

Quality Lead

Glympse Bio is developing an innovative new paradigm to enable noninvasive and predictive monitoring of important human diseases. The company's technology uses precisely bioengineered sensors that interrogate the body for the presence of disease activity, and then carry the message to a patient's urine for analysis. Glympse Bio's platform technology was developed at the Koch Institute for Integrative Cancer Research at MIT by Dr. Gabe Kwong and Dr. Sangeeta Bhatia. This sensor paradigm has been published in leading scientific journals such as *Nature Biotechnology* and the *Proceedings of the National Academy of Sciences*, and broadly covered by the media including The Economist, BBC News, the Boston Globe, TED, and TEDMED.

Glympse Bio recently closed a \$22 million Series A financing co-led by Polaris Partners and Arch Ventures to expand its team, initiate clinical studies, and grow its pipeline. The company's lead program for the diagnosis and monitoring of Non-Alcoholic Steatohepatitis (NASH) is targeted to enter the clinic in early 2019, with multiple follow-on programs in the areas of cancer and infectious disease. Glympse Bio is a fast-paced, high-energy startup fueled by the vision of transforming disease diagnosis and monitoring of human health worldwide.

Glympse Bio is based at LabCentral, a life sciences laboratory incubator in Kendall Square in the heart of the innovation sector in Cambridge, MA. It is in close proximity to prestigious institutions like MIT, Harvard, Broad Institute, Whitehead Institute, and Draper Laboratory. LabCentral is home to 60 startups comprising 200 scientists and entrepreneurs, and offers first-class facility and personnel support for early-stage companies. LabCentral provides an intellectually stimulating and energetic environment to conduct innovative research.

Position Description

Glympse Bio is looking for an experienced and highly motivated Quality Lead to contribute towards the development of activity-based sensors in nonalcoholic Steatohepatitis (NASH), liver fibrosis, and liver cancer. This role will report directly to the Chief Development Officer, and will be directly responsible for all aspects of Glympse Bio's quality strategy.

Responsibilities

- Design, implement, manage and continuously improve Glympse's Quality Management System.
- Establish an effective network of consultants/auditors, and other resources to assist in ensuring all development activities performed by Glympse's staff, or on behalf of Glympse by Third Party Providers, are done with patient safety, data integrity and quality system and regulatory compliance in mind.
- Lead the quality system interactions between Glympse and its suppliers and guide the quality organizations within the company's CROs, CMOs and other outsourced and supplier relationships to achieve company goals. Maximize the use of external resources (CRO's, CMO's, etc.) and integration with internal domain expertise.
- Ensure GXP compliance.
- Maintain quality system and clinical records in a manner that will allow their use

in the various regulatory submissions that will be required for Glympse's products.

Qualifications

- A minimum of 10 years of experience in the Medical Device/Drug industry.
- Demonstrated success in the creation and management of a Quality System compliant with FDA Part 4 and ISO 13485 requirements.
- BS/MS/PhD in a science related field and/or have extensive Medical Device/Drug industry experience.
- Knowledge of In-Vitro Diagnostic (IVD) testing required, knowledge of UPLC/MS IVD measurements or Clinical Test Lab operations, preferred.
- Proven ability to lead key initiatives and motivate combined internal / external teams to work collaboratively to achieve objectives.
- Excellent project management skills.
- Ability to present effectively with internal and external audiences.
- Ability to make well founded recommendations to senior management.
- Demonstrated ability to build a highly productive, lean team that can effectively leverage external resources to achieve organizational and project objectives.
- A team player who collaborates cross-functionally, exercises influence at senior levels, and builds alignment around goals and objectives.
- Highly articulate and fluid communicator in both individual and group settings.

How to apply

Applications should include a curriculum vitae and cover letter to Glympse Bio at jobs@glympsebio.com. All questions and inquiries should be directed to the same email address. Glympse Bio is an Equal Opportunity Employer.