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:

Director of Regulatory Affairs

Description:

A position is immediately available for a Regulatory Affairs Director to formulate regulatory strategy and be responsible for all regulatory submissions related to 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.

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 SAEs, AEs, etc is preferred.
- Experience with orphan drugs and their use in pediatric populations is desired.
- 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 and effectively communicating with regulatory agencies is required.

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.
- Lead creation of regulatory strategy for new products.

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