WuXi AppTec

WuXi AppTec LABORATORY TESTING DIVISION

SAFETY ASSESSMENT SERVICES

OVERVIEW

WuXi AppTec's Laboratory Testing Division is one of the world's preeminent preclinical safety and clinical stage safety assessment laboratories.

Shorten your discovery and development times and lower the cost of drug R&D by partnering with our Safety Assessment team.

20+
Countries Supported

1800+
Safety Assessment Staff

1000+
Safety Assessment Studies Conducted/Year

99%
On-Time Data & Report Delivery

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SAFETY ASSESSMENT SERVICES: INTRODUCTION

Whether you're working on an innovative small molecule or an advanced biologic drug candidate, you can rely on WuXi AppTec's Safety Assessment team to develop a program that meets your specific needs.

Fully Compliant:

- U.S. Food and Drug Administration (FDA)
- Organization for Economic Co-Operation and Development (OECD)
- National Medical Products Administration (NMPA) Good Laboratory Practice (GLP)
- U.S. FDA Standard for Exchange of Nonclinical Data (SEND) and 21 CFR Part 11

State-of-the-Art Facilities:

- Fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)
- Overseen by highly experienced Testing Facility Management (TFM) experts
- Ultra-modern 1,000,000 square foot facility with 500+ animal rooms
- Imaging center equipped with the latest technology, including PET and CT

Fully Integrated with WuXi AppTec's Comprehensive Testing Platform

When our Safety Assessment services are applied to end-to-end projects, you receive multidisciplinary expertise and experience that saves time and cost while yielding invaluable data and insights.

About Our Safety Assessment Staff

- 25% of our staff have graduate degrees
- The senior management team has international experience
- Diplomate of the American Board of Toxicology (DABT) and European Registered Toxicologist (ERT) certifications

11,000+
Safety Assessment Studies Performed

700+
IND/NDA Packages Submitted Globally

Learn more about our Safety Assessment Services by visiting ?

labtesting.wuxiapptec.com/safety-assessment-services

CAPABILITIES AT A GLANCE

General Toxicity

- Acute toxicity study
- Repeat dose toxicity study at 7-day, 14-day, 28-day, 13-week, 26-week & 39-week

Carcinogenicity

- 104-week carcinogenicity study in rats or mice
- 26-week carcinogenicity study in transgenic mice (RasH2)

Genetic Toxicity

- Ames (*in vitro*)
- Micronucleus (*in vitro* or *in vivo*)
- Chromosome abbreviation (*in vitro*)
- Mouse lymphoma assay (*in vitro*)
- Comet assay (*in vitro*)

Safety Pharmacology

- Central nervous system (mouse & rat)
- Respiratory (mouse, rat, dog & monkey)
- Cardiovascular (dog & monkey)
- hERG (*in vitro*)

Special Toxicity

- Local irritation (skin, vessel and eyes)
- Sensitization (ASA and PCA)
- Hemolysis (*in vitro*)
- Phototoxicity study (*in vitro*)
- Ocular toxicity study
- Tissue Cross Reactivity (TCR)

Development & Reproductive Toxicology

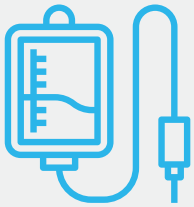
- Seg I fertility and early embryonic development to implantation (mouse & rat)
- Seg II embryo-fetal development (rat & rabbit)
- Seg III pre-and postnatal development (mouse & rat)
- Juvenile toxicity study (mouse & rat)

	Discovery		Preclinical		Clinical		
	Lead Finding	Lead Optimization	Preclinical Candidate (PCC) Studies	IND Enabling	Phase I	Phase II	Phase III
General Toxicology			Single Dose or 7-day Dose Range Finding Tox Screen	Single Dose Or 14-day Tox (Rodent Or Non-rodent), 28-day Tox (Rodent And Non-rodent)	13-, 26-, and 39-week Toxicity (Rodent and Non-rodent)		
Genetic Toxicology				Ames Or Mouse Lymphoma Mutation Assay, Micronucleus Testing (*In Vivo*) Chromosomal Aberration (*In Vitro*)			
Safety Pharmacology				Functional Observation Battery (Rodent), Respiratory Safety (Rodent) Cardio-telemetry (Non-rodent)			
Dart				For NMPA Only Under Certain Circumstances: Segment I-II (Single Species)	Segment I-III		
Carcinogenicity						2-year (Rat), 2-year (Mouse), or 6-month (Transgenic Mouse), (Carcino-genicity Study)	
Other				Tissue Cross Reactivity (TCR)		Juvenile Tox (If Applicable), 4-week Batch Impurity Study (Rat)	

