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:

Sr. Scientist, Downstream Process Development

Job Description:

Capricor seeks a highly motivated and creative individual to be a part of a cutting-edge cell and gene therapy process and product development team. The successful candidate is responsible for leading downstream process development/optimization studies to advance our R&D programs from pre-clinical to IND filing and ultimately to BLA filing and commercial launch. The candidate is also responsible for leading downstream technology transfer activities to Capricor's internal manufacturing site as well as to CMOs.

Responsibilities:

- Lead downstream process development activities
- Design and execute experiments to develop efficient, effective downstream purification processes.
- Champion and progress select therapeutic candidates from early stage Phase I to late stage Phase II and Phase III clinical trials through to commercialization.
- Lead technology transfer processes and working cross functionally between Process Development and Manufacturing departments.
- Work cross functionally with Upstream Process Development, Analytical Development, Manufacturing, Regulatory, and Quality departments for downstream related process improvement, process validation, process change control, deviation investigation and process characterization activities.
- Manage laboratory experiments including scale down studies, validation studies, process range studies, process robustness studies, and manufacturing troubleshooting activities.
- Lead downstream CMC development activities and contributing to IND regulatory submissions.

Requirements:

- PhD or MS in chemical engineering, life sciences or equivalent.
- PhD with 5+ years or MS with 8+ years of biopharmaceutical industry experience in purification (multiple modes of chromatography, depth & membrane filtration & ultrafiltration/TFF). Extensive knowledge of product variant and process-related impurity removal strategies expected. Strong chromatography experience preferred.
- Extensive experience in scaling up, transferring, and supporting purification processes from bench scale to pilot and/or commercial scale.

- Experience with statistical design of experiments, advanced data analysis, process validation and Quality by Design concepts.
- Experience with GMP regulatory guidelines as related to the development of cell and gene therapy manufacturing processes is preferable.

Work Environment / Physical Demands:

- Laboratory environment working with chemical reagents and analytical equipment
- Personal Protective Equipment must be worn as required.
- Must be able to lift up to 20 lbs.
- Must be able to stand/walk to work in lab environment for extended periods.
- Must be able to sit for extended periods to use computer.