Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a Los Angeles, California based cutting-edge biotech company focused on the discovery and development of novel cell and exosome-based therapeutics for the treatment and prevention of a variety of diseases and disorders. Capricor's lead product candidate, allogeneic Cardiosphere-Derived Cells (CDCs), known as CAP-1002, is being investigated as a treatment for Duchenne muscular dystrophy and COVID-19. In addition, the Company is conducting research and development on its exosomes platform technology for a variety of indications. In response to a global pandemic, our team is currently applying its technologies to deploy a novel vaccination approach against COVID-19. Capricor offers exciting opportunities and invites qualified professionals to join our expanding team. Capricor provides competitive compensation and benefits packages.

Position:

Quality Associate / Quality Specialist

Job Description:

Capricor seeks a self-motivated team player with attention to detail, who enjoys organizing, making processes better, and making a difference in patient lives. The successful candidate will serve an essential role in supporting clinical product launch and production. This includes word processing, tracking, issuing, distributing, and archiving company-wide GLP / GCP / GMP controlled documentation, training, and facility support systems.

Knowledge of standard processes involved in document control and experience in an FDA regulated environment is required. The position will report to the Director of Quality.

Responsibilities:

- Process 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 / track / archive: controlled records (i.e., batch / test records, logbooks, validation documents, labels, reports, forms, etc) for change controls, deviations, CAPAs, audits, training, equipment calibration and preventative maintenance.
- Write and/or review policies, standards, procedures and work instructions to document Quality documentation processes and practices.
- Conduct or coordinate deviation investigations, corrective and preventative actions (CAPA), change controls, company-wide training, and internal audits. Write associated reports.
- Support clinical product manufacturing by batch record review, label printing, product packaging, and shipping.
- Support supplier and material management, including ordering, incoming receipt, record keeping etc.
- Inventory database management including accurate and timely updating of lot numbers and quantities.
- Collaborate on development / improvement and implementation of material, facility and quality management systems.
- Other required duties as may be assigned.

Requirements:

- Precise attention to detail
- Excellent record keeping skills
- Strong, demonstrable computer skills in MS Word, Excel, Visio, Access; Adobe suite; and database systems
- Results oriented with dedication to compliance and customer service
- Strong initiative and follow-through
- Comfortable working in a fast paced and dynamic environment.
- Good oral communication skills, strong written communication skills
- Strong working knowledge of Quality Systems and records management in a cGMP environment.
- Strong problem solving skills
- Ability to coordinate and perform multiple activities
- Bachelor's Degree.
- 3-5 years experience (at least some in a cGMP environment)

Work Environment / Physical Demands:

- Must be able to sit and stand for extended periods.
- Must be able to lift / carry reports and materials, move about the office, turn on and operate a computer, printers / scanners in the applicable environment, communicate efficiently and effectively on the telephone or in person, and complete required paperwork.
- Able to fully gown and work in a manufacturing area.