

BIOTECH



TOXIKON AT A GLANCE

Biotech Capabilities

- » In Vivo Services
- » In Vitro Services
- » Analytical/Bioanalytical Services
- » Microbiology/Virology
- » Cell-based Assays
- » Analytical Services
- » Immunogenicity

Locations:

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Along with our comprehension of regulatory, scientific, and commercial environments, Toxikon offers extensive testing services and capabilities for biotechnology product development. With more than 30 years of experience, we are committed to excellence in the quality of our testing services, technical expertise, instrumentation, facilities, and our people, which are all central to your product's successful development.

Moreover, biotechnology and biopharmaceuticals are becoming increasingly important as novel and less toxic therapeutics for human disease. Many of these product structures, including cell-based and stem cell therapies, have limited toxicology and pharmacology information. Our study directors and scientists, most of whom are PhDs and MDs, perform standard guideline as well as customized or sponsor-specific studies. Specialized testing using molecular biology and immunoassay techniques are available as well as animal models to evaluate immunogenicity and immunotoxicology.

When you collaborate with Toxikon, you gain a highly-qualified preclinical CRO and a partner who applies years of know-how and experience to design and complete the standard or custom study requirements necessary for biotech product development. Additionally, our study directors and support staff have the qualifications and knowledge to support the data as it specifically applies to your compound's characteristics and challenges.

At Toxikon, we understand just how critical development support is from concept through essential safety and efficacy studies. 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.

A Full Breadth of Biotech Services

Toxikon's biotech services include:

- » In Vivo
- » Immunotoxicology
- » PK/TK
- » Toxicology and Pathology
- » Immunology
- » Metabolism and Pharmacokinetics
- » Bioanalysis

Services and a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) for biologics, drugs, and medical device testing. With approximately 200 employees, Toxikon is committed to staying at the forefront of biotech product development. Toxikon's safety services include toxicology (acute, subchronic, and chronic toxicity, reproductive toxicity, genetic toxicology, and carcinogenicity), pharmacokinetics, toxicokinetics, bioavailability, ADME, chemical characterization, impurities analysis and synthesis, bioanalysis, and microbiology.

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 assurances 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).

In Vivo

- » Pharmacology
- » Toxicology
- » Genetic Toxicology
- » Immunotoxicology
- » PK/TK

In Vitro

- » Potency Assays
- » RIA/ELISA/PCR
- » Viral Clearance
- » Binding Assays
- » Genetic Toxicology
- » Microbiology
- » Immunogenicity

Analytical/Bioanalytical

- » Method Development
- » Method Validation
- » Comprehensive GLP/GMP Assays
- » Extractables and Leachables
- » Protein Characteristics
- » Stability/Aging Release Testing

Other Services

- » Drug-Drug Interactions
- » Protein Binding
- » Specialized Staining
- » Immunohistochemistry
- » Histology
- » ELISA
- » PCR

Visit www.toxikon.com to learn more about our Biotech development capabilities.