## 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 Process Sciences** |
| **Reports to:** | **CTO** |
| **Group/Division:** | **Manufacturing** |
| **Position Location:** | **Exton, PA** |
| **Exempt/Non-Exempt:** | **Exempt** |

**General Responsibilities:**

The individual will be responsible for transfer, refinement, and development of our cell therapy products. The position includes vector construct development, product characterization and assay development, and participation in bioanalytical testing and validation activities. The Assistant Vice President of Process Sciences is responsible for optimization of upstream and downstream processes and technology transfer to manufacturing; transfer work will involve support as an SME for manufacturing activities. Responsible for the necessary support and documentation required by FDA regulations. This position provides direction and is responsible for developing, maintaining, and improving cell therapy and cell culture methods and processes.

**Responsibilities:**

- Manage lentiviral process development for pre-clinical and clinical candidates and optimize manufacturing processes for both in-house and tech transfer needs.
- Lead process development strategy and execution for gene-edited ex-vivo cell therapy products for rapid transition of early-stage candidates into the clinic.
- Partner closely with Castle Creek Biosciences' research partners to guide process development programs to ensure a streamlined and feasible product development transition.
- Manage technology transfer strategy, protocol development and establish acceptance specifications for transition to GMP facilities for all CMC activities with ability to travel for in-person and in-plant interactions.
- Provide oversight and technical support to the clinical manufacturing programs. Define and build an effective team to oversee process development/transfer and in-house manufacturing oversight through personal leadership, and direct reports.
- Author and review CMC content for IND submissions for clinical trials. Collaborate with other departments to identify efficiencies needed to meet critical corporate objectives, encompassing the area of viral vector, and engineered T cell manufacturing.
- Define departmental goals and manage experimental programs to align with corporate goals. Determine and manage departmental yearly budget.

- Drives and participates in technology development in cell engineering and cell characterization. Developing methodologies to assess cell line according to project specifications. Ensuring cell products meets product quality criteria.
- Develops and validates bioassay methods including cell-based bioassays, binding assays such as ELISA and whole cell immunoassay by flow cytometry, gene expression analysis, and other applicable methods as deemed necessary.
- 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 Biology, Immunology or Virology is preferred.

**Experience:**

- Ph.D. in Cell Biology, Immunology or Virology is preferred with a minimum of 10-12 years post-graduate experience in an industrial setting.
- Possesses expert knowledge of scientific principals and concepts in fields of cell therapy, molecular biology, and cell engineering and has extensive experience with multiple techniques in these fields as documented by publications.
- Ph.D. in Cell Biology, Immunology or Virology is preferred.
- A minimum of 10-12 years post-graduate experience in an industrial setting. functional teams through to successful INDs.
- Biotech experience is strongly preferred with a focus on cell and gene therapy, virology, or biologics. Previous experience with development and manufacture of viral vectors and engineered T cells is strongly preferred.
- Ability to adapt and thrive in a dynamic and entrepreneurial early-stage environment. Superior personnel management and organizational skills.
- A scientifically motivated self-starter, capable of independently conceiving, conducting, and critically analyzing his/her own work with minimal supervision.
- A strong presenter and communicator, with the ability to work in a fast-paced and team-oriented environment.
- Understanding and experience of what it is like to work in a small company start-up.
- Excellent oral and written communication skills while continually demonstrating high levels of interpersonal versatility within diverse populations.
- Strong strategic, analytical and critical thinking skills.
- Ability to build relationships and establish credibility appropriately.

- Self-reliant and results oriented. Drive balanced with patience.
- Exceptional leadership and role modeling skills.