Company Overview

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a Los Angeles, California based cutting-edge biotech company focused on the discovery and development of novel cell and exosome-based therapeutics for the treatment and prevention of a variety of diseases and disorders. Capricor's lead product candidate, allogeneic Cardiosphere-Derived Cells (CDCs), known as CAP-1002, is being investigated as a treatment for Duchenne muscular dystrophy and COVID-19. In addition, the Company is conducting research and development on its exosomes platform technology for a variety of indications. In response to a global pandemic, our team is currently applying its technologies to deploy a novel vaccination approach against COVID-19. Capricor offers exciting opportunities and invites qualified professionals to join our expanding team. Capricor provides competitive compensation and benefits packages.

Position:

Manufacturing Manager

Job Description:

This position is immediately available to support the manufacturing team. Capricor seeks an independent, tenacious, science-oriented individual with manufacturing management experience and strong coaching skills. This individual will be supporting technology transfer to establish a commercial-scale process and to assist the manufacturing team to support cGMP clinical manufacturing for clinical trials.

The Manufacturing Manager will coordinate efforts for an efficient tech transfer process and will provide managerial guidance to the manufacturing team. The responsibilities of primary importance are to ensure the successful and time-sensitive tech transfer, to coordinate the manufacture and release of efficacious cell therapy and exosome products, promote a culture of quality and compliance and achieve continuous manufacturing improvements. The Manufacturing Manager will report to the Vice President of Research and Development.

Responsibilities:

- Hire, train, develop and coach manufacturing staff to ensure proper and effective training, quality standards and standards of performance are met within the manufacturing group. Maintain team motivation and promote employee career progression.
- Supervise the on-the-floor operations of manufacturing facility in a cGMP environment
- Management of Manufacturing team to produce efficacious drug products manufactured on-schedule and within quality standards and operational budget.
- Accountability for accurate SOPs and records to assure all clinical products meet the requirements for quality, safety and efficacy.
- Develop manufacturing plans with resources and schedules to meet clinical demand and new clinical trials.

- Authoring/editing regulatory documents, INDs, SOPs, responses to agencies, etc.
- Maintain strong collaborative relationships with company's quality assurance and control units in order to support all manufacturing deviations, investigations and regulatory submissions.
- Develop phase-appropriate clinical production processes using quality by design (QBD) principles.
- Manage incorporation of new products manufacturing processes.
- Develop timelines, budget and resource requirements for all manufacturing, prospective and grant projects under consideration.
- Identify, escalate and facilitate the resolution of manufacturing, supply chain, analytical and quality issues that may adversely affect production goals.
- Update to company's senior management the status of clinical inventory, manufacturing projects and goals as they related to cross-functional business success.
- Establishes departmental goals with the employees within his/her charge and conducts individual performance reviews.
- Support technology transfer to contract manufacturing organizations (CMO) for potential Phase III and commercial production.
- Collaborate with Research and Development departments to improve the manufacturing process and to support Tech Transfer.

Requirements:

Bachelor's degree required (Master's preferred) with 3+ years of hands-on cGMP manufacturing experience in pharmaceutical or biotech industry and cGMP cell manufacturing experience strongly desired. Candidates must have strong leadership ability, exceptional communication and interpersonal skills, ability to work in a dynamic environment and multi-task and prioritize work. Must have full working knowledge of cGMP regulations. Candidates must have a strong scientific background with knowledge on cell therapy.

Experience:

Manufacturing experience desired plus a minimum of 3 years of manufacturing experience with increasing levels and/or breadth of responsibility.

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