BRI Biopharmaceutical Research Inc.
www.bripharm.com
A Frontage Laboratories Company
Unit 101, 8898 Heather Street, Vancouver, BC, Canada V6P3S8

FRONTAGE
www.frontagelab.com

Senior Bioanalytical Study Director
Full Time
Vancouver, BC, Canada

BRI, A Frontage Laboratories Company, is a Contract Research Organization (CRO) located in Vancouver, British Columbia, Canada with head office located in Exton, Pennsylvania, USA.

BRI is seeking a **Senior Bioanalytical Study Director** to complement a current team of highly experienced bioanalytical scientists within a modern facility engaging in the following LC-MS/MS and ELISA studies:

- Demonstrates competence in state-of the-art multiplex ECL-immunoassay of biotherapeutics (ADC, protein and peptide drugs)
- Provides mentoring and hands-on guidance on small molecule drug and metabolites multi-analyte LC-MS/MS assay
- Leads the development and validation of assays in compliance with GLP regulatory guidance in support of IND/NDA-enabling studies

We are seeking highly motivated team players that enjoy the fast pace, self-learning and highly regulated environment of a CRO.

Position: Senior Study Director, Bioanalytical (Biotherapeutics)

Qualification:

- M.Sc. or Ph.D. in pharmaceutical sciences, bioanalytical chemistry, or related organic analytical chemistry
- 10+ years experience in bioanalytical assays of small molecules and biotherapeutics (mAb, ADC, PDC) plus a minimum of 5 years supervisory experience
- Strong hands-on technical experience in Waters and/or Sciex LC/MS/MS and MSD platform
- Competence in experimental i*n vitro* and i*n vivo* preclinical study design supporting DM/PK and ADME/Tox preclinical and clinical studies
- Knowledgeable in NCA pharmacokinetics, drug metabolism pathways and metabolite data analysis is an asset
- Competence in current bioanalytical regulatory guidance in advising new clients
- Strong technical experience in problem-solving and troubleshooting bioanalytical equipment
- Strong written and verbal communication skills
- Ability to effectively plan and organize study project schedules
- Excellent interpersonal skills and work ethics

Duties:

- Serves as a Study Director responsible for the overall design, conduct and timeline of multiple studies in parallel at a time
- Communicate project timelines, status, and data to sponsors, addressing technical issues effectively as required
- Provides guidance to the bioanalytical team during development and validation of novel assays and to support high-volume sample analysis
- Engages in PK data assessment, metabolism and metabolite data interpretation
- Contributes to study reports and provide scientific guidance to report writers
- Supports business development team by sharing with clients scientific concepts and insights
- Ensures the study team operates within current safety standards and GLP regulatory guidance

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