described in ICH S5.

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 governmental agencies. ***toXcel*** coordinates submission of documents and materials to EPA, ECHA, or FDA and can track their progress during Agency review. Scientists and regulatory specialists 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, including the Developmental Neurotoxicity Study (OECD 426) and the Extended One Generation Reproductive Study (OECD 443)
- Developmental and Reproductive Toxicology (DART), as described in ICH S5
- Ocular Toxicology
- General Toxicology (Acute, Subchronic, Chronic, Carcinogenicity, Mutagenicity, and other special studies)
- *In vivo* study design and study monitoring
- *In vitro* study design and study monitoring, including strategies for the classification of potential skin and eye irritants
- Review of draft reports
- Risk assessment
- Mechanistic and Mode-of-Action Testing
- Drug Safety Profiles

For further information on how ***toXcel*** can meet your specific needs, please don't hesitate to contact us.

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