

**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 and COVID-19. In addition, the Company is conducting research and development on its exosomes platform technology for inflammatory 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:** Senior Director of Clinical Development

This position is immediately available

**Description:**

With the support of the Vice President of Clinical Operations, the Senior Director of Clinical Development will have primary responsibility for the planning and directing of clinical research activities and will manage the entire cycle of clinical development, including study design, placement, medical monitoring, analysis, regulatory reporting and publication. Specifically, the Senior Director of Clinical Development may be responsible for the following:

- Evaluating pre-clinical and translational work for the purpose of generating early clinical development plan and IND applications;
- Participate in clinical development strategies for investigational agents;
- Planning clinical trials (design, operational plan, settings) based on these clinical development strategies;
- Monitoring and managing the conduct of ongoing or clinical trials for investigational agents including ongoing review of safety and other duties of a medical monitor;
- Analyzing and summarizing the clinical findings from studies to support decisions regarding safety and efficacy as well as Biologic License Applications, clinical study reports and publications;
- Participation in internal and joint internal/external research project teams relevant to the development of new investigational agents.
- Provide local medical expertise input into Product Development for cell and exosome-based therapeutics;
- Foster close professional and scientific relationships with medical thought leaders and clinical investigators;
- Serve as the medical expert for safety and pharmacovigilance activities related to clinical trials;
- Review, write and approve clinical protocols, informed consent documents, clinical study reports, and investigational brochures in conjunction with Clinical Operations and Medical Writing;



- Support the conduct and review of clinical trials and analyze clinical trial results;
- Ensure compliance with relevant SOPs, ICH, GCP and other national and international regulatory requirements;
- Demonstrate ability to identify unmet clinical needs, evaluate product opportunities from a clinical perspective, and help develop strategies that leads to efficient development of such opportunities;
- Provide scientific input into evidence generation and publication strategy;
- Review manuscripts for publication and abstracts and posters for presentation at scientific meetings;

In executing these duties, the Senior Director of Clinical Development may supervise the activities of the Clinical team in the execution of clinical studies; work closely with a cross-functional group of experts (commercial, regulatory affairs, statistics, CMC, preclinical pharmacology, toxicology) to manage clinical development projects; establish patient advocacy outreach plans and participate in advocacy outreach activities; staying abreast of competitors' drugs and clinical development programs; and serve as internal and external expert on scientific and medical questions relevant to his/her areas of responsibility.

### **Requirements:**

The Senior Director of Clinical Development will be responsible for maintaining a strong scientific knowledge by maintaining awareness of scientific developments within Capricor's area of expertise, in terms of new scientific findings and research methodologies; identification of scientifically and operationally strong investigators who can assist in the development Capricor's investigational agents; establishing communications with prominent clinical investigators in his/her field of interest, particularly those who will be willing and able to assist in the evaluation of new investigational agents; and attend appropriate scientific meetings to maintain his/her competency and to maintain awareness of research activities in his/her area of responsibility.

In accomplishing these goals, the Senior Director of Clinical Development may author detailed development documents, presentations, budgets and position papers for internal and external audiences; facilitate collaborations with external researchers around the world.

### **Qualifications:**

Qualifications include MD or MD/PhD, five or more years of experience in industry, demonstrated record of scientific scholarship and achievement, a proven track record in clinical medicine and background in biomedical research, and strong interpersonal skills as well as ability to function in a team environment. Strong problem solving ability and scientific analytical skills are required, as are excellent written and oral communication skills, including strong formal presentation skills. Prior specific experience in clinical research is desirable.

Preferred qualifications include Five (5) or more years of clinical research experience and/or basic science combined with clinical teaching and patient care activities; clinical research/medical affairs experience in the biopharmaceutical industry (biotech, pharmaceutical or CRO); and



knowledge of pharmaceutical product development, product lifecycle and commercialization process with advanced understanding of other functions, including, but not limited to, Clinical Operations, Commercial, Regulatory, and Medical Affairs.

Applicants should submit a cover letter and their CV to [careers@capricor.com](mailto:careers@capricor.com).