

DEVICES



TOXIKON AT A GLANCE

Devices Capabilities

- » In Vivo Services
- » In Vitro Services
- » Analytical Services
- » Efficacy Studies
- » Cleaning Validation
- » Manufacturing Support

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

Toxikon is well-known throughout the global medical device industry, and we have been proudly meeting the development challenges of component, raw material, and finished device manufacturers for more than 30 years. While outsourced medical device testing has increased along with the proliferation of new and increasingly complex medical devices, Toxikon continues to be the leader in device testing evaluation requirements.

With regulatory agencies in the U.S. and abroad, it is important to partner with a CRO that can guide you through the preclinical regulatory landscape to reach the clinical stage and, ultimately, to market. Our study directors have a deep understanding of the issues medical device makers face, and that's just one aspect of Toxikon's service offerings.

Our facilities include capabilities to conduct proof of concept and efficacy studies, analytical, complete biocompatibility, extractables and leachables, microbiology, sterilization support, genetic and molecular toxicology, reusable device and combination product evaluations, and more.

Toxikon: Your Team of Experts

Our study directors work closely with you to design biocompatibility assessments to measure the magnitude and duration of alterations in homeostatic mechanisms, favorable and adverse, in determining biological and chemical responses. Some of the services for medical device development that Toxikon offers are:

- » Substantial models for comprehensive evaluation of various cardiovascular, gastrointestinal, ocular, orthopedic and neurological devices;
- » Custom studies for devices for drug delivery applications to treat wounds, as well as gastroenterological, urologic, respiratory, and other disorders;
- » Complete biocompatibility toxicity, sensitization, irritation, cytotoxicity, and other studies that comply with ISO 10993 guidelines;
- » Advanced, high-capacity facilities with modern surgical suites and on-site housing for small and large species;
- » A full array of specialized imaging, measurement and monitoring equipment.



Services at a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) that is registered with the FDA for medical device, drug and biologic testing. With more than 200 employees, we are committed to staying at the forefront of medical device technology by continually evaluating our research techniques.

Our highly skilled professional and technical staff possesses the tools and modern equipment to provide comprehensive research throughout the preclinical development process. Toxikon's full range of services are centralized at our corporate headquarters in Bedford, MA, to leverage advanced and integrated research capabilities. These disciplines include vascular, dental, dermatological, gastrointestinal, neurological, ophthalmic, pulmonary, reproductive, urogenital and orthopedic, to name a few. 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

- » Class Testing
- » Sensitization
- » Irritation
- » Biocompatibility
- » Intracutaneous
- » Subcutaneous
- » Toxicology
- » Systemic Toxicology
- » Pyrogenicity
- » Reproductive
- » Developmental

In Vitro

- » Biocompatibility
- » Molecular Biology/
Virology
- » Metabolism
- » Genetic and Molecular
Toxicology
- » Immunotoxicity/
Cytotoxicity
- » Cell Culture Based
Assays
- » Hemocompatibility
- » Microbiology

Analytical Services

- » Material characterization
- » Extractables and
Leachables
- » Compendial Testing
- » Residue Analysis (EO,
EC, EG)
- » ICH Storage/Stability
Testing
- » Accelerated Aging
- » Forced Degradation
- » Photostability
- » Particulate Analysis

Other Services

- » Efficacy Studies
- » Cleaning Validation
- » Manufacturing Support
- » Surgical Services
- » Complete Pathology
and Histology
- » Coagulation Studies

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