# Job Posting

**Posting Date:** _23Mar2021__ **Internal Closing Date:** __02Apr2021___

**Salary Range: $__negotiable____** **Status:** ☒ **Exempt** ☐ **Nonexempt**

☒ **Full-time** ☐ **Variable Hour**

**Notes: Position posted on LinkedIn at:** https://www.linkedin.com/jobs/view/2476960945/

# CMC Project Manager

**Summary:** The CMC Project Manager is responsible for managing GMP pharmaceutical development projects for multiple therapeutic programs to meet development and delivery goals.

**Other Information:**

- Must be authorized to work in the US
- This position does not offer relocation assistance
- Ability and willingness to travel, including overnight

**Essential Duties and Responsibilities:**

- Utilizes project management techniques and tools to manage multiple project timelines, coordinate planning, preparation, and resources for CMC campaigns, evaluate timing, risks, and issue management, ensuring project deadlines and performance metrics are met
- Drafts (and/or may review/approve) SOPs, plans, policies and other documents in support of CMC activities
- Supports quality control oversight for pharmaceutical development drug substance (DS), drug product (DP), and clinical trial supplies (CTS) activities related to the release of products in accordance with all SOPs, cGMPs, company policies and procedures, and FDA requirements (e.g. review/approve batch records, release/reject API raw materials, intermediates, DS/DP and CTS, etc.)
- Reviews and may be responsible for approving all specifications and master production instructions
- Reviews and may be responsible for approving all procedures impacting the quality of intermediates, DS/DP and CTS
- Acts as unblinded sponsor representative collaborating with Clinical Development and contract manufacturing organizations (CMOs) for the manufacture, packaging, labeling, and blinding of clinical supplies, manages CTS shipping and returns; maintains CTS inventory system; unblinds clinical trials
- Conducts product quality reviews, manages quality incident investigations, deviations, corrective and preventive action (CAPA) plans; follows through and verifies effectiveness
- Conducts internal quality reviews to prepare for/support internal Quality Assurance (QA) department audits

- Vets and selects CMOs, including acting as subject matter expert (SME) for vendor assessments and quality audits (in collaboration with the QA department)
- Monitors CMOs, ensuring compliance of the manufacturing and packaging of pharmaceutical dosage forms and drug substances
- Acts as SME for reviewing and/or approving validation protocols and reports
- Ensures timely investigations, decisions, and resolution of critical/major deviations and final batch disposition
- Ensures quality-related complaints are investigated and resolved
- Proactively prevents compliance gaps and leads process improvement efforts within the following quality system functions: complaint investigation, change control, CAPAs, quality incident reporting, supplier quality, validations, risk management, and training
- Responsible for CMC document management, curating documents for operations, deviations, etc. and entry into file system and/or trial master files
- Utilizes technical expertise and writing skills, including reviewing various reports for content (as applicable), formatting issues, spelling/grammar errors, etc.
- Supports business development due diligence efforts

**Supervisory Responsibilities:**

Although this position does not have any direct reports, incumbent may be delegated responsibility for managing consultants, CMOs, and other vendors supporting the scope of PDQ activities.

**Education, Experience, and Other Requirements:**

- Minimum bachelor's degree in physical or life sciences, or equivalent experience is preferred
- Thorough knowledge of and experience working within cGMP regulations and knowledge of GCPs as they relate to CTS
- 5 years industry experience in drug development environment
    - Quality control and laboratory experience, including the following equipment: analytical testing equipment, high performance liquid chromatography (HPLC), dissolution, moisture KF-titration, UV spectrophotometer, solid dosage processing equipment, tablet press, capsule filling, granulation, and fluid bed instruments
    - Quality control for formulation development and analytical method development of different dosage forms
    - GMP CMC experience, including various delivery systems: e.g. nanotechnology, solid dispersions, spray drying, self-emulsifying solid dispersions, and liquid capsules
    - GMP CMC packaging and labelling experience
- Experience or familiarity within FDA regulated CMO environment, including manufacturing of DS/DP, labeling, CTS and/or commercial products
- Minimum 3 years project management experience
- Excellent communications skills and experience conducting meetings involving internal/external matrix teams
- Technical writing skills is a plus
- Familiarity with FDA submissions or experience with CMC submissions is a plus
- PMP certification is a plus
- Proven track record with a focus of meeting commitments, working collaboratively with cross-functional matrix teams, supporting teammates, solving problems, addressing risks before they become issues, and elevating issues that may negatively impact project goals
- Effective interpersonal skills; able to negotiate and build consensus for plans and priorities; demonstrated competence building strong working relationships with colleagues and stakeholders through collaboration
- Ability to motivate both individually and collectively

- Proficiency using Office 365 (Word, Excel, Project, Outlook), Acrobat Reader, and various internet browsers

*This job description is a summary and is not intended to be comprehensive in detail.*

Internal Number: 20210323