

### TOXIKON AT A GLANCE

#### Services

DEVICES



BIOTECH



PHARMA



CUSTOM



#### Capabilities

- » In Vivo
- » In Vitro
- » Acute/Subchronic/Chronic Toxicology
- » Irritation
- » Cytotoxicity
- » Genotoxicity

#### Locations:

##### Corporate Headquarters

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#### Acute Systemic Toxicity

- » Material mediated pyrogenicity in rabbits
- » Systemic injection

#### Subacute/Subchronic/Chronic Toxicity

- » 14, 28, 90 day
- » Range finding, recovery groups
- » Dose routes: IV, IP, IM, subcutaneous, dermal, oral and nasal
- » Customized studies
- » Single dose, repeat dose or continuous infusion
- » Chronic studies in rodents/dogs

#### In Vivo Mutagenicity / Genotoxicity

- » Chromosomal aberration
- » Mouse micronucleus (blood/bone marrow)
- » COMET assay

#### Animal Models

- » Mouse, hamster, gerbil, rat, guinea pig, ferret, rabbit, cat, dog, swine, sheep and goat

#### In Vivo Laboratory Support

- » Analytical chemistry
- » Clinical chemistry
- » Hematology
- » Histopathology
- » Radiography
- » Surgical research
- » Microbiology
- » Micro surgery
- » Carcinogenicity
- » 6 month transgenic mouse model
- » 2 year carcinogenicity rodents
- » 2 year toxicity/carcinogenicity rodents
- » 18 month carcinogenicity rodents

#### Toxicokinetics / Metabolism

- » Elucidation of metabolic pathway
- » Single / multiple dose

#### Reproductive Toxicity

- » Multigeneration studies
- » Developmental toxicology

#### Irritation

- » Bladder
- » Dermal
- » Intracutaneous
- » Nasal
- » Ocular
- » Oral/mucosal
- » Penile
- » Rectal
- » Vaginal
- » Vascular

#### Implants

- » Bone
- » Brain
- » Custom implants
- » Dental
- » Dermal
- » Intraperitoneal
- » Muscle
- » Ocular
- » Subcutaneous
- » Vascular

#### Cytotoxicity

- » Agar overlay
- » Clonal assay
- » Direct contact
- » Inhibition of cell growth assay
- » MEM elution
- » MTT, NRU, XTT

#### In Vitro Mutagenicity / Genotoxicity

- » Ames assays-salmonella and E. coli
- » Cell transformation in BALB/c-3T3 cells

# Biocompatibility Assessment Overview

## Services at a Glance

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

### In Vitro Mutagenicity / Genotoxicity

- » CHO/chromosomal aberration assay
- » CHO/HGPRT gene mutation assay
- » CHO/sister chromatid exchange
- » Chromosomal aberration in human lymphocytes
- » Rat lymphocyte cytogenetic assay
- » SCE assay in human lymphocytes
- » UDS assay in primary rat hepatocytes

### Hemocompatibility

- » Complement activation C3A, C5A
- » Hemolysis – rabbit, human
- » Lee and white coagulation

- » PT assay
- » Thrombogenicity assay in dogs
- » UPTT assay

### Chemistry Services

- » Material characterization
- » Physicochemical and other compendia analysis
- » Extractables and leachables
- » Degradation profile
- » Metals analysis, including biological matrices
- » Residual analysis
- » Particulate analysis

### Microbiology Support

- » Antimicrobial effectiveness
- » Endotoxin testing

- » Sterility-direct transfer, membrane filter, package integrity and penetration
- » Total bioburden – AAMI, ISO

### Sensitization

- » Buehler sensitization
- » Kligman maximization
- » Murine local lymph node assay

### Enhanced

- » ISO Class 7 (Class 10,000) sterility suites
- » Continuous IV infusion studies
- » In vivo efficacy testing
- » Surgical suites
- » Reusable device processing
- » Virology

### Special Services

- » Customized studies
- » Neurotoxicity
- » Pharmacokinetics/ Toxicokinetics
- » Reproductive toxicity and teratology
- » Specialized surgical procedures
- » Wound healing

### Regulatory and Technical Capabilities

- » FDA, ISO, EMEA, MHLW, WHO

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