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WuXi AppTec
An Integrated R&D Service Company

Preclinical services designed to shorten development time, reduce costs by up to 50% and improve research success

WuXi AppTec's Integrated Research and Development Services

WuXi AppTec Preclinical Services

WuXi AppTec provides a full range of *in vivo* and *in vitro* preclinical safety evaluation studies which are part of our integrated portfolio of drug discovery and development services.

By focusing on quality, scientific expertise, flexibility and responsiveness, WuXi partners with our Sponsors to provide a wide range of IND/NDA enabling toxicology and laboratory services that meet global regulatory standards.

Our services are designed to help our worldwide customers shorten the time and lower the cost of Research and Development through cost effective and efficient outsourcing solutions.

Preclinical Services

■ Toxicology Services

- General Toxicolgy (acute, sub-chronic, chronic)
- Genetic Toxicology (screening and regulatory assays)
- Safety Pharmacology
- Immunotoxicology
- Anatomic and Clinical Pathology

■ Laboratory Services

- Analytical Chemistry
- Bio-analysis; TK modeling
- Immunology
- Biomarkers

■ Lead Optimization Package (EDT) Laboratory Services

- Compound Synthesis
- Genotox screening assay
- QT Assay *in vitro* and *in vivo*
- Target organs and dose-limiting toxicities in two species (Dog and Rat)
- Biomarker studies

WuXi AppTec is an AAALAC-accredited CRO with a statement of GLP compliance from an OECD member country (Belgium) and a certificate of GLP compliance from China's SFDA (State Food and Drug Administration)

Every one of WuXi's employees takes great pride in providing our Sponsors with flexible, quality driven, expedient solutions to meet both the needs of the individual and their organization.

Experienced teams of scientists, researchers and technicians have enabled WuXi AppTec to create an environment to undertake preclinical research to the highest of standards with a knowledge that spans a wide range of compounds and therapeutic areas

Management Team

Role	Name	Experience
Vice President Quality Assurance	Robert Coldreck, RQAP-GLP	> 36 years
Vice President Operations	Stephen Mason, MSc , ERT	> 18 years
Executive Dir. of Lab Sciences & Sr. Study Dir. of Genotoxicology	Robert Y. Jiang, PhD	> 20 years
Executive Director Toxicology	Susan McPherson, MSc, ERT	> 24 years
Executive Director Business Development and Marketing	Julie-Ann Cabana, BSc, MBA	> 12 years
Executive Director of Pathology & Sr. Veterinary Pathologist	Xiuying Yang, MD, PhD, Dipl, JSTP, Dipl, JST	Pathologist >26 years toxicological pathologist > 14 years
Executive Director of Facility Operations	Hui Xu, BS	> 20 years
Executive Director of Veterinary Sciences and Animal Welfare	Scout Chou, BS, MS, VMD	> 12 years
Senior Director of Lab Services	Millie Chen, PhD	> 8 years
Senior Director of Toxicology Operations	Charlie Barker, BS, LAT	> 18 years
Senior Director, Bioanalysis.	DuXi Zhang, PhD	> 10 years
Director of Toxicology Operations	Sandra Burlock, BSc	> 15 years
Associate Director Pathology Operations	Isabelle Godin, Dip. Animal Health	> 12 years

Over 230 combined years of experience in the preclinical industry

Why Chose WuXi?

Fully integrated Services:	✓Integrated quotation, contract, logistics and invoice process across WuXi to shorten the overall processing time
	✓Fully integrated services within WuXi leading to accelerated timelines
Management/Staff:	✓Dedicated management with over 150 combined years of experience in the preclinical industry
	✓Multi-disciplinary scientific expertise including western trained staff
	✓Knowledge that spans a wide range of compounds and therapeutic areas
Facility:	✓Full AAALAC accreditation
	✓Recognized with a statement of GLP compliance from OECD member country (Belgium) and GLP certification from China SFDA
	✓Large NHP capacity – quick start lead in time to start NHP studies from date of authorization
	✓Logistics support for import and export of test article/biological samples
Regulatory Filing:	✓Fully compliant with FDA, OECD and SFDA GLP requirements
	✓Assist clients with study and program design for global filing
	✓Experience with international filing including US, Europe and China
Cost Saving:	✓Potential for up to 50% cost savings over US study costs
	✓Global IND/NDA filing capability to enable additional cost saving and shorten drug development timeline
Customer Responsiveness:	✓Rapid turnaround and flexibility
	✓Focus on communication
	✓98% on time reporting standard of study data and report

WuXi AppTec Preclinical Services, Suzhou, China

Laboratory and Animal Facilities:

- GLP and non-GLP capabilities
- Full service preclinical laboratory supporting both IND and NDA requirements
- Species: mouse, rat, guinea pig, rabbit, dog, nonhuman primate
- 314,000 square foot facility; 108 animal rooms

Compliance and Accreditations:

WuXi has worked with scientists and government authorities to establish services that meet international regulatory requirements.

- AAALAC accredited facility
- OECD – received a statement of GLP compliance from the Belgium regulatory authorities
- Chinese SFDA – received certificate of GLP compliance
- Bioanalytical - bioequivalency inspection conducted by US FDA
- WuXi has conducted IND and NDA enabling studies for submission to the US FDA

CONTACT INFORMATION

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