November 2017

Director of Manufacturing Position at Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics. The Company's lead programs target Duchenne muscular dystrophy. The Company has two lead product candidates under investigation: CAP-1002, an allogeneic cell therapy product, and CAP-2003, based on the use of extracellular vesicles (EVs) obtained from cardiosphere-derived cells. CAP-1002 is in development for the treatment of advanced heart failure and Duchenne muscular dystrophy-associated myopathy. CAP-2003 represents exosomes isolated from the company's proprietary cardiosphere-derived cells (CDCs), and is being developed as a next-generation therapeutic platform in regenerative medicine.
Capricor is in a manufacturing tech transfer process for being able of producing CAP-1002 for Phase II/Phase III clinical trial and to establish a commercial-scale process.

Position:
Director of Manufacturing

Job Description:
This position is immediately available to lead manufacturing tech transfer to establish a commercial-scale process and to lead the Manufacturing Team to support cGMP clinical manufacturing for clinical trials. Capricor seeks an independent, tenacious, science-oriented individual with leadership manufacturing experience and strong coaching skills.
The Manufacturing Director will coordinate efforts for an efficient tech transfer process and will provide managerial leadership to the Manufacturing group. 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 products, promote a culture of quality and compliance, and achieve continuous manufacturing improvement. The Manufacturing Director will report to the VP of Regenerative Therapies.

Responsibilities:

- Manage technology transfer to contract manufacturing organizations (CMO) for phase 3 and commercial production.
- Collaborate with Research and Development departments to improve the manufacturing process and to support Tech Transfer.
- Management of Manufacturing team to produce efficacious drug cellular products manufactured on-schedule and within quality standards and operational budget.
- Accountability for accurate specifications, 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.
- Maintain strong collaborative relationships with company's quality control units in order to support all manufacturing deviations, investigations and regulatory submissions.
- Evaluate new technologies and novel, relevant applications of existing technologies for potential implementation to improve Company's products and processes.
- Develop phase-appropriate clinical production processes using quality by design (QBD) principles.
- Manage incorporation of new products manufacturing processes.

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.
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.
Contribute to regulatory filings and interact with regulators as requested to ensure timely start of clinical trials and establishing a strong collaborative relationship with regulatory agencies
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.

Requirements:
Bachelor's degree required (PhD preferred) with 8+ years of hands-on cGMP manufacturing experience in pharmaceutical or biotech industry and at least 5 years of experience on cGMP cell manufacturing. 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 and desirable GTP knowledge. Candidates must have a strong scientific background with deep knowledge on cell therapy.

Experience:
Manufacturing experience required plus a minimum of 3 years of direct management experience of manufacturing professionals with increasing levels and/or breadth of responsibility.

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