Capricor

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 post myocardial infarction (heart attack), heart failure and Duchenne muscular dystrophy. The Company has two lead product candidates under investigation: CAP-1002, a cardiac cell therapy, and Cenderitide, a natriuretic peptide receptor agonist. CAP-1002 is in development for the treatment of post myocardial infarction, advanced heart failure and Duchenne muscular dystrophy-associated cardiomyopathy. Cenderitide is in development for the outpatient treatment of heart failure as well as potential other indications. In addition, the Company is conducting research and development on its exosomes platform technology for cardiac diseases and other potential indications.

Position:
Director of Manufacturing

Closes:
2016-09-30

Job Description:
This position is immediately available to lead our Manufacturing Team to support our cGMP clinical manufacturing for Phase 1 and Phase 2 clinical trials. Capricor seeks an independent, tenacious, science-oriented individual with leadership manufacturing experience.

Responsibilities:

- Oversee management of all Manufacturing to produce drug products which are manufactured on-schedule and within quality standards and operational budget.
- Manage technology transfer and manufacturing for all cell therapy-related contract manufacturing organizations, including raw material suppliers.
- Manage incorporation of new products manufacturing processes
- Develop manufacturing plans with resources and schedules to meet clinical demand and new clinical trials.
- Develop phase-appropriate clinical production processes using quality by design (QBD) principles.
- Hire, train, develop and evaluate manufacturing staff to ensure proper 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.
- Maintain strong collaborative relationships with company’s quality control units in order to support all manufacturing deviations, investigations and regulatory submissions.
- Accountability for accurate specifications, SOPs and records to assure all clinical products meet the requirements for quality, safety and efficacy.

- 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.
- Support the design, development, build-out, and validation of the company's future clinical/commercial manufacturing facility

Requirements:
Bachelors degree required (PhD preferred) with 5+ years of hands-on cGMP manufacturing experience in pharmaceutical or biotech industry and at least 3 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.

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