

CUSTOM



TOXIKON AT A GLANCE

Custom Capabilities

- » Research and Development
- » Surgical and Efficacy
- » Synthesis and Formulation
- » Ocular Drug Development
- » IND/NDA Enabling Studies
- » Reproductive Toxicology
- » Carcinogenicity
- » Pathology

Locations:

Corporate Headquarters

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Toxikon offers custom research and testing services in support of drug and device discovery and development.

Our product development capabilities are focused on discoveries that improve the quality of life, while delivering quality science. Along with R&D/Discovery, these capabilities include ocular drug development, surgical programs, synthesis and formulation, IND/NDA enabling studies, reproductive toxicology, carcinogenicity, and pathology capabilities. Working closely with our clients, we are committed to providing customized services that meet the required objectives of our clients' programs.

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.

Beyond Toxicology

While our reputation has been built on our vast toxicology experience, Toxikon's Custom Capabilities include:

- » Conducting ophthalmic studies in small and large animal models, including acute irritation, ocular distribution (PK/PD), acute and repeat dose toxicity, implantation, drug screening and drug efficacy;
- » Well-designed facilities, including surgical suites, with adjacent pre- and post-operative care areas to meet unique development needs, including dedicated necropsy for a variety of animal models and physician training;
- » Design and synthesis of small molecules and analogs for lead generation and lead optimization, preparation of building blocks, scaffolds and intermediate compounds, custom synthesis of lead compounds from milligrams to large scale, and synthesis of reference compounds and metabolites;
- » A variety of pathology evaluations and expertise, clinical chemistry and hematological studies.

Services and a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) that is registered with the FDA for drug, biologic, and medical device testing. With approximately 200 employees, Toxikon is committed to staying at the forefront of drug, biotech, and medical device 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).

Ocular Testing Program

- » Intra-vitreous Injections
- » Slit-Lamp Exams with Draize and McDonald-Shadduck Scoring Systems
- » Direct Ophthalmoscopy and Indirect Ophthalmoscopy
- » Aesthesiometer, Tonometry, Pupilometry and ERG
- » Anterior/Posterior Segment and Fundus Photography
- » Confocal Microscopy
- » Specialized Surgical Services

Efficacy and Surgical Research Services

- » Surgical Suites
- » Full IND/NDA Enabling Studies
- » Mobile Fluoroscopy
- » Complex Image Analysis
- » Ultrasound, Endoscopy, Digital X-Ray Imaging
- » Orthopedic Equipment
- » EKG
- » Phacoemulsification
- » Hematology/Hemodynamic Analysis
- » Power Injectors
- » Electrocautery Units

R&D/Drug Discovery

- » Antiviral
- » HIV
- » Hepatitis
- » Kinase Inhibitors
- » Effective Anticancer Therapy Discovery

Synthesis and Formulation

- » Custom Synthesis
- » Specialty Studies

Developmental/Reproductive Toxicology

- » Amniotic Fluid/Fetal Blood Collection
- » Infusion Exposure (continuous, intermittent or slow)
- » Neurotoxicity and Behavioral Assessments
- » Landmarks of Development

Pathology

- » Urinalysis
- » Coagulation
- » Hematology
- » Necropsy
- » Histology
- » Pathology Interpretation
- » Specialty Ocular Evaluations
- » Molecular Detection
- » Tissue Distribution
- » Clinical Chemistry

Visit www.toxikon.com to learn more about our Custom service capabilities.