

Toxicology Services

Discovery and Safety Studies

WuXi AppTec offers a full-range of *in vivo* and *in vitro* non-clinical safety evaluation programs. As the uniqueness of each product requires a case-by-case approach, we partner with clients to ensure that all study components meet specific program objectives.

Testing services are based on the current FDA, ISO, ICH, OECD, KFDA, EMEA, JMHLW, JP, EPA, AAMI, HIMA, USP, ANSI, and ASTM guidelines and requirements, and our quality systems have been audited and accepted by regulatory authorities worldwide. WuXi AppTec scientists have extensive experience in designing non-clinical safety testing programs, and our services have supported a number of successful regulatory submissions in the U.S., Europe and Asia.

We are expanding our services with the construction of a 323,450 square-foot non-clinical drug safety evaluation center in Suzhou, China. This center will offer additional capacities to WuXi AppTec's existing toxicology services.

Study Components

➤ Animal Models

Mice	Dog
Rat	Pig
Guinea Pig	Goat
Rabbit	Sheep
Non-human Primate	

➤ Routes of Administration

Dermal	Intraperitoneal
Intracardiac	Intraocular
Intracranial	Oral
Intradermal	Subcutaneous
Intramuscula	Intravenous (bolus)
Intravenous (continuous infusion)	

➤ Clinical Pathology

Serum Chemistry
Hematology
Coagulation
Urinalysis

➤ Anatomic Pathology

Histology/Histopathology
Paraffin/Plastic Sections
Immunohistochemistry

Testing Services

➤ Acute Toxicity (*in vivo*)

- Range Finding
 - Up/Down
 - Limit Test
 - Maximum Tolerated Dose (MTD)
- Fixed Dose
- Local Tolerance

➤ Repeat Exposure (*in vivo*)

- Range Finding
- Subacute/Subchronic/Chronic

➤ Genotoxicity (*in vitro* and *in vivo*)

- In vitro* Bacterial Mutagenicity
- In vitro* Mouse Lymphoma
- In vitro* Chromosomal Aberrations
- In vivo* Mouse Micronucleus

➤ Tumorigenicity/Carcinogenicity

➤ Blood and Tissue Sampling

- Pharmacokinetics/Toxicokinetics
- ADME
- Collection for qPCR

➤ Immunotoxicity

- Delayed-type Hypersensitivity
- Immunogenicity/Anaphylaxis
- Antibody Sampling

➤ Biodistribution and *In Vivo*

- Gene Expression Studies
- Nucleic Acid Extraction
- qPCR Analysis

Additional Features

- Model development
- Study design development
- GLP-compliant facilities
- Dedicated, isolated study suites
- Web-based access to study progress

Complete biocompatibility/safety testing, and custom implant studies also available.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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