**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**

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| **Job Title:** | **Validation Specialist** |
| **Reports To:** | **Quality Associate Director** |
| **Group/Division:** | **Quality Assurance** |
| **Position Location:** | **Exton, Pa** |
| **Number of Direct Reports:** | **0** |
| **Exempt/Non-Exempt:** | **Exempt** |

**General Responsibilities:**

Validation is a service group to the Operational Departments of Manufacturing, Quality Control and Facilities. Validation includes oversight, leadership and management of Castle Creek Biosciences validation program, including process validation, facility and utility qualification, equipment qualification and computer systems validation.

**Responsibilities:**

- Author/review technical protocols and final reports
- Implement and track site equipment requalification program
- Take the initiative to create and implement the site validation strategies
- Develop systems to monitor and ensure validated state is maintained for key processes and systems
- Remain knowledgeable and current on manufacturing processes, quality systems and relevant GMP related to validation
- Maintain current knowledge of industry standards and regulatory expectations
- Provide subject matter expertise for overall validation program during regulatory and partner inspections
- Alert senior management to any validation issues related to GMP, product quality or patient safety
- Support regulatory filings and interact with FDA or other regulators regarding validation topics
- Identify gaps in systems and develop feasible plans for correction
- Work to ensure compliance with internal policies and procedures, and industry guidance's and regulations, such as 21 CFR Parts 11, 210 and 211, and 600

**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
- 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
- Excellent leadership, technical, management, problem solving and project management skills
- Ability to comprehend technical information related to facilities, utilities, equipment, processes, computer validation, scientific approaches and regulatory expectations

**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

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.