**DMPK Met ID Assistant Director or above**

**Responsibilities：**

* Biological sample (plasma, bile, urine, feces, plant, tissue) processing
* Profile biological samples using HPLC
* Conduct in vitro and in vivo metabolism studies.
* Conduct LC-MS/MS analysis and interpretation.
* Identification of drug metabolites using liquid chromatography-tandem mass spectrometry, NMR, and other analytical methodologies.
* Elucidation of metabolic pathways.
* Prepares scientific reports that document the analytical results and interpretation for the identification of drug metabolites.
* Collaborate with other scientists in a team to support metabolism studies.

**Basic Qualifications:**

* A Ph.D. degree in organic or analytical chemistry, natural product chemistry, biochemistry, pharmaceutical science or related is required.
* 5 years’ experience in one of pharmaceutical DMPK areas
* Knowledge of LC/MS application in pharmacokinetics and drug metabolism.
* Experience in LC-MSMS method development in quantitation and metabolite profiling of biological samples is plus.
* Experience and knowledge of drug biotransformation and identification of drug metabolites.
* Experience in analytical method development using mass spectrometry and spectral data interpretation.
* Good oral and written communication skills.

**Primary Location:** China – Shanghai

**Analytical Development and QC director**

**Responsibilities：**

* The incumbent is to lead an Analytical Development and QC group (approx. 20 - 40 Scientists) in ADQC to conduct all analytical development and quality control activities from early phase to late phase support for drug product and support of regulatory filing.
* Lead the group to meet the preset goal/budget of department through streamlining/optimizing the workflow and maximizing the operation efficiency while maintaining full compliance.
* Develop/build a world class analytical development and QC team including planning, recruiting/hiring, coaching/mentoring, and training for staffs and group leaders. Provide technical guidance/direction to subordinators as well as evaluate new analytical technologies to enhance department capabilities
* Play a leading role in project management interaction with internal and external clients, formulation development, process development and quality assure units, etc.
* Prepare, review and approve all analytical related documents, supervise project review meeting by TC or on-site visits to ensure projects meet the expected quality and within the desired timelines and budget
* Able to handle regulatory inspections from FDA, EMA. CFDA etc and GMP audits and from clients as well as internal quality assurance unit
* Assist senior management to expand business with existing customers and broad the customer basis by participating strategy development and business development activities with department head

**Basic Qualifications:**

* Ph.D. degree or equivalent in Analytical Chemistry or other directly related science discipline with pharmaceutical industry experience of 8 - 10 years in Analytical R&D/Quality Control within CMC/pharmaceutical development function; a minimum of 3-5 years of managerial experience desired
* Excellent managerial skill in both people and projects being able to lead a large group of scientific staffs and a large portfolio of development programs
* Proven good track record of accomplishments in the Analytical R&D and CMC development area - managing different phases of new drug development program and launching new products in major global markets desirable.
* Strong technical know-how to guide the team to maintain a leading industry role in analytical development as a contract research organization (CRO).
* Must be familiar with requirements of FDA, EMA and CFDA regulations, ICH guidelines and GMP/GLP as well as drug product development process.
* Superb communication skills in written and verbal, and outstanding interpersonal skills are essential job requirements.

