Efficacy and Surgical Research Services (ESRS)
Rely On Our Expertise And Capabilities
Toxikon is a Contract Research Organization (CRO), with ISO/IEC 17025 accreditation that is registered with the US FDA and Japanese MHLW for drug and medical device testing. The Company provides in vivo, analytical, and in vitro testing services for the pharmaceutical, biotechnology, and medical device sectors. 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, bioanalytical, and microbiology. Toxikon’s certifications allow it to meet regulatory requirements for data acceptability.

Toxikon was founded in 1982. The Company has two primary locations: a 117,000 square foot state-of-the art facility in Bedford, Massachusetts consisting of two buildings, 15 Wiggins Ave. and 25 Wiggins Ave. (Bedford), and a 20,000 square foot European lab operation in Leuven, Belgium (Leuven). Toxikon’s laboratory facilities are fully accredited including GLP/GMP registrations, and the Bedford facilities have full USDA, OLAW, and AAALAC animal testing credentials. In addition, both facilities are ISO accredited, enabling GLP and non-GLP work across both facilities. The Company currently has approximately 80 animal rooms, and has extensive and fully equipped surgical suites, along with support services that include efficacy and research services, and histology and clinical pathology.

The Company currently serves over 1,000 active customers across the pharmaceutical, biotechnology and medical device sectors through-out the world.

Toxikon’s clients represent more than 40 countries internationally. In addition to the laboratory facilities, Toxikon has remote technical sites in India, Japan, Minneapolis (USA), Israel, Germany, and Korea. Toxikon has approximately 250 full-time employees.
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Toxikon’s facilities are fully registered with the 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).
Toxikon has been a leader in preclinical research for drugs, medical device and combination products since 1977. Our experience spans non-invasive to interventional procedures. Toxikon's ESRS preclinical development capabilities include:

» Custom Disease Model Development and Validation
» Cardiovascular
» Dental
» Dermatological
» Device Validation and Verification
» Efficacy
» Gastrointestinal
» Neurological
» Ophthalmic
» Orthopedic
» Proof of Concept
» Prototype Development
» Pulmonary
» Reproductive
» Urogenital
» Vascular
Toxikon offers a fully equipped, AAALAC-accredited facility that is conveniently located in Bedford, MA, just outside Boston, and right in the heart of the Bay State's thriving life science sector. Our sophisticated operating rooms are adaptable to meet the complexities of various surgical programs. Our facilities include:

» Modern Surgical Suites
» Mobile Fluoroscopy
» Complex Image Analysis
» Ultrasound
» Endoscopy
» Digital X-Ray Imaging
» Microsurgery
» EKG
» Hemodynamic Analysis
» Power Injectors
» Electrocautery Units
» Wound Healing
» Orthopedics
» Anastomosis
» Implants
» Necropsy Suites
» Conference Rooms
Toxikon is committed to the challenges of developing drugs, biologics, and medical devices for the treatment and prevention of cardiovascular and vascular diseases and related complications.

Services include:

- Interventional Research
- Structural Heart
- Embolic Protection
- Transeptal Procedures
- IVC Filters
- Other IC Procedures (Balloons)
- Complex Bifurcation Stenting
- Diagnostics and Imaging
- Electrophysiology
- In vivo Thrombosis
Toxikon also offers extensive GLP and Non-GLP studies that focus on orthopedic medical devices, drug and combination products. Whether routine or a customized study, Toxikon has the expertise to conduct and analyze a myriad of orthopedic studies.

Services include:

» Critical Size Defect Studies
  • Calvarial Defect
  • Radial Defect
  • Mandibular Defect
» Heterotopic Models of Osteogenesis
» Bioabsorbable Materials
» Cartilage Defect Models
» Standard Analysis
  • Mechanical Testing
  • Micro CT
  • Histology
  • Digital Radiology
  • Histomorphometrics
Toxikon's Center for Independent Research (TCIR) provides access to Toxikon's expertise for your product development. Designed to be home to small and large companies alike, TCIR's laboratories provide all the essential resources and equipment of a modern research environment. Obtaining space at TCIR means your organization becomes part of a thriving community that encourages the advancement of innovation.

Customizable options include, but are not limited to:

» Personalized Research Space
» Vivarium
» Surgical Suites
» Analytical
» Histopathology
» Clinical Pathology
» Formulation
Toxikon offers a full range of Bioskills & Post-Market Physician Training:

» Animal Model Based Training
» Cadaver Based Training
» Surgeon to Surgeon Training
» Salesforce Training for Market Launch
» Physician Training for Market Penetration

Toxikon offers a large open OR that accommodates up to 8 tables for individual or group training events. Advanced AV system and broadband internet with conference rooms and large seminar rooms with AV capabilities for didactic training.
When you collaborate with Toxikon, you gain a highly qualified preclinical CRO and a partner who applies years of knowledge and experience to design comprehensive protocols necessary for drug and medical device development.

- Urinalysis
- Coagulation
- Hematology
- Clinical Chemistry
- Necropsy
- Histology
- Specialty Ocular Evaluations
- Molecular Detection and Biomarkers
- Tissue Distribution
- Disease Model Development
- Full IND/NDA Enabling Studies
- Analytical and Bioanalytical Services
- Pharmacokinetics / Toxicokinetics
- Complete Pathology
Toxikon offers a variety of scalable pathology evaluations. Our experienced team, which includes board-certified anatomic and clinical pathologists and technologists, are dedicated to providing comprehensive research programs. Our pathology capabilities and research facilities meet the highest standards of preclinical and translational research in compliance with laboratory accreditations.

Our laboratory has extensive experience in:

» H&E Staining
» Special Staining
» Immunohistochemistry
» Plastic Embedding
» Histomorphometrics
» Micro CT
To learn more about the service offerings at Toxikon please contact us at the appropriate facilities.

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