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 RDEB. Fibrocell is also developing FCX-013 for the treatment of moderate to severe localized scleroderma and is currently enrolling the Phase 1 portion of a Phase 1/2 clinical trial. For more information, visit www.fibrocell.com or follow Fibrocell on Twitter at @Fibrocell.

Job Description

Job Title:	**Regulatory Affairs Specialist**
Reports to:	**Director, Regulatory Affairs**
Group/Division:	**Clinical**
Position Location:	**Exton, Pa**
Number of Direct Reports:	**0**
Exempt/Non Exempt:	**Exempt**

Primary Responsibilities:

Responsible for the day-to-day activities and delivery of Regulatory Affairs support services. Role includes management of Regulatory Files (e.g. IND, BLA) and research, review and communication of applicable regulations and guidance documents. The Regulatory Affairs Specialist will also be responsible for developing tools for tracking information, documentation of regulatory activities, and providing Regulatory Affairs support to other Functional Units as needed.

General Responsibilities

- Prepare or assist with the preparation of regulatory documents for submission to Regulatory Agencies, including writing, publishing, and correct placement in eCTD hierarchy
- When necessary work with outside regulatory consulting groups on regulatory submissions
- Manage IND and BLA project deliverables and timelines in close cooperation with Project Teams
- Conduct meetings with internal teams and vendors as needed, including preparation of meeting agendas, minutes, action items
- Maintain Regulatory records, including archive of submissions and FDA correspondences files
- Ensure submissions comply with applicable regulations and guidance documents
- Track submissions and ensure timely filing of documents
- Provide support with responses to FDA letters, supplemental requests, and amendments as needed
- Advise Project Teams on regulations as they apply to IND and BLA development
- Keep informed of new regulations, standards, policies, and guidance issued by relevant regulatory authorities that may impact the company
- Comply with applicable FDA and international regulatory laws/standards and the Company Code of Conduct
- Efficiently and effectively navigate through regulatory hurdles and barriers

- Serve as a liaison with Clinical development
- Assist with tracking the progress of clinical trials
- Ensure high quality and timely delivery processes are maintained in accordance with corporate, industry and regulatory standards

Computer Skills:

- Working knowledge and experience in basic computer programs such as Microsoft Word, PowerPoint, Visio, Excel, Outlook and Microsoft Project.
- Experience with an eCTD viewer is preferred

Education:

- Bachelor's degree in a Health or Science field;

Experience:

- 1 to 3 year of prior experience in Regulatory, Clinical, Quality, or Preclinical role
- 1 year of experience in the research or pharmaceutical industry.
- Demonstrated capacity of understanding Regulatory, Clinical, CMC, Quality, and Preclinical development information and ability to translate the information into appropriate regulatory documentation.
- Must be resourceful, and take initiative to secure required information for regulatory documentation purposes.
- Self-motivated and self-directed, with excellent time management skills.
- Strong attention to details.
- Strong computer and project management skills
- Strong communication skills (both written and oral).
- Take ownership and responsibility for assigned actions. Complete tasks on time to keep commitments, or notify appropriate person(s) with an alternative plan.
- Adapt to changes in the work environment, and demonstrate flexibility.
- Treat people with respect, work with integrity and uphold company values. Maintain professional behavior under all circumstances including in very difficult situations.
- Experience in Regulatory Affairs preferred.

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.

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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: _____