

PHARMA



TOXIKON AT A GLANCE

Pharma Capabilities

- » In Vivo Services
- » In Vitro Services
- » Analytical and Bioanalytical Chemistry
- » Microbiology / Virology
- » Molecular Biology / Immunogenicity
- » Pharmaceutical Analysis Services

Locations:

Corporate Headquarters

Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730
800.458.4141
info@toxikon.com
www.toxikon.com

Toxikon Europe N.V.

Romeinsestraat 12
B-3001 Leuven
Belgium
+32.16.400484
info@toxikon.be
www.toxikon.be

Contact information:

Mark A. DeSorbo

Manager of Marketing and Communications
781.275.3330 ext. 187
mark.desorbo@toxikon.com

At Toxikon, we understand how important on-time delivery is for meeting your goals for IND, NDA, and other international submission requirements. That's why we approach your pharmaceutical development needs—from efficacy and safety to analytical studies—using a very systematic approach. We apply our extensive knowledge, experience, and diverse capabilities specifically to meet your program requirements. As your development partner, we work side-by-side with you to learn the intricacies of your application, and deliver timely data and quality reports.

While our reputation has been built on our vast toxicology experience, Toxikon's scientific experts know how to navigate the regulatory landscape during the development of both large and small molecules. It starts with proof of concept and efficacy, and progresses through pharmacokinetics, toxicokinetics, formulation development, and a full range of analytical and bioanalytical services. Toxikon has the ability to use a wide variety of small and large animal models, including mice, rats, guinea pigs, rabbits, dogs, cats, hamsters, goats, swine, and non-human primates. Our facilities include surgical suites with special imaging and analysis capabilities for all specialized and/or custom programs.

A Practical Approach to Preclinical Development

We understand how critical development support is from concept through essential safety and efficacy studies. Toxikon's 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. With Toxikon, you get more than a highly qualified CRO, you gain a partner, who understands and has the experience to design, validate and execute all preclinical program requirements. Toxikon's full breadth of preclinical pharmaceutical services includes:

- » Pharmacology, PK/TK
- » Safety Pharmacology
- » Toxicology and Pathology
- » Biodistribution
- » Reproductive Toxicology
- » ADME
- » Bioanalysis
- » Xenografts
- » PCR
- » Immunology

Services at a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) registered with the FDA for drug, biologics, and medical device testing. With approximately 200 employees, Toxikon is committed to staying at the forefront of pharmaceutical 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, full bioanalytical analysis, and microbiology. Additionally, full IND/NDA enabling studies are performed with a multidisciplinary approach to program management. Toxikon holds extensive certifications and licenses 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).

In Vivo

- » Whole Animal Assays
- » PK/TK/ADME/DMPK
- » IND/NDA Enabling Studies
- » Small/Large Model Imaging
- » Genetic Toxicology

In Vitro

- » Binding Assays
- » Cell Culture Based Assays - Molecular
- » Microbiology/Virology
- » Immunogenicity
- » PCR
- » Genetic Toxicology

Analytical/Bioanalytical

- » Method Development and Validation
- » Dose Analysis and Verification
- » Sample Analysis
- » API
- » Extractables and Leachables
- » Metabolite Synthesis and Identification

Other Services

- » Drug-Drug Interactions
- » Protein Binding
- » General safety tests
- » Pathology
- » Histology
- » Disease Models
- » Ocular

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