Company Information

Castle Creek Biosciences is a privately held company that develops and commercializes gene therapies for patients with rare and serious genetic diseases. The company's lead gene therapy candidate, FCX-007, is being evaluated for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), the most severe and debilitating form of epidermolysis bullosa (EB). The company is also advancing clinical research evaluating a diacerein topical ointment, CCP-020, for the treatment of epidermolysis bullosa simplex (EBS) and other forms of EB. In addition, Castle Creek Biosciences is developing FCX-013, a gene therapy for the treatment of moderate to severe localized scleroderma. Castle Creek Biosciences is a portfolio company of Paragon Biosciences. For more information, visit castlecreekbio.com or follow Castle Creek on Twitter @CastleCreekBio.

Job Description

Job Title: **Sr. Director Tech Ops Program Strategy and Management**
Reports to: **CTO**
Group/Division: **Manufacturing**
Position Location: **Exton, PA**
Exempt/Non-Exempt: **Exempt**

General Responsibilities:

The Sr. Director will be responsible for the integration, creation, and execution of multiple complex CMC development plans. Partner with project teams and Technical Operations function to drive planning, risk management, scheduling, and budgeting to ensure goals are achieved. Manage interfaces with contract organizations and external collaboration partners using strong partnership and teamwork, progressing activities as planned and on schedule Identifies key goals and supports development of CMC strategies and methodologies with input from internal stakeholders Partners with CMC teams to establish, implement, and maintain high-quality detailed project plans while collaborating with other internal functions such as Non-clinical, Clinical, Regulatory Affairs and Cell Manufacturing as needed.

Responsibilities:

- Develops detailed CMC project timelines, performing critical path analysis and supporting scenario planning for CMC deliverables
- Ensures integration of CMC activities into overall program plan, monitoring project deliverables and ensuring tasks are on track
- Establish, implement, and manage CMC risk management process (strategic, execution, quality, safety, environmental, etc.) and works collaboratively to develop contingency/mitigation plans to keep projects on track while resolving CMC team challenges
- Prepares high quality presentations in partnership with CMC teams for communication with internal and external stakeholders, ensuring transparent communication of activities and status within CMC teams, program teams, and key stakeholders
- Supports development and adherence to CMC project budgets through pro-active identification and resolution of any program, project, or resource issues
- Ensures development and implementation of effective processes and innovative solutions to support efficiencies in the management of projects
- Establish, implement, and manage project management systems to support high performing CMC project teams Facilitate effective meetings, preparing clear agendas & minutes, fostering robust communication, resolving conflicts, clarifying meeting objectives and ensuring desired outcomes.

- Strategically develops CMC plans, goals, and logistics for projects, gaining cooperation and consensus
- Work independently and with the team to develop a cross-functional development plan from current stage through product launch.
- Work in close support of the Team Project Managers
- In coordination with the Team Project Manager, regularly interacts with functional areas beyond CMC, such as Regulatory, Quality, Supply Chain, Technical Operations, CDMO's and Clinical
- Manage the execution of CMC deliverables, both short and long-term, via clearly defined milestones, and timelines. Minimize timeline deviations by clearly identifying program risks and communication of strategies.
- Working with Project Management and CCB leadership, build and sustain robust business processes to support cross-functional clinical trial execution.
- Proactively communicate key issues and any other critical topics in a timely manner to the appropriate management level and/or to any other relevant project team member(s).
- Facilitate regular CMC project team meetings, issue written minutes, and follow up on action items.
- Maintain overall project dashboard, schedule, budget, project plans, operational plans, and routine reports to sponsors and stakeholders.
- Represent company to external partners groups as required

Computer Skills:

- To perform this job successfully, an individual should have knowledge of Database software; Project Management software; Spreadsheet software and Word Processing software. It is critical that the candidate have significant experience in Microsoft Project and the use of Gantt charts**.**

Education:

- BS/MS in Molecular, Cellular Biology, virology, immunology or related discipline; PhD Preferred.

Experience:

- B.S./M.S. with 8 plus years of relevant biotech/pharmaceutical development or project management work experience
- 2+ years of demonstrated project management and change management experience in a clinical pharma/biotech setting.
- Experience in either preclinical or early clinical phase company with hands on experience in GXP/GMP environment.
- Strong technical knowledge of CMC development, CMC Regulatory Affairs, Quality, cGMP requirements, and Biotech Operations CMC technical and project management experience with biologics and combination products is required
- Strong interpersonal skills to elicit, synthesize, and manage the cross-functional inputs required for a robust development plan.
- Ability to communicate effectively with a diverse range of scientists, physicians, engineers, regulatory specialists and business professionals.
- Entrepreneurial spirit with a team attitude, demonstrated leadership skills and an ability to integrate across all company projects.

Disclaimer:

This position description is written as a guideline to inform Castle Creek Biosciences Employees of what is generally expected of them at each job level. The description is not intended to be all encompassing or limiting in any manner; rather, it is hoped it will add understanding and better reflect the work performed at all

levels of employment within Castle Creek Biosciences. Duties and responsibilities other than those listed may be included as needed within the work group or the company.