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. In addition, the Company is conducting research and development on its exosomes platform technology for inflammatory indications. Capricor offers exciting opportunities to join our expanding team. Capricor provides competitive compensation and benefits packages.

Position:

Quality Assurance Manager

Description:

This position is immediately available to support our cGMP manufacturing, clinical trial inventory management and Quality Systems. Capricor seeks an independent, organized, self-motivated individual with demonstrated attention to detail, organizational skills and familiarity with cGMP manufacturing.

The successful candidate will be responsible for supporting Quality in the timely disposition of clinical product to ensure inventory is available to support ongoing clinical trials. The duties will include document management, creation and review of standard operating procedures, deviation investigation, FDA regulated label issuance, inventory management and drug product batch record review for regulatory and best practice compliance and optimization respectfully.

Responsibilities:

- Administer the document control system, including issuing document request form numbers, reviewing and approving documents, making documents effective, and archiving
- Write and review SOPs and other documents to maintain the Company's Quality Systems
- Administer the label system, including printing, issuance, and reconciliation
- Perform batch record review to support the disposition of clinical lots of investigational drug ensuring the records are compliant with internal and cGMP regulations and addressing compliance issues if necessary
- Review deviations to ensure adequacy of investigations, root cause and appropriate CAPA
- Responsible for initiation, review, and implementation of the change control processes
- 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
- Conduct Quality review of internal and external production documentation, including batch records, analytical records and any supporting documentation to ensure compliance with cGMP, and develop and implement enhancements to Quality System procedures
- Collaborate with internal departments to ensure effective regulatory and customer audit responses/corrective actions are generated in a timely manner

- Assess and approve audit corrective action plans for internal and external cGMP Compliance audits
- 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. Must have demonstrable computer skills in Microsoft Word, Excel, Access and database systems. Good oral and written communication skills. Familiarity with cGMP environment. Must be comfortable working in a fast paced and dynamic environment. Must demonstrate initiative, independence, and leadership.

Experience:

Candidates with cGMP experience, Quality systems design, and root cause analysis are strongly desirable.

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