FIBROCELL

Company Information

Fibrocell Science, Inc. (NASDAQ: FCSC) is an autologous cell and gene therapy company translating personalized biologics into medical breakthroughs for diseases affecting the skin and connective tissue. Fibrocell's most advanced product candidate, FCX-007, is the subject of a Phase 1/2 clinical trial for the treatment of recessive dystrophic epidermolysis bullosa. Fibrocell is also developing FCX-013, the Company's clinical stage candidate for the treatment of moderate to severe localized scleroderma. Fibrocell's gene therapy portfolio is being developed in collaboration with Intrexon Corporation (NYSE: XON), a leader in synthetic biology. For more information, visit www.fibrocell.com or follow Fibrocell on Twitter at @Fibrocell.

Job Description

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 Fibrocell's 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 GxP, 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 guidances 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 Fibrocell 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 Fibrocell. Duties and responsibilities other than those listed may be included as needed within the work group or the company as a whole.