

TOXIKON AT A GLANCE

Services

DEVICES



BIOTECH



PHARMA



CUSTOM



Capabilities

- » Bacterial Mutation Assays
- » Mammalian Cell Mutation Assays
- » Mammalian Cytogenetics Assays
- » Cell Transformation Assays
- » DNA Damage/Repair
- » Comet Assay

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Genotoxicity evaluation constitutes an essential part of preclinical testing program for device and drug approval. A variety of genetic toxicology screening assays also play an important role in lead compound selection in the early phase of drug development.

Our facilities and experienced laboratory management can offer the highest quality of work in compliance with ICH, OECD, ISO 17025 and many other globally-recognized standards. With decades of experience, our team will collaborate with you as an extension of your firm to facilitate drug and device development, achieve product safety and regulatory compliance, as well as maintain the highest levels of laboratory quality control. Toxikon can offer you services that will facilitate product development by reducing the potential for product and process failure. By partnering with us and learning your application, Toxikon provides specific solutions and results that will facilitate development. Our genetic toxicology assays identify potential genotoxic agents to humans, and support our full suite of toxicology programs for decision analysis.

Toxikon: Your Team of Experts

At Toxikon, we understand the importance of sound science for drug and medical device development, and we are committed to supporting you through the entire product development cycle, from concept to final product. Our approach involves three main values. First, we are committed to quality and scientific excellence. Second, our client-centric, collaborative approach will give you confidence knowing that our scientists understand your application, and third, the know-how to navigate the regulatory landscape for your product's development path.

The genetic and molecular toxicology studies at Toxikon are conducted to elucidate molecular mechanisms involving :

- Clastogenicity
- Aneugenicity
- DNA effects; frameshift, transverse and transition mutations
- Carcinogenicity



Genetic and Molecular Toxicology Overview

Services at a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) registered with the FDA for drug, biologic, and medical device testing. With approximately 200 employees, Toxikon is committed to staying at the forefront of life science product development. Toxikon's safety services include toxicology (acute, subchronic, and chronic toxicity, reproductive toxicity, genetic toxicology, carcinogenicity), pharmacokinetics, toxicokinetics, bioavailability, ADME, chemical characterization, impurities analysis and synthesis, bioanalysis, and microbiology. Additionally, full IND/NDA enabling studies are performed with a multidisciplinary approach to program management. Toxikon's extensive certifications and licenses allow it to meet international regulatory requirements for data acceptability and harmonization.

To meet all applicable international GxP requirements, Toxikon's facilities are fully registered with FDA and USDA, and accredited with the Association for the Assessment and Accreditation of Laboratory and Animal Care International (AAALAC), and the International Organization for Standardization (ISO). Toxikon also has assurance with the National Institutes of Health so federally funded work can be performed at our facilities in compliance with NIH's Public Health Service Policy on Human Care and Use of Laboratory Animals (PHS Policy).

Bacterial Mutation Assays

- » Salmonella / E. coli reverse mutation assay
- » Plate incorporation method
- » Pre-incubation method
- » High throughput salmonella / E. coli screening assays
- » Spot testing

In vitro Mammalian Cell Mutation Assays

- » Mouse lymphoma assays using L5178Y TK+/- cell line
- » Chinese hamster ovary (CHO) HGPRT assay

In vivo mammalian cell gene mutation assays

- » Big Blue™ mutation assay systems (Transgenic mice or rats screened for lac1 or C11 mutant frequency)

In vitro Mammalian Cytogenetics Assays

- » Chromosome aberrations in Chinese hamster ovary cells
- » Chromosome aberrations in human peripheral blood lymphocytes
- » In vitro micronucleus assay in CHO cells

In vivo cytogenetics assays

- » Chromosome aberrations in mouse and rat bone marrow
- » Bone-marrow erythrocyte micronucleus test using mouse and rat
- » Microscopic / Flow cytometry methods

Additional In vivo assays

- » Dominant lethal assay (Mouse/Rat)
- » Sperm head abnormal morphologies (Mouse/Rat)

DNA Damage/Repair Assays

- » In vivo / In vitro unscheduled DNA synthesis
- » In vivo / In vitro sister chromatid exchange
- » Comet Assay

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To learn more about Toxikon and our development capabilities, please visit us at www.toxikon.com