# Company Information

# Fibrocell Science, Inc. (Nasdaq: FCSC) is an autologous cell and gene therapy company translating personalized biologics into medical breakthroughs. Fibrocell’s most advanced product candidate, azficel-T, uses its proprietary autologous fibroblast technology and is in a Phase II clinical trial for the treatment of chronic dysphonia resulting from vocal cord scarring. In collaboration with Intrexon Corporation, a leader in synthetic biology, Fibrocell is also developing gene therapies for skin and joint diseases using gene-modified autologous fibroblasts. Fibrocell is in preclinical development of FCX-007, its orphan gene-therapy product candidate, for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). Fibrocell is also in preclinical development of FCX-013, its gene-therapy product candidate, for the treatment of linear scleroderma. In addition, Fibrocell and Intrexon will be commencing preclinical development of a gene-therapy for the treatment of chronic inflammatory and degenerative diseases of the joint, including arthritis and related conditions. For more information, visit [www.fibrocell.com](http://www.globenewswire.com/newsroom/ctr?d=10133469&l=16&a=www.fibrocellscience.com&u=http%3A%2F%2Fwww.fibrocellscience.com%2F).

# Job Description

**Job Title: Quality Control Analytical Associate**

Reports To: Quality Control Supervisor

Group/Division: Quality Control

Position Location: Exton, PA

Number of Direct Reports: 0

Day/Shift (if applicable):

Exempt/Non-Exempt: Exempt

**General Responsibilities:**

Performs testing in support of product manufacturing, employing manual and automated analytical equipment for cell count and cell viability testing, cell identity, endotoxin testing, collagen content determination and sterility testing.

**Responsibilities:**

* Execute Analytical Test Methods for bulk intermediate testing and final product release testing
* Execute testing for raw materials
* Author and revise QC SOPs and ATMs as necessary to maintain compliance
* Review of 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, including notification to area supervision
* Communicate with the individual Operations Departments (Manufacturing, Quality Assurance, Facilities) to ensure that Company objectives are met on schedule
* Maintain housekeeping in the laboratories
* Assist the Quality Control Supervisor in daily operations, as needed
* Perform Growth Promotion testing on prepared media
* Direct Sterile Media Fill Trials and perform support testing
* Authoring and/or executing protocols and generating technical reports
* Analytical method validation
* Equipment qualification
* Training of other employees
* 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

**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:**

* 3-5 years Quality Control experience in a similar role in the biologics or pharmaceutical industry
* 2-3 years experience in mammalian cell culture in an academic or industrial laboratory
* Knowledge of basic laboratory skills (aseptic technique, etc.) are required
* Knowledge of Current Good Manufacturing Practice and Industry standards
* Familiarity with analytical equipment including UV absorbance plate readers, Flow cytometers, microscopes and pH meters
* Experience in aseptic processing and mammalian cell culture production
* Excellent verbal and written skills
* Good interpersonal communication skills
* Must be open to occasional off shift and weekend work

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.

The above information is for exclusive use within. Fibrocell Science 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: