Manager, Stability & QC

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:

- Review and approve execution of QC tests as per batch records
- Creates, reviews and revises stability protocols and reports
- Coordinate stability testing schedules, maintain strong vendor relationships to ensure timely completion and reporting of results
- Reports stability data and performs trending and statistical analysis
- Perform QC testing and data review as needed to support product release and stability studies
- Author, review, and approve GMP documentation (SOPs, protocols, technical reports, test methods, protocols, specifications, and summary reports to support GMP manufacturing)
- Maintains an accurate inventory for all GMP Stability drug substance and drug products that are received, stored, and removed for testing
- Subject matter expert of applicable methods and assays, QC compliance, GMPs and applicable regulations and guidance
- Ensures timely submission of GMP-related documentation and archival
- Proactively identifies and analyses issues and coordinates potential resolution with the CMC or cross functional team
- Initiate workflows for protocol and report uploads/approvals in relevant electronic documentation systems

Requirements

- BS or equivalent and 6+ years or Master's
- Minimum 4 years laboratory experience in biotech industry
- Minimum of 2-3 years in Quality Control and/or Stability
- Biologics QC experience and technical knowledge
- At least 3-5 years' experience working in a GMP environment
- Experience authoring SOPs, stability protocols and reports as well as annual product performance reports

- Strong communicator and collaborator who possesses a flexible approach to problem solving and ability to apply risk-based decision making
- Strong knowledge of cGMP/ICH/FDA/EMA regulations
- Experience working with CROs, vendors, and relationship management
- Strong understanding of applicable regulations and guidelines pertaining to pharmaceutical product development, manufacturing, testing, and clinical operations
- Experience with Veeva, QMS and Quality Docs preferred
- Ability to Travel (approximately 20%)

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