



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- Analytical Development
Reports to:	Assistant Vice President Process Sciences
Group/Division:	Manufacturing
Position Location:	Exton, PA
Exempt/Non-Exempt:	<u>Exempt</u>

General Responsibilities:

The Principal Scientist-Analytical Development will lead and implement analytical method development, transfer, improvement and troubleshooting for cell and gene therapy products. He/she will lead drug product formulation evaluation to maintain quality attributes and increase stability. The incumbent will apply and incorporate novel methodologies to improve efficiencies and enhance understanding of company product pipelines.

Responsibilities:

- Design, develop, and execute analytical methodologies and qualification for cell and gene therapy programs and ensure phase appropriate analytical strategy is applied
- Improve efficiencies by incorporating and applying state-of-the-art analytical techniques to strengthen drug product understanding.
- In collaboration with Process Development will design and execute formulation screening to enhance stability of products
- Define and execute strategies for effective use of methodologies for cellular and viral release, stability, and characterization.
- Serve as a subject matter expert, author technical reports and relevant sections of CMC documentation in support of regulatory submissions and amendments.
- Develop and/or update process protocols, SOP, and testing result forms
- 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 Biochemistry, Cell and Molecular biology or relevant scientific

Experience:

Castle Creek Biosciences is an Equal Employment Opportunity Employer



- Ph.D. in Biochemistry, Cell and Molecular biology or relevant scientific background with a minimum of 5 years post-graduate experience.
- Comprehensive experience with cell- and molecular-base analytical assays/techniques for cell and gene therapy.
- Functional knowledge of cell culture and method robustness
- Understands and applies Quality by Design principles.
- 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.

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