Senior Manager of Analytical Validation / CMC Project Management

Background: Checkmate Pharmaceuticals, Inc. is a clinical stage company that is leveraging its expertise in the field of CpG oligonucleotides to discover and develop immunotherapies designed to increase the efficacy of existing immunotherapies and to provide new treatment options for patients and their healthcare providers. Checkmate's lead product candidate, CMP-001, is an investigational cancer immunotherapeutic that has been shown to reverse resistance to PD-1 therapy in some patients. Checkmate is a publicly held company headquartered in Cambridge, MA. Additional information regarding Checkmate is available at www.checkmatepharma.com.

Location: Cambridge, MA

Responsibilities may include:

- Manage and organize overall project timelines and activities across DS and DP with additional focus on specific vendor deliverables such as clinical resupply, process development tracking, pre-PPQ and PPQ planning
- Review, track, and manage all analytical method validation planning, development, qualification across all testing sites
- Effectively communicate project updates and coordinate with program management and across function groups to ensure CMC objectives are consistent with corporate goals
- Manage external vendor relationships and activities against analytical deliverables and CMC budget
- Author and review regulatory and study documents, protocols, and reports; interpret analytical data and participate in laboratory investigations as needed
- Generate high quality documentation to support regulatory filings and internal communications
- Responsible for ensuring all reports are approved and consistent with regulatory filing requirements
- Support the development of contract SOWs, team up with legal and finance to define scope and budget, facilitate the negotiation and execution of SOWs; track deliverables for invoicing/budget forecasting
- Effectively communicate with team members, senior leaders and key internal and external stakeholders on the status, objectives, risks, and mitigation plans associated with the various CMC projects

Qualifications:

- Bachelors with 8 years' experience, or Master's with 5-10 years' experience
- BS/MS in Chemistry, Biochemistry, Chemical Engineering, or closely related field.

- Expertise in widely used analytical methods, such as UV-spectroscopy, gas chromatography (GC), liquid chromatography (Ion Chromatography, UPLC, HPLC, prep-scale), mass spectrometry (MS), elemental impurities by ICP-MS, infrared spectroscopy (FTIR), Karl Fischer (KF), and wet chemistry techniques
- Excellent verbal and written communication skills with demonstrated technical writing ability, attention to detail and superior organization skills
- A strong knowledge of cGMP, ICH, FDA and regulatory guidelines
- Knowledge of USP and EP compendia for raw material and finished product testing
- Ability to work with minimal supervision and to set priorities to meet timelines
- Strong knowledge of Microsoft Suite, Project, and Veeva Vault

Candidates must be authorized to work in the U.S.
This is a full-time position and is eligible for company benefits.

Checkmate is an EEO employer

Send resumes to: careers@checkmatepharma.com