



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 Assurance Manager
Reports To:	VP Quality Operations
Group/Division:	Quality Assurance
Position Location:	Exton Pa.
Number of Direct Reports:	
Day/Shift (if applicable):	
Exempt/Non-Exempt:	<u>Exempt</u>

General Responsibilities:

Responsible for monitoring and improving upon the quality of manufactured products. Measures, evaluates and applies the disposition of manufactured Bulk Drug Substance and Drug Product Injection lots, including generation of Certificates of Analysis.

Responsibilities:

- Supervise a staff of QA Specialists
- Track Bulk Drug Substance record review and disposition lifecycle
- Direct employees by assigning and maintaining timelines for product disposition
- Review of Quality Control testing data against established specifications
- Review and approval of Protocols and General Technical Reports
- Review and approval of Disruption to Controlled Environment (DCE), including data compilation
- Review and approval of Raw Material Specification (RMS) revisions
- Author Change Controls
- Raise critical quality issues to upper management
- Write and revise Quality Systems SOPs as necessary to maintain compliance
- Verification of associated Quality documentation, as needed, ie, issuance of Batch Records, labels, etc.
- Training of employees and management of validated training system
- Assist Quality Assurance Management in daily operations, as needed

Computer Skills:

- 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:

Castle Creek Biosciences is an Equal Employment Opportunity Employer



- Minimum five years of Quality experience in the biologics or pharmaceutical industry
- Experience supervising QA staff
- Excellent knowledge of CGMP guidelines, 21 CFR Parts 210 and 211 and other regulatory standards
- Writing experience in a similar role in the biologics or pharmaceutical industry
- Experience in aseptic processing and/or mammalian cell culture production considered a plus
- Flexibility and ability to adjust to changing priorities and unforeseen events using excellent time management skills
- Ability to execute multiple tasks
- Ability to work with a high degree of accuracy and detail
- Positive work attitude that supports teamwork and continuous improvement

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: _____