Small Molecule Bioanalysis

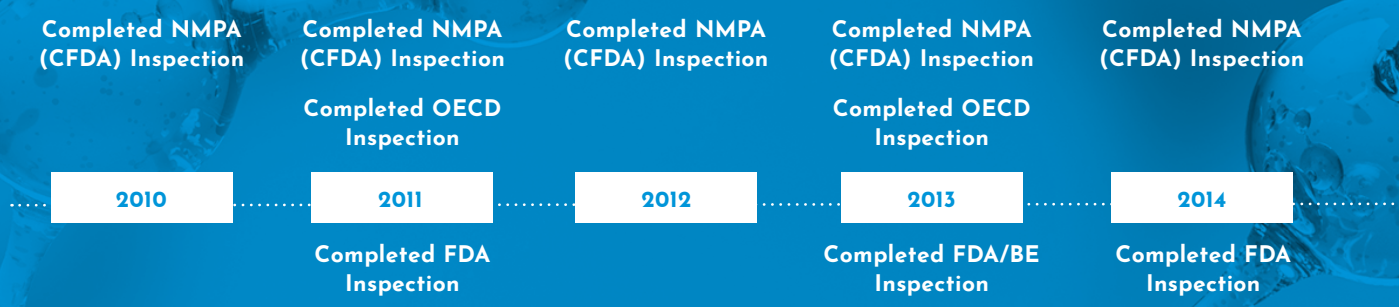
药明康德
WuXi AppTec

Global Bioanalytical Services

Having the right bioanalytical strategy will help you make informed decisions faster. WuXi AppTec's bioanalytical experts understand what it takes to advance innovative therapies from discovery to IND and beyond.

With WuXi AppTec as your partner, you have access to our highly experienced team of experts to help you move your molecule to the next milestone. As an extension of your lab, our team offers a customized approach that meets your dynamic needs, from study design to submission.

WuXi AppTec's Track Record of Regulatory Inspections



Bringing Industry-leading Expertise to Your Project

Accelerate your drug development programs with our dedicated bioanalytical teams.

Access our team of experts	•20+ years of experience in GLP/GCP bioanalysis •Over 150 novel compounds supported each year •Experienced global project management team •Vast bioanalytical capability: >500 staff •Global bioanalytical laboratory of over 200,000 square feet
Trusted partner for global programs	•Supported 2,000+ preclinical and clinical studies •Currently collaborating with 200+ active clients
Meeting all regulatory requirements for submission	•Completed FDA, EMA, PMDA, NMPA (CFDA) study inspections with minor observations and no deficiencies •CAP accredited – central lab services (China) •Completed 5 GLP inspections and certifications by OECD •Client inspections: >50 each year •Submitted data accepted by worldwide health authorities
Scalable operations to meet your preclinical and clinical needs	•Automated high throughput capable systems to quickly scale up your projects •Seamless method transfer between facilities to meet clients' global clinical needs

