**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**

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| **Job Title:** | **Assistant Vice President of Manufacturing** |
| **Reports to:** | **CTO** |
| **Group/Division:** | **Manufacturing** |
| **Position Location:** | **Exton, PA** |
| **Exempt/Non-Exempt:** | **Exempt** |

**General Responsibilities:**

This position will lead the GMP readiness activities for manufacturing area start-up and new product introduction. Develop and execute the clinical manufacturing plan aligned with clinical supply forecasts ensuring effective capacity and resource management and consistent performance to plan. Collaborate with process development and analytical sciences to develop and transfer new products to manufacturing.

**Responsibilities:**

- Lead the manufacturing organization, including cell and viral manufacturing at Castle Creek Biosciences Exton, PA facility.
- Lead GMP readiness activities for manufacturing area start-up and new product introduction. Develop and execute the clinical manufacturing plan aligned with clinical supply forecasts ensuring effective capacity and resource management and consistent performance to plan.
- Collaborate with process development and analytical sciences to develop and transfer new products to manufacturing.
- Partner with Regulatory and assist in the preparation of global regulatory filings and serve as a key subject matter expert during regulatory interactions.
- Develop and maintain operating procedures and policies in accordance with Current Good Manufacturing Practices. Build and develop a best-in-class, high-performance organization.
- Provide effective leadership to the team and associated functions to ensure the execution of objectives and the development of employees.
- Develop a training program for manufacturing staff to ensure team members have a clear understanding of manufacturing & compliance procedures and the science behind the procedures.
- Partner with internal product development teams and external collaborators to develop and commercialize T cell product candidates.
- Develop and manage operational budgets and capital plans in support of company and departmental objectives.

- Work with Supply Chain and Engineering to develop long range capacity and facility master plans consistent with the company's long -range strategic plan.
- Drive the implementation and adoption of digital manufacturing operations management software to drive efficient
- Drive an operational excellence culture with a focus on continuous improvement, right-first time and mistake-proofing principles, and lean implementation.
- Ability to be highly productive in a fast -paced, cross functional team-oriented work environment.
- Proven ability to be a self-starter, who effectively plans, organizes and executes to meet key deliverables.
- Develops, identifies, and modifies new and existing formulations, technologies, and platforms for improved performance and/or cost reduction.
- Ensures budgets, schedules, and performance requirements are met.
- Interacts internally and externally with executive-level management requiring negotiation of difficult matters to influence policymaking bodies both internally and externally.
- Willingness to fully engage with a high energy team in pursuit of organizational goals and strategies.
- Ability to prioritize and successfully execute multiple tasks simultaneously.
- Willingness to offer full accessibility and thrive within a transparent work environment.
- Ability to maintain confidential information with a high regard for integrity.
- Ability to work independently and as part of a team.

**Computer Skills:**

- To perform this job successfully, an individual should have knowledge of Database software, Spreadsheet software and Word Processing software.

**Education:**

- Ph.D. in cell culture engineering, cell biology, or equivalent field

**Experience:**

- At least 10 years of experience in implementing cell culture systems for cGMP manufacturing Demonstrated experience in scaling cell culture processes beyond the bench-scale into large production scale (multi-1000L)
- Experience with commercial cell culture systems, including single use bioreactors, commercial media formulations, and high cell density cell handling systems.
- Experience in tech transfer and scale up of cell culture systems from pilot to production scale, including transfer to various Contract Development and Manufacturing Organizations (CDMOs)
- Experience establishing and maintaining robust PPQ and process control strategies. Several years leading and managing a team of dedicated scientists and technicians
- Strong cross functional leadership skills including refined verbal and written communication skills Strong engineering skills, including facility fit and process engineering assessment into different facilities.
- Experience with allogeneic or autologous cell therapy
- Experience with complex regulatory filings, including initial BLA and post-approval regulatory activities.