

Manager - CMC

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 CMC expert to join to contribute towards the development of activity-based sensors in nonalcoholic steatohepatitis (NASH), liver fibrosis, and liver cancer. This role will be responsible for driving CMC development of our programs and ensure a reliable supply chain for both preclinical and clinical development. Our noninvasive sensors are designed to provide physicians with accurate and predictive clinical data to transform the management and care of patients. This position provides the opportunity to lead the development of cutting-edge combination products with both drug and device development aspects.

Responsibilities

Your responsibilities will include the following:

- Work with Glympse Bio R&D staff and/or external consultants to transition manufacturing, analytical methods, and software into a reliable supply chain comprising both drug and device constituents that conforms with appropriate quality and regulatory standards
- Lead and manage GMP manufacturing and analytical development and validation at CRO/CMOs
- Manage and oversee stability studies for drug substance and drug product
- Design and implement formulation strategies to enable toxicology and clinical development of peptide-based sensors

- Lead and manage device-related CMC development for mass spectroscopy assay and commercial software
- Draft or review CMC sections of regulatory filings for both drug and device constituents

Qualifications

- BS/MS in chemical engineering, chemistry, or related field
- 5+ years of experience in a pharma/biotech/medical device industry setting
- Experience managing CROs and CMOs
- Experience with combination product development (quality and regulatory perspective)
- Familiarity with aspects of peptide CMC, including GMP production, analytical development and validation, and formulation development
- Familiarity with device CMC development, including design controls
- Excellent oral and written communication 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.