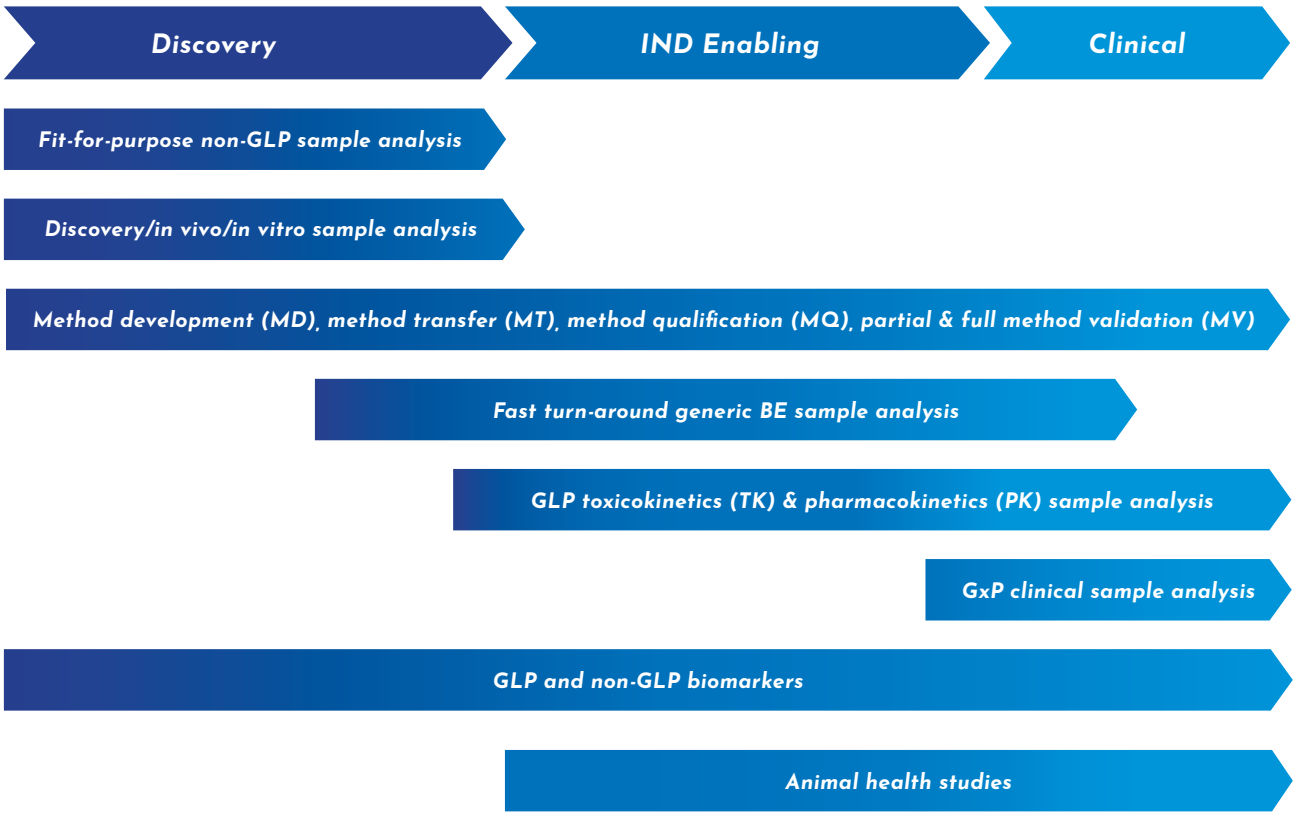
2015	2016	2017	2018	2019
Completed NMPA (CFDA) Inspection	Completed NMPA (CFDA) Inspection	Completed NMPA (CFDA) Inspection	Completed NMPA (CFDA) Inspection	Completed NMPA (CFDA) Inspection
Completed OECD Inspection		Completed OECD Inspection	Completed PMDA Inspection	Completed OECD Inspection
Completed FDA/BE Inspection	Completed EPA Inspection	Completed FDA Inspection		Completed FDA Inspection

Small Molecule Bioanalytical Services

Key Highlights

- Over 200 validated non-proprietary methods
- Over 40 validated new methods for proprietary/innovator molecules each year
- State-of-the-art LC-MS/MS platforms with HPLC and UPLC capabilities
- Over 500,000 sample analysis capacity per year
- Automated high throughput capable systems including Janus® and CyBio®-SELMA
- 21 CFR Part 11 compliant validated systems; Analyst®, MassLynx™, Watson LIMS™

Industry-Leading Services for Your Drug Development Journey



LC-MS/MS Quantitation of Peptides & Proteins

Rapid Method Development

- 2-4 weeks for peptides
- 4-6 weeks for proteins

Extensive Experience

- Resolve non-specific binding
- Sensitivity tune-up
- Trypsin digestion conditions
- Microelution SPE optimization

Diversified Peptides & Proteins

- Different species and matrices
- Hybrid Immunoaffinity LC-MS

Fast synthesis capabilities

- 2 weeks turnaround time
- Synthesize surrogate peptide
- Synthesize SIL-IS

Extensive Experience for Diverse Small Molecule Compound Classes

- Common new chemical entity (NCE)
- Polar/non-polar, and low MW analyte
- Endogenous analyte
- Unstable analyte
- Amino acids & peptides
- Insulin analogs
- Biomarkers
- Vitamins
- Lipids
- Oligonucleotides
- Antibody-drug conjugates

Proven Expertise Across Species & Matrices

Species	Biofluids	Tissues (easy to homogenize)	Tissues (difficult to homogenize)	Micro-sampling techniques
Human	Plasma	Brain	Intestine	DBS
Mouse	Serum	Liver	Testicle	Microdialysis
Rat	Whole Blood	Spleen	Prostate	Capillary
Rabbit	Cerebrospinal Fluid	Heart	Skin	
Pig	Urine	Lung	Muscle	
Dog		Kidney	Ovary	
Monkey		Stomach	Fat	
		Uterus	Bone	
			Eye	

