Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapies for the treatment of cardiac and other medical conditions. Capricor's lead candidate, CAP-1002, is a cardiac cell therapy that is currently being evaluated for the treatment of heart disease associated with Duchenne muscular dystrophy and myocardial infarction (heart attack). Capricor is exploring CAP-2003, its exosome product candidate, for use in cardiac and inflammatory conditions. Capricor offers exciting opportunities to join our expanding team. Capricor provides competitive compensation and benefits packages.

Position:
Document Control Manager

Job Description:

Capricor seeks an organized, self-motivated individual with demonstrated attention to detail and organizational skills to aid in the management of documentation to support clinical product candidates. The successful candidate will be responsible for coordinating the processing of all company-wide GLP / GCP / GMP controlled documentation into the management system. This position requires a working knowledge of the regulatory requirements and practices of a compliant pharmaceutical or biotechnology company.

Responsibilities:

- Process all master controlled documentation through the GxP (GLP / GCP / GMP) documentation system, including but not limited to word processing, tracking, issuing, distributing, and archiving, utilizing manual or an electronic document management system.
- Coordinate all controlled history records, i.e., batch / test records, logbooks, validation documents, labels, reports, forms, etc., including issuing, tracking, distributing, and archiving.
- Coordinate recording of training activities, including notification of requirements, tracking, and archiving of training records.
- Coordinate / track all change control, deviation and CAPA documentation including issuing, tracking, and archiving.
- Process incoming and outgoing business partner and CMO / CRO / CTL correspondence according to pre-defined procedures.
- Write and/or review policies, standards, procedures and work instructions to document QA documentation processes and practices.
- Effectively communicate (written and oral) with a variety of contacts, including management, business associates, and other staff personnel.
- Other required duties as may be assigned.

Requirements:

Candidates must have a minimum Bachelor's Degree in a technical field, attention to detail, strong work ethic, good record keeping skills and follow-through. Minimum 2-4 years' experience in a pharmaceutical, biotechnology, or medical device document control environment.

Experience:

- Quality systems design, and biopharmaceutical records management. Knowledge of operational, regulatory, medical, quality assurance and control, technical, business, and management fundamentals, processes and practices.

- Experience and proficiency with the Microsoft Office suite of tools, including Word, Outlook, PowerPoint, Excel, Visio, Project, Access, and Adobe suite.

- Ability to perform electronic searches for medical literature, regulatory guidance, and other technical information retrieval activities using a variety of international databases.

- Good oral and written communication skills. Must be comfortable working in a fast paced and dynamic environment. Must demonstrate initiative, independence, and leadership.

Applicants should submit a cover letter and their CV to careers@capricor.com