

Job Posting #: 0001
Job Title: Project Manager, CMC

Description:

The Project Manager, CMC is responsible for identifying, coordinating and executing tasks related to the effective organizational and tactical management of the supply chains supporting bioanalytical assay development and research mechanism of action studies, IND-directed nonclinical studies and human clinical trials. The scope of responsibilities may also include participation in the selection of contract manufacturing providers, managing outsourced activities at these contract organizations, the selection and employment of reagent suppliers, storage facilities and various other related service providers. This individual may also represent the CMC discipline in the various internal and joint development teams, as required.

Responsibilities:

1. Assist in the development of supply chain strategies for multiple products.
2. Assist in the execution of plans and strategies to meet CMC goals and objectives,
3. Assist in the management of internal and contract activities through use of project management processes (e.g. Gantt chart timelines, CMC plan templates, presentations, etc.)
4. Maintain cooperation and consensus among key internal and external participants and stakeholders involved in supply chain activities.
5. Maintain proactive communication with internal and external CMC stakeholders.
6. Help identify and clearly communicate emerging issues and risks to senior management in a timely manner.
7. Provide input in the development of supply chain budgets.
8. Provide diligent project management and oversight of CMC contractors, sub-contractors, and advisors.
9. Assist in communication with contract manufacturing and other supply chain providers.
10. Solve difficult problems that arise throughout the CMC development process.
11. Multi-task to effectively manage efforts on multiple projects.
12. Participate in the composition and review of proposed contracts, IND sections and other regulatory filings, and other documentation related to CMC.

13. Travel to contract organization sites as necessary to ensure coordination of project related activities.

Education/Experience:

1. BS/MS/Ph.D. in a scientific discipline, or equivalent combination of education and experience.
2. Intimate knowledge of biopharmaceutical manufacturing processes typically developed through a minimum of 10 years of progressive experience in a biopharmaceutical manufacturing environment, with at least 5 years in a hands-on role involving mammalian cell culture process development and production of development-stage protein therapeutics.
3. Fluent in applicable regulations (GLP and GMP, etc) and Guidance documents, and expert at developing compliance and quality strategies through the implementation of "best practices" for CMC.
4. Strong project management and interpersonal skills.
5. Excellent leadership, teamwork and organizational abilities.
6. Superior verbal and written communication skills; ability to effectively communicate cross functionally and at all levels.
7. Demonstrated commitment, tireless determination, and proactive persistence in driving successful project results.
8. Previous success in mentoring colleagues, nurturing team relationships, maintaining procedural and ethical standards, and cultivating a healthy and progressive team culture.
9. Proficient PC and MS Office skills.