



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:	Quality Assurance Specialist
Reports To:	Associate Director, Quality
Group/Division:	Quality Assurance
Position Location:	Exton, Pa
Number of Direct Reports:	0
Exempt/Non-Exempt:	<u>Exempt</u>

General Responsibilities:

Quality Assurance is a service group to the Operational Departments of Manufacturing, Quality Control and Facilities. The Quality Assurance Specialist interacts with each group to ensure accurate and compliant release of intermediates and final product.

Responsibilities:

- Review of Manufacturing Batch Record documentation for accuracy, completeness and compliance with effective SOPs to ensure the strength, identity, safety, purity and quality of the product
- Review and disposition of manufactured Bulk Drug Substance and Drug Product Injection lots
- Review of Quality Control testing data against established specifications
- Quarantine and Final Disposition of raw materials to Manufacturing and Quality Control
- Receipt of Quarantine Bulk Drug Substance vials for storage and distribution of Bulk Drug Substance vials for testing and/or manufacture
- Packaging of Biopsy Kits for shipment
- Packaging of final product for shipment
- Assist the Quality Assurance Management in daily operations, as needed
- Conducting Quality on the Floor audits within the Aseptic Processing Area (APA)
- Establish and monitor Quality Assurance programs and procedures to ensure compliance
- Write and revise Quality Systems SOPs as necessary to maintain compliance
- Training of other employees
- Conducting deviations and investigations through the use of problem solving tools

Computer Skills:

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

Castle Creek Biosciences is an Equal Employment Opportunity Employer



Education:

- Minimum Bachelor of Science degree in a scientific discipline
- Minimum two years in a similar role in the biologics or pharmaceutical industry a plus
- Familiarity with Batch Records and controlled documentation
- Experience in aseptic processing and mammalian cell culture production considered a plus

Experience:

- Detail oriented
- Excellent verbal and written skills
- Good interpersonal communication skills
- Must be open to occasional off shift and weekend work
- Positive work attitude that supports teamwork and continuous improvement