Frontage Laboratories

Scientist, Analytical Services-CMC

Location: Exton, PA

Responsibilities:

- Performs routine sample analysis, and a variety of tasks to support product development, ensuring agreed timelines
- Assists method development
- Performs method validation under supervision
- Reports and resolved any unexpected issues under supervision
- Complies with all relevant cGMP, and/or GLP regulatory requirements while carrying out assigned studies

Requirements:

- B.S. in Chemistry, or related discipline with 3-5 years relevant experience in pharmaceutical, or related industry
- Hands-on experience with HPLC, UPLC, GC, LC/MS, IC, and Dissolution Testing
- Excellent oral and written communication skills
- Capable of setting priorities based on a fast-paced changing environment
- Good team player to work with Formulators and QA
- CRO experience is a plus

Scientist/Senior Scientist, Sterile Pharmaceutical Drug Development

Location:
Exton, PA (CMC)

Position Summary:
The Scientist position is responsible for development and manufacturing of parenteral, ophthalmic and other sterile dosage forms. The individual will lead projects and act as a scientific project leader.

Responsibilities:

- Perform necessary literature and patent search to support studies for development of drug products and generate data/development reports for use by the sponsors as part of their regulatory submissions or patent filings
- Plan, perform and lead various stages of product development, including pre-formulation, formulation development, process development, optimization, scale-up studies/technology transfer
- Incorporate Quality-by-Design tools in drug development. Develop prototype formula and evaluate the predetermined QTPPs and CQAs, and continue to improve the formula to reach the development goal
- Write and review GMP documentation, including manufacturing batch records, and appropriate study protocols, and lead project-specific clinical manufacturing
- Collaborate with team members (Analytical Scientists, Quality Assurance, Material Coordinator, and Manufacturing Technicians) to meet timelines for drug product delivery and assist in working out investigation plans related to manufacturing investigations as required
- Interact and collaborate with sponsor to facilitate transfer of knowledge and deliverables of drug product
- Follow company policies and conduct work according to appropriate Frontage SOPs and comply with cGMP guidelines

Requirements:

- Ph.D. in Pharmaceutics, Chemistry, Polymer Chemistry or Chemical Engineering, with 1-3 years of experience, or Master's with equivalent experience
- In depth knowledge of theory and techniques in pharmaceutics and drug delivery
- Solid knowledge in sterile product development and manufacturing per cGMP compliant procedures, as well as for IND and ANDA
- Hands on experience in sterile product development including emulsion, suspension, and lipid-based delivery systems. Protein/biologics experience is a plus
- Strong written and verbal communication and presentation skills
- Good understanding of regulatory stability requirements, including FDA/ICH guidance in regards to sterile drug development

Senior Metabolism Scientist-DMPK

Exton, PA (Corporate)

Position Responsibilities:

- **Perform in vitro DMPK studies such as intrinsic clearance determination, reaction phenotyping, enzyme inhibition and induction, plasma protein binding**
- **Conduct metabolism studies using various in vitro models. Identify and quantitate metabolites using LC/MS and LC/MS/MS**
- **Operate and maintain LC/MS equipment**
- **Carry out bi-directional transport studies using Caco-2 cells**
- **Prepare written reports for clients upon completion of each task.**
- **Work with Study Directors/Sponsors in study design, protocol preparation, and overseeing conduct of studies**
- **Effectively manage numerous tasks/projects simultaneously to meet internal/external deadlines while maintaining organizational integration within DMPK team**
- **Ensure all laboratory operation and record-keeping are of high quality and compliant with Frontage SOPs or other applicable regulations**

Position Requirements:

- **PhD orMS plus 5 + years relevant industry experience in biochemistry, in vitro DMPK or similar discipline with coursework and research relevant to pharmacokinetics and/or drug metabolism.**
- **Knowledge of LC/MS/MS analytical techniques**
- **Broad post-graduate experience in vitro techniques relevant to DMPK as demonstrated through publications**
- **Significant experience and leadership in enzyme kinetics, enzyme inhibition/induction and in vitro systems used in DMPK research**
- **Knowledge of cell culture and in vitro systems used for bi-directional transport studies is a plus**

Sr. Scientist, Principle Scientist, or Manager of Biologics Product Analytics

Frontage Labs is a specialty contract research organization offering bioanalytical labs, preclinical and clinical studies, biometrics, analytical testing and CMC product development for novel compounds, generic pharmaceuticals and consumer products. With operations in the U.S. and China, eight state-of-the-art research facilities and over 700 staff globally, Frontage helps companies build a strong scientific foundation at the earliest stages of development, and provides product support through commercialization.

Summary:

In this role, you will apply your knowledge of protein chemistry and expertise in cellular and molecular biology to characterize therapeutic proteins, cell and gene products. Act as Analytical Project Leader, you will closely interact with clients and manage projects from initiation to successful completion.

Roles and Responsibilities:

- Independently develop and apply biochemistry, biophysics methods, immunoassays, and other state of the art analytical technologies to analyze and characterize oligonucleotides, cell and gene products, biotherapeutic proteins, their conjugates, and variants.
- Perform method development, validation, tech transfer, product characterization, impurity profiling, routine and stability testing across varieties of biologics products.
- Prepare project proposals, protocols, reports, Certificate of Analysis, investigation reports, and generate cGMP documents.
- Act as Analytical Project Leader, closely interact with clients through various means of communication and ensure high client satisfactions.
- Manage projects from initiation to completion and ensure the projects are on time, on budgets, and meeting pre-established quality standards.
- Train, develop junior staff, and collaborate with cross functional teams including QA, QC, formulation, and small molecules.
- Under strategic direction of BDMS leader, contribute and/or lead the creation of new service portfolios for emerging biotherapeutics.

Skills/Knowledge Required:

- PhD in Biological Science, Biochemical Engineering, or related discipline with 4+ year's relevant industrial analytical development experience, or MS with 8+ year's analytical development experience for biologics. Job title to be commensurate with the experiences and qualifications.
- Established track record of success in cell and gene therapy product characterization, cell-based assay, and flow cytometry experience.

- Preference will be given to the candidates with relevant experiences in Lentiviral and AAV vector construction and characterization.
- It is a plus to have experience in applying biochemistry (e.g., icIEF, CE-SDS, HPLC, LC-MS, ELISA, etc.) and biophysics (CD, DSC, DLS, etc.) analytical method for characterization and release of biologics such as recombinant proteins and monoclonal antibodies.
- Experience planning and coordinating analytical projects across multiple stakeholders both internally and externally.
- Experience working in a GMP and GLP environment.
- Experience leading teams, managing labs and budgets.
- Prior experiences working in Contract Service industry is a plus.
- Excellent oral and writing communication, and organization skills.

Employment at Frontage Labs:

Frontage Labs offers competitive salary and generous benefits including paid vacations, health insurance, 401K, disability insurances, and many others. On top of these benefits, we offer many opportunities to help you advance your career. So come and join us today!