**Company:**

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a cutting-edge biotech company focused on the discovery and development of novel therapies for the treatment of rare diseases. 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 inflammatory 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:** Director of Quality

This position is immediately available

**Duties:**

- Assuming responsibility for all Quality Assurance activities for clinical and manufacturing, including product disposition, deviation investigations and resolution, change control, documentation control, stability programs, IP supply chain, incoming component release, oversight for validation, maintenance, facilities, critical utilities and laboratories;
- Implementing remediation activities;
- Hosting regulatory inspections, responding to regulatory inquiries and requests for information;
- Identifying and leading process improvement initiatives;
- Reviewing data and batch release of all clinical and commercial products to ensure products meet all specifications and are manufactured in compliance with cGMP guidelines and global regulations;
- Overseeing product complaints, deviation, OOT/OOS, and other non-conformance resolutions;
- Establishing and overseeing compliance at contract manufacturing organizations through establishing key performance indicators, and governance processes to ensure ongoing performance;
- Overseeing and approving Annual Product Quality Reports;
- Reviewing regulatory submissions;
- Establishing and overseeing phase appropriate quality system (e.g. GLP, GCP, GMP) for development and clinical products;
- Serving as Capricor's training officer including creating employee training records, cGMP quiz modules and facilitating training compliance
- Performing day to day quality assurance oversight for production batch record countersignatures and Quality observations
- Providing first line QA review of batch records for completeness
- Providing coordination of equipment preventative maintenance and calibration schedules;

- Administrating Capricor's Document Control system; and
- Administrating Capricor's deviation, investigation, CAPA and change control system.

**Requirements:**

The Director of Quality will be responsible for maintaining and overseeing the Company's quality systems. In accomplishing these goals, the Director of Quality may author detailed quality documents, including manufacturing and clinical SOPs; help facilitate technology transfer activities and oversee internal quality oversight across the organization.

**Qualifications:**

Qualifications include five or more years of experience in industry, demonstrated record of achievement, a proven track record in quality assurance in biomedical research, and strong interpersonal skills as well as ability to function in a team environment. Strong problem solving ability and scientific analytical skills are required, as are excellent written and oral communication skills, including strong formal presentation skills.

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