



Company Information

Castle Creek Biosciences (“Castle Creek”) 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). In addition, Castle Creek is developing FCX-013, a gene therapy for the treatment of moderate to severe localized scleroderma. Castle Creek is a portfolio company of Paragon Biosciences. For more information, visit castlecreekbio.com or follow Castle Creek on Twitter @CastleCreekBio.

Job Description

Job Title:	Quality Control Analytical Associate
Reports To:	QC Supervisor
Group/Division:	Quality Control
Position Location:	Exton, PA
Number of Direct Reports:	0
Day/Shift (if applicable):	
Exempt/Non-Exempt:	<u>Exempt</u>

General Responsibilities:

Performs testing in support of product manufacturing, employing manual and automated analytical equipment for cell count and cell viability testing, cell identity, endotoxin testing, collagen content determination and sterility testing.

Responsibilities:

- Execute Analytical Test Methods for bulk intermediate testing and final product release testing
- Execute testing for raw materials
- Author and revise QC SOPs and ATMs as necessary to maintain compliance
- Review of Quality Control raw data for accuracy, completeness and compliance with effective SOPs to ensure the strength, identity, safety, purity and quality of the product
- Timely response to Out Of Specification (OOS) results, including notification to area supervision
- Communicate with the individual Operations Departments (Manufacturing, Quality Assurance, Facilities) to ensure that Company objectives are met on schedule
- Maintain housekeeping in the laboratories
- Assist the Quality Control Supervisor in daily operations, as needed
- Perform Growth Promotion testing on prepared media
- Direct Sterile Media Fill Trials and perform support testing
- Authoring and/or executing protocols and generating technical reports
- Analytical method validation
- Equipment qualification
- Training of other employees
- Completion of thorough Laboratory Investigation Reports (LIRs) to ensure that potential problems and root causes are identified, impact assessed and actions to prevent recurrence are considered and implemented

Computer Skills:

Castle Creek Biosciences is an Equal Employment Opportunity Employer



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

Education:

- Minimum Bachelor of Science degree in a scientific discipline

Experience:

- 3-5 years Quality Control experience in a similar role in the biologics or pharmaceutical industry
- 2-3 years experience in mammalian cell culture in an academic or industrial laboratory
- Knowledge of basic laboratory skills (aseptic technique, etc.) are required
- Knowledge of Current Good Manufacturing Practice and Industry standards
- Familiarity with analytical equipment including UV absorbance plate readers, Flow cytometers, microscopes and pH meters
- Experience in aseptic processing and mammalian cell culture production
- Excellent verbal and written skills
- Good interpersonal communication skills
- Must be open to occasional off shift and weekend work

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 as a whole.

The above information is for exclusive use within. Castle Creek Biosciences and may not be used or duplicated by others without written consent.

**Position Description and Essential Job Functions
Applicant Review**

Please read and sign after reviewing the Position Description and Essential Job Functions.

I have the ability to perform the essential functions of this position with or without reasonable accommodation.

Printed Name: _____

Signature: _____

Date: _____