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:	**Principal Scientist- Process Development**
Reports to:	**Assistant Vice President Process Sciences**
Group/Division:	**Manufacturing**
Position Location:	**Exton, PA**
Exempt/Non-Exempt:	**Exempt**

General Responsibilities:

The Principal Scientist-Process Development will lead the development projects to improve yield and quality of cell and gene therapy products in the pipeline. The candidate will lead and support different product including cell therapy and viral vector manufacturing. He/she will lead development projects to improve understanding of impact of culture and process conditions on product attributes. He/she will collaborate with cross-functional groups.

Responsibilities:

- Design and execute process development, optimization and scale-up of production processes using sound scientific principles and statistical approaches (DoE)
- Spearhead the development, evaluation and implementation of novel expansion and automation strategies for cell and gene therapy products
- Conduct statistical data analysis and provide critical review of results
- Apply innovative technologies to enhance viral vector and cell culture productivity and quality.
- Participating in strategic program discussions and providing high quality data driven decision making in collaboration with MSAT to define and identify critical process parameters
- Oversee the initial technical transfer of specific Process Development protocols to manufacturing team
- Serve as a subject matter expert, author technical reports and relevant sections of CMC documentation in support of regulatory submissions and amendments.
- Prepare and review vector construct and characterization report as supporting documents for Regulatory Filings
- Develop and/or update process protocols, SOP, and batch records
- Willingness to fully engage with a high energy team in pursuit of organizational goals and strategies.
- Excellent problem solving and troubleshooting skills
- Ability to prioritize and successfully execute multiple tasks simultaneously.
- Willingness to offer full accessibility and thrive within a transparent work environment.
- Ability to work independently and as part of a team.

Education:

- Ph.D. in Biochemical, Chemical, or Biomedical Engineering or relevant scientific background is preferred.

Experience:

- Ph.D. in Biochemical, Chemical, or Biomedical Engineering or relevant scientific background with a minimum of 5 years post-graduate experience.
- Experience with viral vector process development is required.
- Experience in cell culture materials, technologies and unit of operations (bioreactor systems) at multiple scales.
- Direct experience of viral vector purification techniques (chromatographic and filtration methods)
- Solid understanding and experience analytical assays use to characterize gene and cell therapy products
- Must be detail oriented, self-motivated, flexible, and able to prioritize and manage several fast-paced projects concurrently
- Outstanding verbal and written communication skills for technical and non-technical audiences
- Demonstrated ability to work in cross-functional teams as a strong team player as well as independently

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.