Regulatory Affairs Manager Position at Capricor

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of 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.

Position:
Regulatory Affairs Manager

Job Description:
A position is immediately available for a Regulatory Affairs Manager to help formulate regulatory strategy and be responsible for all regulatory submissions related to our current and new products in our pipeline. Products may include cells, exosomes, and other regenerative therapeutics. We are seeking highly motivated candidates capable of independent work in a collaborative environment.

Responsibilities:

- Manage all aspects of regulatory submissions process from initial IND, annual reports, safety updates, preparation for submissions to be in compliance with FDA, international regulations and company policies and SOPs.
- Develop processes, SOPs and guides related to the effective management of the regulatory function.
- Ensure timely submission of all required regulatory documents and manage regulatory dossiers.
- Interface with regulatory agencies through written correspondence, face to face meetings etc.
- Perform regulatory surveillance and feedback to organization regarding new regulations, changes in regulatory landscape etc.
- Participate in creation of regulatory strategy for new products.

Requirements:
A Bachelor’s degree or higher in a Biological Science is required. Ten years of work experience supporting all aspects of creation and delivery of US FDA regulatory submissions for Clinical Trials and Commercial licensure. Technical understanding of cell therapy manufacturing processes, analytical assays, sterility assurance and clinical trials strategy to enable creation of regulatory submissions in concert with content experts. Experience with safety assessment and reporting requirements for SAE’s, AE’s etc is preferred. Experience creating and submitting INDs is required. Experience in creating and submitting BLAs is desired. Experience in OUS regulatory submissions is desired. RAPS certification desired. Excellent communication skills and the ability to work as part of a team are required. Experience in independently executing regulatory submissions.

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