



Title: CMO Project Manager

Location: Worcester, MA

Reports to: Head of Alliance and Program Management

Overview:

Knowledgeable and energetic professional with strong project and vendor management skills that enjoys working in a high energy, entrepreneurial environment. Manage relationships and execution of key CMO vendors entrusted with manufacturing vector and drug product on a commercial scale. The CMO project manager will ensure that CMO's develop detailed plans based on contractual commitments and that complementary plans are developed internally to enable strong vendor collaborations, seamless integration of shared activities, and flawless execution. This is a highly visible and critical role that offers a chance to make significant contributions to various development programs.

Specific Responsibilities:

- Act as point of contact for active CMOs under contract
- Pressure-test external CMO plans to ensure completeness and appropriate risk mitigations
- Serve as internal vector and cell processing SME to ensure RFPs lead to comprehensive and fit-for-purpose CMO contracts
- Serve as internal SME for CMO contracts, vendors and commitments
- Lead internal activities for change controls related to CMOs
- Project manage internal commitments generated by CMO activities, proactively identify risk and resource issues, follow up and follow through on all outstanding actions to keep CMOs on schedule
- Provide CMC and Program Management leadership with frequent status updates
- Identify key decision points and partner with CMC and Program Management leadership with frequent status updates
- Chair internal cross functional meetings to ensure alignment between internal and external CMO project plans
- Optimally utilize project management tools and offer continuous improvement solutions

Qualifications and Experience:

- BS/BA degree in a scientific discipline or health sciences with a demonstrated track record of success
- 5+ years of experience in bio pharmaceutical gene and cell therapy manufacturing
- Knowledge with advanced understanding of CMO/CTO business and technical processes
- Knowledge with advanced understanding of other functions including, but not limited to: Research, Pre-Clinical, Regulatory, Clinical, Process Development, Manufacturing and Operations, and Commercial
- Knowledge of Good Manufacturing Practices and Product Development Process requirements
- Knowledge of applicable quality and regulatory standards requirements for pharmaceutical industry
- Experience in oncology and rare disease development a plus
- PMP certification desired
- Strong organizational and interpersonal skills
- Strong planning and execution skills
- Strong negotiation skills
- Strong critical thinking/problem-solving skills
- Strong written and oral communication skills
- Demonstrated competencies in all aspects of planning and project management