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

Position:

Vice President of Regulatory Affairs

Description:

A position is immediately available for a Vice President of Regulatory Affairs to provide strategic leadership and direction for all company regulatory projects and to oversee the execution of activities to support the company's registration goals. Products under development include cells, exosomes, and other regenerative therapeutics. The Vice President of Regulatory Affairs will develop long term strategies and execute short term goals for regulatory, clinical and CMC, in alignment with the company's commercial goals. This position will be expected to lead and collaborate with multiple internal teams to ensure that all programs are implemented in accordance with company strategy and in compliance with regulatory agencies, and that overall business strategies are translated to guarantee optimal time to market.

Requirements:

- PhD, M.D. or J.D. degree is highly preferred
- 15+ years regulatory affairs experience in a pharmaceutical or biotech company, including senior management experience
- Experience with orphan drugs and their use in pediatric populations is desired
- Technical understanding of cell therapy is required
- Excellent communication skills and the ability to work as part of a team are required

Responsibilities:

- Develop robust regulatory strategies and policies
- Lead regulatory intelligence initiatives
- Ensure effective planning, preparation and submission of INDs, BLAs and other regulatory documents / applications as required
- Liaise closely with the CMC and clinical teams to ensure all regulatory requirements are met and all information needed for ongoing documentation and registration is produced
- Represent regulatory affairs on internal project teams
- Build, manage and effectively lead a team of regulatory personnel and consultants
- Establish and manage relationships with external regulatory authorities and maintain correspondence / communication and other records of interactions
- Plan, coordinate and lead meetings with regulatory agencies
- Advise colleagues on regulatory matters and provide guidance in conducting studies that comply with regulatory requirements

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