Analytical Scientist / Senior Scientist

Company Description

Imagine a future where a simple urine test can detect deadly diseases before they get out of control. A future when diseases can be intercepted, and people don't become patients. At Glympse Bio, we are working to turn this vision into a reality. Take a glimpse into that future, where we are taking a glimpse inside the body. Named as *FierceMedTech*'s 2018 Fierce 15, our company is about 'taking steps over, around or through what many have accepted as the limits of current medical technology' and we attract and hire talent to do just that.

Position Description

We are seeking a resourceful and experienced Analytical Scientist/ Senior Scientist. This new position is focused on developing analytical assays that are a key component of the Glympse Bio Test System. Experience with developing and validating analytical assays in a regulated (CLIA / GLP / GMP) environment is central to this role although you will primarily work in an unregulated environment. You will also have direct responsibility for taking assays from our research team and performing essential experiments to ensure the assays can be validated and scaled up to support clinical studies for our lead programs in Non-Alcoholic Steatohepatitis (NASH) oncology and infectious diseases. You will report to the Director / Head of CMC and join an energetic and growing team at Glympse. The successful candidate will have a keen interest in analytical assay development, excellent communication skills and an interest in gaining cross functional skills in an innovative startup.

Responsibilities

- Facilitate short-term and long-range planning assay development and validation activities to support rapid expansion of the GBTS pipeline
- Works with Director of CMC using design of experiments (DOEs) approaches to support assay development, qualification and validation and performs analytical studies required to support product validation
- Develops new Standard Operating Procedures for laboratory test procedures. Maintains SOPs to assure constant compliance with corporate and future regulatory requirements.
- Facilitate tech transfer from Glympse Bio research teams of analytical assays and performs analysis to support the development of the GBTS for multiple analytes in biological samples using ELISAs, UV, FLR, HPLC and LC-MS/MS methods
- Identify gaps in assay development and validation activities, critical reagents, reference standards and goals for LOD/LOQ assessments
- Lead investigations related to atypical assay performance, identify critical components for optimization and ensure timely completion of activities
- Ensure cross functional teams (Regulatory, Biology, Chemistry) team members are aware of integrated project timelines, and provide timely updates with cross-functional impact
- Performs training on laboratory instrumentation for team-members in research positions and collaborates with them develop to best practices

- Maintains knowledge of current LDT and CLIA regulations, and provides instrument/software qualification, method validation, method verification and method transfer test support.
- Collaborates with Regulatory to support the assembling of supplemental information for regulatory submissions, stores data in LIMS / Benchling / electronic laboratory notebooks as needed.
- Makes and implements timely decisions within the established authority and consistent with company policies, procedures and practices.

Qualifications

Required Education & Experience

- PhD in Chemistry, Analytical Chemistry, Biochemistry or related discipline
- 2-5yrs of experience in developing, qualifying and validating assays in a regulated (CLIA / GMP / GLP) environment
- Experience in tech transfer of assays, and participating in program development activities
- Experienced with analysis of samples in biological matrices, troubleshooting assays, mapping out critical milestones for assay validation and executing with minimal oversight
- Experienced with statistical analysis of assay validation data using ICH and or CLIA guidelines, e.g. LOQ, LOD, precision, accuracy, system suitability, and data reporting using SAS, SPSS, JMP or other statistical software

Preferred Skills

- Ability to manage projects across multiple programs and execute assays across multiple technologies e.g. ELISAs, HPLC, UV, FLR, LC-MS/MS
- Keen interest in assay optimization with experience with Design of Experiments (DOE) approaches to validate assays
- Interest in continuous improvement, open mind and ability to communicate ideas clearly
- A creative self-starter with the ability to pre-empt problems, escalate issue quickly and troubleshoot with technical teams

Must be authorized to work in the US.

Additional information

Compensation & Benefits

Glympse Bio provides competitive compensation and benefits packages that support and reward the contributions of each member of the team.

About Glympse:

We are a dynamic and high energy team that is committed to pushing scientific boundaries in pursuit of our goals. We are creative, agile, resilient, and always have the 'courage to continue'. We work as a team, committed to each other's success, in an environment where every team member is important.

Website: www.Glympsebio.com

Glympse Bio is an Equal Opportunity Employer committed to a culturally diverse workforce. All qualified applicants will receive consideration for employment without regard to race; color; creed; religion; national origin; age; ancestry; nationality; marital, domestic partnership or civil union status; sex, gender, gender identity or expression; affectional or sexual orientation; disability; veteran or military status or liability for military status.