Manager/Senior Manager/Associate Director, Clinical Operations Job Description

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**Company Introduction:**

I-Mab Biopharma was formed by a 2017 merger between Third Venture Biotech (founded by Dr. Jingwu Zang, Tigermed and Bioscikin) and Tasgen Bio (founded by I-Bridge Capital, Tasly Shanghai and Genexine Inc.) in Shanghai, China. With the most innovative biologics R&D platform in China, I-Mab is positioned as a global player to develop the First-in-Class and Best-in-Class biologics in the areas of immuno-oncology and immuno-inflammation. I-Mab has adopted the dual-drive model of “Licensed-in advanced stage China Portfolio + In-house developed Global Portfolio”, and hence established a well-structured and risk-balanced pipeline. There are currently 16 projects under development, which includes potential First-in-China blockbuster drugs licensed-in from notable international pharmaceutical companies and global Best-in-Class & First-in-Class drugs developed independently. As of end of 2017, I-Mab has already launched a global phase II MRCT, and expected to initiate 1 phase III study, 3 phase II studies, 1 phase I study as well as 2 US IND filing drugs within the pipeline in 2018. Considering the quantity, quality and progress of its pipeline, I-Mab is now among one of the top innovative biopharmaceutical companies in China.

**Description:**

The US office will focus on the clinical development of I-Mab assets and look for collaboration and partnership opportunities in US. Under I-Mab US office, this role will be the operational lead of clinical trials (pre-IND through Phase 1-2) and will be the strategic partner to project clinical lead to develop the clinical operational strategy by providing operational input and design into the Clinical Development Plans. She/he will also implement program management principle through drug discovery to development process.

**Location:** Rockville, Maryland

**Responsibilities:**

* Lead the evaluation, selection and management of Contract Research Organizations (CROs) and other external vendors to ensure successful clinical trial implementation and execution;
* Manage day to day activities of all aspects of clinical studies including study plans, timelines, resources, problem identification and resolution, status reports and budget to ensure timely delivery of completed study reports to the project teams;
* Develop and ensure execution of activities outlined in various study plans (data management, safety management, risk mitigation, and study communication plans;
* You will be responsible for pipeline related business planning, timeline/resource/budget management, risk management, program/portfolio reporting;
* Maintain confluent information exchange flow and transparent team communications between China headquarter and US subsidiary;
* You will function as core team member in co-development programs, manage and align on cross-company activities and objectives;
* Manages external stakeholders including CROs, clinicians, CRAs, or statisticians when required by the project including selection, coordination of project specific training, payment and recruitment etc;
* Management of study staff including training in a metric setting;

**Qualifications:**

* Life sciences or medical background is required. Post graduate degree in life sciences highly preferred;
* Pharmaceutical industry experience is required; experience of CRA is highly desired;
* Skills in MS office is a must; Skills in MS project is preferred;
* The ability to work with cross-functional teams in a matrix environment is a must;
* Demonstrated ability to resolve conflict and influence teams without formal authority is required;
* Ability to speak and write in Mandarin is preferred.

Please send CV to Claire Xu, MD PhD, US Site Head of I-Mab Biopharma

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