Castle Creek Biosciences

Company Information

Castle Creek is a privately held holding company that holds and invests in companies in areas of unmet medical need such as rare genetic diseases. The company, through its subsidiaries Fibrocell Science, Inc. and Castle Creek Biosciences, LLC, develops and commercializes gene therapies for patients with rare and serious diseases of the skin and connective tissue with high unmet need. 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 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 Supervisor/Manager**
Reports to:	**Director of Quality**
Group/Division:	**Quality Control**
Position Location:	**Exton, PA**
Number of Direct Reports:	
Day/Shift (if applicable):	
Exempt/Non-Exempt:	**Exempt**

General Responsibilities

Provides leadership to QC Operations to ensure that QC processes are optimized and managed efficiently in the laboratories, including cell count, cell viability, purity, collagen content, sterility, endotoxin, Gram stain and environmental monitoring.

Specific Responsibilities

- Manage QC Analysts and EM staff
- Establish and monitor Quality Control programs and procedures to ensure compliance with compendial standards
- Provide direct support of all compliance requirements of CGMP standards and FDA regulations involved in the manufacturing processes of a biological product
- Write and revise Quality Control SOPs and ATMs as necessary to maintain compliance
- Training and development of employees
- Development of goals for direct reports
- Conduct yearly performance reviews of employees, monitoring progress toward objectives
- Ensure full compliance with applicable health and safety regulations (OSHA) is achieved and maintained
- Assist in hosting inspections related to GMP and/or Quality Control
- Assist the head of Quality in daily operations, as needed

- Execution of Analytical Test Methods for bulk intermediate testing and final product release testing
- Execution of testing for raw materials
- Review of all 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
- 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
- Maintaining the viable and non-viable Environmental Monitoring Program, ensuring monthly trend analysis and yearly evaluation of alert and action levels, as compared to historical data and compendia standards
- Ensuring adequate and complete Installation/Operation/Performance Qualification for laboratory equipment
- Ensuring all method validation is current
- Maintaining traceability of sample management within the laboratory and establishing testing priority of samples
- Performance of internal audits to ensure compliance with CGMP's
- Housekeeping of the laboratories

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/Experience

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- Minimum Bachelor of Science degree in a scientific discipline
- Minimum 7 years Quality Control experience, with a minimum of 3 years of Management experience in a similar role in the biologics or pharmaceutical industry
- Excellent knowledge of CGMPs guidelines, 21 CFR Part 11 and other regulatory standards

Ability and/or Skills

- Excellent verbal and written skills
- Ability to execute multiple tasks
- Good interpersonal communication skills and managerial background

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.