GENERAL TOXICOLOGY

Preclinical toxicology assessment is critical to the progression of your new drug candidate – and a required step prior to First-In-Human (FIH) studies. WuXi AppTec offers both IND- and NDA-enabling toxicology studies and services, including:

- Formulation analysis and bioanalysis (GLP and non-GLP)
- Early Diagnosis Testing (EDT)
- Single dose (acute toxicity)
- Dose Range Finding (DRF) or Maximum Tolerated Dose (MTD)
- Repeat dose (subacute, subchronic and chronic)



10+ Routes of Administration

Including intravenous, topical and intramuscular

Comprehensive In-House Toxicologic Pathology Capabilities

Including necropsy, histopathology, immunopathology and more

GET MORE DETAILS ON OUR WEBSITE

GENETIC & *IN VITRO* TOXICOLOGY

The genetic and *in vitro* toxicology group performs both non-GLP and GLP assays (such as genotoxicity, in silico mutagenicity prediction, phototoxicity and *in vitro* electrophysiology) for regulatory filings as well as screening assays for safety lead optimization. Utilizing industry-leading instruments, technologies, and expertise, our study directors are committed to presenting rapid, high-quality data that can inform of potential risk during subsequent stages of development.

Genetic Toxicology Screening Assays

- Micro-Ames assay
- Mini-Ames assay
- Microwell micronucleus assay

Genetic Toxicology GLP Assays

- Ames assay
- *In vitro* chromosomal aberration assay
- *In vitro* micronucleus assay
- Mouse lymphoma assay
- *In vivo* micronucleus assay
- *In vivo* alkaline comet assay
- *In vivo* chromosomal aberration assay
- *In vivo* Pig-a gene mutation assay

In Silico Mutagenicity Prediction

- Leadscope model applier (expert rule-based and statistical-based models)

GLP or Non-GLP Phototoxicity Assays

- MEC
- ROS
- 3T3 NRU phototoxicity assay
- 3D RhE phototoxicity assay
- *In vitro* phototoxicity assay

GLP or Non-GLP *in vitro* Electrophysiology Assay

- hERG assay
- Peak hNav1.5 assay
- Late hNav1.5 assay
- hCav1.2 assay

SAFETY PHARMACOLOGY

Quickly and accurately assess the potential for toxicity across major therapeutic areas (including CNS, cardiovascular and respiratory) with *in vitro* and *in vivo* safety pharmacology studies, including:

- Functional Observational Battery studies in rats and mice
- CNS system evaluation in mice, rats, canines and NHPs
- Non-GLP cardiovascular safety screening assays
- hERG assay
- Cardiovascular telemetry studies in conscious canines, NHPs and minipigs
- Jacketed External Telemetry in conscious canines and NHPs

PONEMAH® SOFTWARE

Data Collection & Assimilation

ICH COMPLIANCE

International Conference on Harmonization

LEARN MORE ABOUT SAFETY PHARMACOLOGY

DEVELOPMENTAL & REPRODUCTIVE TOXICOLOGY (DART)

Assess the reproductive safety of your drugs, chemicals or pesticides after repeated or chronic exposure with our IND- and NDA-enabling DART studies and services for Segment I, II and III.

- Dose-range-finding study on embryo-fetus development
- Fertility and early-development-to-implantation studies (Segment I)
- Definitive embryo-fetus development study (Segment II)
- Fetal/neonatal, peri/postnatal development studies (Segment III)

LEARN MORE

CARCINOGENICITY TESTING

Assess for the development of non-neoplastic and neoplastic lesions in organs and organ systems to identify tumorigenic potential in animals and determine the risk of long-term pharmaceutical use in humans.