**Primary Location:** China – Shanghai

**Small Molecular Bioanalysis Director**

**Responsibilities：**

* Responsible for small molecule bioanalysis in support of pre-clinical studies. Communicate with clients, evaluate business opportunities and participate discussions with clients on LC/MS/MS based small molecule bioanalysis strategy including method development, transfer, validation and sample analysis.
* Lead the method development and validation of LC/MS/MS assays used for TK, late stage DMPK (large animals PK/PD) and biomarker studies. Ensure scientific integrity and GLP compliance.
* Work/colleborate with Toxicology and DMPK services to deliver bioanalytical data to support tox and DMPK studies timely
* Manage the operation of small molecule laboratory and staffs
* Plan and provide immunology related training to staff as required
* Accountable for all business and operational aspects pertaining to pre-clinical small molecule bioanalysis for DMPK/Tox studies. Actively participle client visits, teleconferences to discuss client projects. Prepare proposals on bioanalysis method development, transfer, validation or sample analysis.
* Serve as the technical expert in small molecule bioanalysis to establish LC/MS/MS based assays to ensure method transfer and new method development for supported projects
* As laboratory director, ensure that (1) basic operation tasks are clearly defined, （2）staff assignment are appropriate for their level and capability, (3) assignments are completed within the timelines, (4) study personnel understand clearly their responsibilities and acknowledge relevant standard operating procedures (5) contingency plan is in place for unforeseen events that affects timeline and deliverables and the impact of any deviations from the study protocol and/or standard operating procedures on the quality and integrity of the study is assessed and recorded, and take appropriate corrective action if necessary, (6) Communicate effectively with the QA unit and address study related findings during the conduct of the study
* Communicate effectively with other departments/function areas. Set priority for the lab and allocate appropriate human resources/work schedule to ensure timely delivery.
* Plan and provide regular trainings to staff to ensure adequate training is provided to staff to execute the required work assignments.

**Basic Qualifications:**

* PhD degree or equivalent in chemistry fields with 8 years of work experience in GLP LC/MS/MS area, or equivalent trainings/experience acquired through work in the fields
* Hands-on experience in designing/conducting/monitoring small molecule bioanalysis studies (GLP and non-GLP)
* Expertise in LC/MS/MS techniques including knowledge of various MS and LC platforms especially ABSciex MS, Shimazu and Waters HPLC/UPLC)
* Experience in managing GLP laboratory and studies.
* Staff management experience of small molecule bioanalysis (GLP) functions
* Fluent oral and written English skills. Oversea education and working experience highly preferred.

**Primary Location:** China – Shanghai or Suzhou

**Large Molecular Bioanalysis Director**

**Responsibilities：**

* Responsible for large molecule bioanalysis in support of pre-clinical studies. Communicate with clients, evaluate business opportunities and participate discussions with clients on large molecule bioanalysis strategy including method development, transfer, validation and sample analysis.
* Lead the method development and validation of immunochemistry assays (ELISA and flow cytometry based) used for TK, immunogenicity and biomarker studies. Ensure scientific integrity and GLP compliance.
* Manage the operation of Immunology Laboratory and staff
* Plan and provide immunology related training to staff as required
* Accountable for all business and operational aspects pertaining to pre-clinical large molecule bioanalysis. Actively participle client visits, teleconferences to discuss client projects. Prepare proposals on bioanalysis method development, transfer, validation or sample analysis.
* Serve as the expert in immunoassay development for both ELISA and flow cytometry based assays to ensure method transfer and new method development for supported projects
* As laboratory director, ensure that (1) basic operation tasks are clearly defined, （2）staff assignment are appropriate for their level and capability, (3) assignments are completed within the timelines, (4) study personnel understand clearly their responsibilities and acknowledge relevant standard operating procedures (5) contingency plan is in place for unforeseen events that affects timeline and deliverables and the impact of any deviations from the study protocol and/or standard operating procedures on the quality and integrity of the study is assessed and recorded, and take appropriate corrective action if necessary, (6) Communicate effectively with the quality assurance personnel and deal with their findings during the conduct of the study
* Communicate effectively with other departments/function areas. Set priority for the lab and allocate appropriate human resources/work schedule to ensure timely delivery.
* Plan and provide regular trainings to staff to ensure adequate training is provided to staff to execute the required work assignments.

**Basic Qualifications:**

* PhD degree or equivalent in biology, immunology or related fields with 8 years of work experience, or equivalent trainings/experience acquired through work in the fields
* Hands-on experience in designing/conducting/monitoring large molecule bioanalysis studies
* Experience in immunology techniques including knowledge of ELISA, ECL Assay, immunochemistry and flow cytometry
* Experience in managing GLP laboratory and studies.
* Staff management experience of immunology functions
* Fluent oral and written English skills. Oversea education and working experience highly preferred.Fluent oral and written English skills. Oversea education and working experience highly preferred.

**Primary Location:** China – Shanghai

Contact POC: Helen\_Sun@wuxiapptec.com for job application and more information.