Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a Los Angeles, CA 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 Manager

Capricor is seeking a self-motivated team player and leader 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 clinical product launch and production, providing leadership in quality operations, quality systems, and process improvements.

Responsibilities:

- Manage and improve Quality Systems, including training and document, label, and change management. This includes supporting routine issuance, review, and approval of associated documents.
- Identify and support continuous improvement projects in collaboration with different cross functional teams to drive phase appropriate compliance with an eye to quality and efficiency.
- Provide quality oversight of cGMP activities supporting all material and product disposition including both internal production and that in collaboration with external CMOs.
- Perform review and approval of quality documentation such as, equipment, system, process, and method validations, master batch records, change control, investigations, risk assessments and technical reports.
- Review documents and provide input, coaching and feedback to promote continuous improvement.
- Participate in clinical document and data review for ongoing and upcoming trials including, but not limited to, drug accountability review
- Serve as unblinded clinical trial supplies manager and ensure sufficient inventory to support ongoing clinical trials (managing from production through testing to storage and clinical distribution)
- Establish and improve the systems and processes required to conduct audits/inspections
- Participate in validation, audits, and perform training as necessary
- Collaborate with internal departments to ensure effective regulatory and customer audit responses/corrective actions are generated in a timely manner
- Other required duties as may be assigned

Requirements:

- Bachelor's Degree. 7+ years-experience
- Excellent ability to coordinate and perform multiple activities
- Excellent team interpersonal and collaboration skills
- Strong oral communication skills, strong written communication skills
- Strong working knowledge of Quality Systems in a cGMP environment.
- Strong problem-solving skills

- Precise attention to detail
- Strong, demonstrable computer skills in MS Word, Excel, Visio, Access; Adobe suite; database systems, and various e-quality system solutions.
- Results oriented with dedication to compliance and customer service
- Strong initiative and follow-through
- Comfortable working in a fast paced and dynamic environment.
- Candidates with cGMP experience, Quality systems design, and root cause analysis are strongly desirable

Work Environment / Physical Demands:

- Must be able to sit and stand for extended periods
- Must be able to lift / carry reports and materials up to 40 pounds, move about the office, communicate efficiently and effectively on the telephone or in person, and complete required paperwork
- Able to fully gown and work in a manufacturing area

Applicants should submit their resume to careers@capricor.com.