

Manager – Regulatory Affairs

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 Manager of Regulatory Affairs to contribute towards the development of activity-based sensors in nonalcoholic steatohepatitis (NASH), liver fibrosis, and liver cancer. This role will be responsible for leading combination product regulatory activities, including drug and device development, protocol reviews, clinical trials, and health authority correspondence and submissions. The candidate will have an opportunity work with a world-class R&D team to develop cutting-edge products to improve patient care.

Responsibilities

Your responsibilities will include the following:

- Provide regulatory interpretation, position and strategy for drug – device combination products, including development of constituent parts and clinical trials.
- Support drug and device development activities from a regulatory standpoint during early phase, development, clinical trials, submissions and post market requirements
- Support development of design control documentation and quality systems for combination products
- Support combination regulatory submissions, including collecting Health Authority (HA) feedback, IDE, CTA, BLA, NDA and PMA applications and MAA filings.
- Conduct HA correspondence on combination product topics and participate in HA meetings on this topic

Qualifications

- BS/MS in life science related field
- 10+ years of experience in a pharma/biotech/medical device regulatory affairs setting; RAC certification
- Expertise with combination products, including clinical trials, and design controls for device development; experience interacting with, managing and coordinating a wide variety of consultant experts
- Experience preparing combination product regulatory submissions to global health agencies
- Experience interacting with health authorities for combination products
- Human factors experience a plus
- Excellent oral communication and technical writing skills

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.