Site Stats: Shanghai, China

BIOANALYTICAL CAPABILITIES– IMMUNOCHEMISTRY & LC-MS

Gross Ft²: 18,970 | Number of PhDs: 2 | Total BioA Employment: 120 | Number of LC-MS/MS: 23

Instruments & Technology	► TOMTEC QUADRA4™ automation platform ► Liquid chromatography ► Mass spectrometers ► Analyst software	► Electrochemiluminescence (MSD QuickPlex SQ120) ► SpectraMax Plate Reader ► Gyros Immunoassay Lab System ► Watson LIMS® 7.5 ► SoftMax Pro ► MSD Discovery Workbench
Related Onsite Solutions	► Drug discovery and lead optimization ► Drug metabolism and pharmacokinetics ► General toxicology	► Dose formulation and analysis ► Toxicological pathology ► Ophthalmology ► EPDS ► Regulatory strategy and consultation
LC-MS Metrics–2018	► 111 methods developed ► 113 methods validated	► 305 sample analysis studies ► >220,000 samples analyzed
Immunoanalysis Metrics–2018	► 151 methods developed ► 95 methods validated	► 178 sample analysis studies ► >72,000 samples analyzed
Specialized Expertise	► **Complex methods:** Chiral compounds, Liposomes, Fatty Acids, Hormones	► Antibody-Drug Conjugates ► **LC-MS/MS:** Peptides & Nucleic acids

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EXCEPTIONAL SCIENCE, TRUSTED INSIGHTS

9 International Regulatory Inspections **PASSED**

- **FDA GLP & BE …** Jul 2015
- **CFDA GLP…** Sep 2012, Jan 2016, Mar 2019
- **Belgium OECD GLP…** Jun 2011, Jun 2013, Jan 2016, Mar 2018
- **UK MHRA GLP…** May 2013

59 Clinical BioA Study Audits **PASSED**

- **NMPA National & Provincial Onsite Inspections*…**2016-2018

* *Since July 2015, CFDA (former name of NMPA) has mandated self-inspection and verification of clinical data for NDA submissions; clinical trial onsite inspections are now a routine step for NDA applications in China*

35 CFDA Approved Drugs **SUPPORTED**

- **21 NCEs or New Biologics and 14 generic drugs**

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