

## Associate Director/Director in Pharmacokinetics

### Responsibility:

- Lead to design, conduct and report pharmacokinetics (PK), toxicokinetics (TK), tissue distribution and excretion studies including study designs in small and large animals, LC-MS/MS bioanalytical method development, sample analysis, data modeling and analysis, reporting and interpretation.
- Lead the bioanalytical method development and non-GLP validation of LC-MS/MS methods for discovery and regulatory PK/TK studies.
- Direct IND-enabling PK/TK studies including study protocol, report and writing and review according to regulatory technical guidelines (US FDA, China NMPA, EMA) under a GLP-like setting.
- Develop new PK assays as needed to address specific project or study issues, or new service capability.
- Keeps up to date with emerging new mass spectrometric technologies, new animal surgery and formulation delivery technologies, and regulatory technical guidelines.
- Communicate effectively with clients for study update, project management and technical support.
- Communicate effectively with functional groups or departments. Set priority for the lab and allocate appropriate human resources/work schedule to ensure timely report delivery.

### Qualifications

- A M.S., or Ph.D. degree in drug metabolism, pharmaceutical science, organic chemistry, analytical chemistry, biochemistry, or related discipline with 8 - 15 years' experience in pharmaceutical and biotechnological companies, or contract research organizations.
- Hands-on experience in designing, conducting, analyzing and reporting PK, TK, tissue distribution and excretion studies to support preclinical projects in discovery and GLP-like settings.
- Working experience in designing and conducting IND-enabling PK/TK studies to support China and US NMPA regulatory filing in a GLP-like setting.
- A thorough understanding in formulations, cassette-dosing, dose administration routes (oral, intravenous bolus and infusion, intraarterial, intramuscular, intraperitoneal, intratracheal, subcutaneous, transdermal, oropharyngeal aspiration, intrarectal, intranasal, etc.) and special delivery of test compounds in various small and large animal species (mice, rats, dogs, monkeys, rabbits, mini-pigs, etc.) and various surgery technologies (bile-duct cannulation, jugular cannulation, portal vein cannulation, carotid artery cannulation, etc.) in PK/TK studies.
- Expertise in LC-MS/MS quantitation techniques including various MS/MS and LC platforms especially AB Sciex MS/MS, Shimadzu and Waters HPLC/UPLC, bioanalytical method troubleshooting.
- Experience in leading and supervising a group of lab scientists.
- Excellent oral and written communication, interpersonal, and organizational skills is required, along with demonstrated ability to interface effectively with clients and project team members.