

Quality Control Analyst II Position at Capricor

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 cardiac diseases and other potential inflammatory indications. Capricor offers exciting opportunities to join our expanding team. Capricor provides competitive compensation and benefits packages.

Position:

Quality Control Analyst II

Job Description:

A position is immediately available for a Quality Control Analyst II to perform QC testing of existing products, coordinate shipping of samples for outsourced testing, perform data analysis, assemble and complete QC data documentation, perform OOS investigations, and participate in assay qualifications. The incumbent will also collaborate with the process development group in developing new assays and analytical methods. Products may include cells, exosomes, and other regenerative therapeutics. We are seeking highly motivated candidates who are capable of independent work in a collaborative environment.

Requirements:

- A Bachelor's degree in a relevant Biological Science discipline is required.
- 2-3 years of experience working in a GMP Quality Control laboratory or a combination of experience in a GMP/GLP setting is required.
- Mammalian cell culture methods and molecular biology skills are required.
- Experience with laboratory methods including flow cytometry, DNA isolation, ELISAs, endotoxin detection etc.
- Experience with method qualification/validation is desired.
- The ability to independently perform laboratory analysis, troubleshoot, and improve methods.
- A history of successful, independent laboratory work should be demonstrated.
- Excellent communication, time-management skills and the ability to work as part of a team are required.
- Computer literate. Ability to work with Outlook, MS Office, and other electronic systems.

Responsibilities:

- Perform QC analysis testing on current products to support batch disposition. Responsible for in-process intermediates, final formulated bulk drug substance and final drug product.
- Interface with outsourced laboratories to coordinate sample receipt, testing, and on time reporting of results.
- Prepare and maintain mammalian cell cultures.
- Perform data analysis, organize records, reports and databases in a timely manner.



- Write technical reports or documentation such as deviations, qualification/validation protocols, and investigation of OOS results.
- Collaborate with Process Development to troubleshoot and optimize current assays and future analytical methods.
- Train other employees to perform relevant techniques and procedures as needed.
- Write or revise quality control Standard Operating Procedures.
- Carry out Environmental Monitoring of manufacturing facility and relevant samples generated.
- Coordinate with third party vendors to maintain calibration of equipment.
- Work closely with the Manufacturing and Quality Assurance department staff to resolve issues regarding the facility and products manufactured.
- Present data internally.
- Receive and inspect materials.
- Work under minimal supervision to meet project goals.
- Other duties as assigned.

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