State-of-the-Art Instrumentation to Rapidly Deliver High-Quality Scientific Results

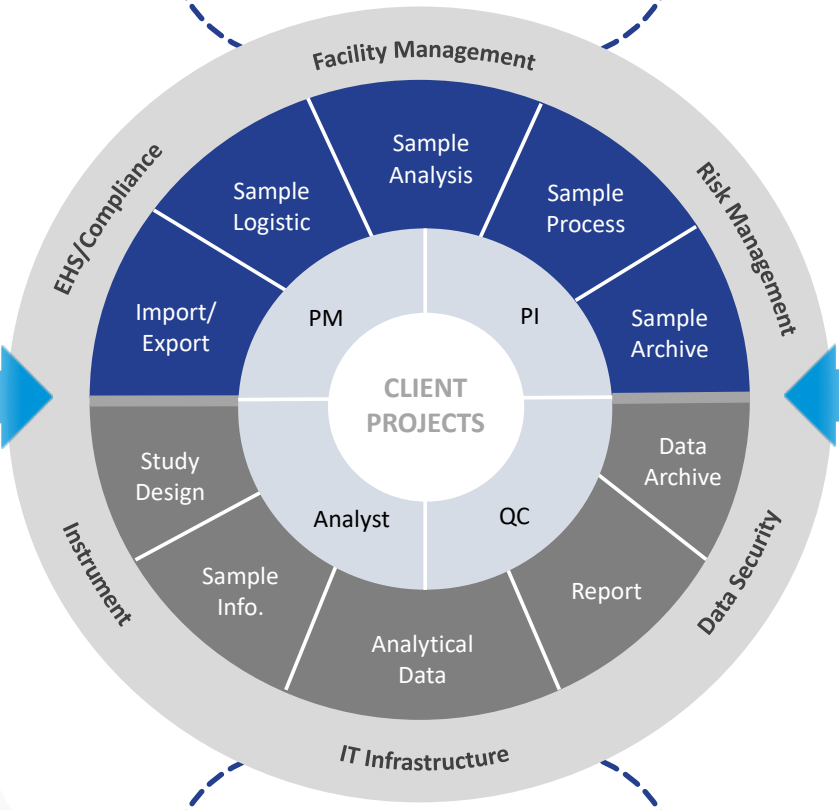
70+ LC-MS/MS instruments globally

- SCIEX API Triple Quad™ 4000/5000/5500/6500/6500+ LC-MS/MS
- Waters Xevo® TQ-S LC-MS/MS
- Waters UPLC®/Shimadzu HPLC/Agilent HPLC/Shimadzu UPLC
- Fully automatic LC method scouting system
- PerkinElmer Janus® liquid handling system
- TomTec® liquid handling system

Comprehensive Quality Management System

- Global sample reception
- Customs clearance experience
- Dedicated sample management team

- 24-hour centralized temperature control and alarm system
- Sample storage
- Refrigeration equipment (4°C, -20°C, -80°C)



Testing Facility Management

Quality Assurance

- Fully validated Watson LIMS™
- Backup generators

- Daily incremental backup of data
- Weekly full data backup, stored in two locations
- Perform recovery tests regularly

Global Bioanalytical Facilities

Our mission is to provide the most comprehensive capability and technology platform for the global pharmaceutical and healthcare industry to fulfill the vision that every drug can be made and every disease can be treated.

Integrated Bioanalytical Service for Global Submissions

- GLP/non-GLP bioanalytical facilities
- Central lab services – safety lab and clinical kits (China)
- Innovator and generic drug bioanalytical support
- Clinical and preclinical study support
- Extensive experience in supporting bioanalytical studies for global regulatory submissions
- Strong regulatory audit history from FDA, OECD, EMA, PMDA, and NMPA (CFDA) with no major findings
- Successfully filed IND/NDA packages with major regulatory agencies
- DEA inspected, state licensed for radio-activity use (US)

Contact Us to Learn More

labtesting.wuxiapptec.com | info_ltd@wuxiapptec.com

NEW JERSEY | SHANGHAI | NANJING | SUZHOU | ATLANTA | ST. PAUL

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