104-WEEK

Carcinogenicity Study in Rats or Mice

26-WEEK

Carcinogenicity Study in Transgenic Mice (rasH2)

LEARN YOUR OPTIONS

OPHTHALMOLOGY SERVICES

Advance drug development for a wide range of ophthalmic indications with the most advanced ocular pharmacodynamics (PD), pharmacokinetic (PK) and toxicology evaluation techniques. Explore tests, methods & models.

Ocular PD Studies

Assess the efficacy of new ocular drugs via 30+ in-house animal disease models and the ability to develop new models specific to your needs

Ocular PK Studies

Assess tissue distribution and PK caused by ocular or systemic administration, conducted across a variety of species, tissues and liquids

Comparative Ophthalmology Examination

Across a variety of ocular studies, including eye irritation, new ocular drug toxicity and toxicokinetic (TK), PD and PK

PATHOLOGY

Our American College of Veterinary Pathologists (ACVP) and Chinese College of Veterinary Pathologists (CCVP) evaluate thousands of slides across a variety of animal species every year. Explore our pathology services.

SMALL MOLECULE

LARGE MOLECULE

GENE & CELL THERAPY

180,000+
Tissues Evaluated/Month

Toxicologic Pathology

Our full scope of services includes general toxicologic pathology, carcinogenicity, irritation pathology and more.

Immunopathology

- Tissue Cross-Reactivity studies for a broad range of antibodies
- Standardized staining with commercially available antibodies and research antibodies

Clinical Pathology

We offer a complete range of clinical pathology services in a variety of animal species, including Routine and Non-Routine Serum Hematology, Chemistry, Coagulation and Urinalysis.

Necropsy & Histology

Our full-service necropsy and histology laboratories are staffed by experienced technologists who provide trimming, embedding, sectioning and special staining to support the evolving needs of our clients' programs.

PRECLINICAL IMMUNOLOGY SERVICES

Our experienced immunology team provides a full range of services to support the development of your therapeutic, including immunohistochemistry (IHC), immunochemistry, tissue cross-reactivity (TCR) and vaccine development.

Immunohistochemistry

To localize the protein of interest, we use your supplied or commercial antibodies on fresh-frozen sections, PFA-fixed frozen sections, and formalin-fixed paraffin-embedded sections.

- Customized assays
- Staining protocol optimization
- Immunostaining results interpretation

Tissue Cross-Reactivity

Our comprehensive TCR studies support your research efforts and provide definitive information for regulatory submission.

EXPLORE PRECLINICAL IMMUNOLOGY SERVICES

14 WEEKS
Rapid scheduling & Reporting for Entire Project

U.S. FDA, EMA & NMPA
Requirements Met

BIOSAFETY LEVEL 2
Biosafety Laboratory Certificate

VACCINE DEVELOPMENT

The importance of vaccine research and development has increased exponentially with the occurrence of new, highly problematic infectious diseases. For companies at the forefront of developing drugs to meet these critical needs, WuXi AppTec provides a full range of services to drive vaccine programs through the drug development process with maximum efficiency and speed.

Vaccine Testing Programs

- Product characterization: identity, titer, mass, purity, potency, sterility
- GMP cell banking and characterization
- Lot release testing
- Viral clearance/inactivation validation studies
- Biodistribution studies

Vaccine Types

- Therapeutic
- Prophylactic
- DNA and RNA
- Bacterial
- Fungal
- Viral

30+

Human and Animal Viruses Available as High-titer Stocks

LEARN MORE ABOUT VACCINE DEVELOPMENT

YOUR SUCCESS IS OUR SUCCESS

At WuXi AppTec, we care passionately about the success of your program.

We understand the importance of meeting drug development milestones, giving you robust data and keeping your drug on the path to success.

How Can We Help You?

Talk to an expert about your upcoming project.

LET'S TALK

About WuXi AppTec Laboratory Testing

WuXi AppTec's Laboratory Testing Division is a comprehensive integrated testing platform supporting customers across the full spectrum of their development efforts to deliver innovative medicines to patients. From discovery through preclinical to clinical and beyond, we enable scientists to transform their ideas into healthcare products that ultimately improve life.

Improving Health. Making a Difference.

10/2024