



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](https://twitter.com/Fibrocell).

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.

Fibrocell 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