

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapies for the treatment of cardiac and other serious medical conditions. Capricor's lead candidate, CAP-1002, is a cardiac cell therapy that is currently being evaluated for the treatment of heart disease associated with Duchenne muscular dystrophy and myocardial infarction (heart attack). Capricor is advancing its proprietary exosome product candidate, CAP-2003, for the treatment of ophthalmic disorders and is exploring other therapeutic areas. Capricor's portfolio also features Cenderitide, a dual natriuretic peptide receptor agonist, which may have application for the outpatient treatment of advanced heart failure and other potential indications. Capricor offers exciting opportunities to join our expanding team. Capricor provides competitive compensation and benefits packages.

Position:

Quality Control Director

Description:

A position is immediately available within our QC group for a Director of Quality Control to oversee QC analysis of existing products, participate in defining analytical strategy for new products and continuously improve existing methods. The incumbent will participate in creating new assays and analytical methods in collaboration with R&D team and facilitate their successful transfer into QC. 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:

- Cell culture and molecular biology skills are required
- Experience with analytical assay development for biotechnology products is required.
- Experience in a GMP laboratory is required
- Experience with laboratory methods including flow cytometry, Real-Time PCR, DNA isolation, ELISA, bioactivity assays, endotoxin detection etc. is required
- Experience with method qualification/validation is required
- The ability to independently perform laboratory analysis, troubleshoot, and improve methods is required
- A history of successful, independent laboratory work should be demonstrated
- An M.S. or Ph.D. in a relevant Biological Science is desired
- Excellent communication skills and the ability to work as part of a team are required

Responsibilities:

- Oversee QC analysis on current products to support batch disposition. Responsible for in-process intermediates, final formulated bulk drug substance and final drug product.
- Manage all aspects of QC laboratory including sample management, data analysis and investigation of OOS results
- Develop in house methods to assess the quality of purchased materials
- In collaboration with Process Development, to develop relevant *in vitro* and *in vivo* assays and analytical methods to support current and future products
- Work closely with Process Development group to transfer methods into QC laboratory



- Qualification and validation of methods to assess the quality of final drug product including *in vitro* and *in vivo* functional assays
- Qualify, interface with and manage outsourced laboratories to ensure acceptable, on time reporting of results
- Develop, revise and review SOPs, test methods, qualification/validation protocols and reports
- Troubleshoot and optimize current methods
- Preparation of dossiers and data packages for interactions between Capricor and Regulatory Agencies and interaction with agents from Regulatory
- Perform data analysis, identify trends, organize records, reports and databases
- Hire, train and manage QC analysts to perform relevant techniques and procedures as needed
- Manage environmental monitoring program of manufacturing facility
- Present data internally

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