Company:

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:

Senior Technical Writer (Ph.D.)

This position is immediately available

Duties:

- Development process may include writing interpreting and summarizing clinical and non-clinical data, and compiling information.
- This candidate must have strong experience with writing submissions. Documents may include preclinical and clinical publications, federal and state grant submissions (NIH, DOD, etc), CSRs, INDs, manuscripts, abstracts, posters, and presentations.
- Will participate in ensuring compliance of clinical documents with national and international regulatory requirements and guidelines and procedures (as applicable). Includes collaborating with medical editors to ensure documents are publication ready.
- Develop knowledge of all therapeutic areas.
- Experience in the analytical evaluation of scientific data
- Exceptional organizational skills and meticulous attention to detail
- Independently author a broad range of scientific documents, such as such as CSRs, subject narratives, clinical sections of INDs, NDAs and BLAs, protocols and/or briefing documents
- Act as a project manager for complex writing projects and have responsibility for resource coordination and utilization, timelines and review and oversight of deliverables
- Perform internal document reviews, editing and QC as needed
- May be asked to participate in business development efforts, including project proposals
- Works with the Nonclinical, Clinical, and Regulatory Affairs team members to prepare documents under strict timelines; documents may include pre-clinical study protocols and reports and clinical study protocols
- Provides leadership in planning and completing required documents for regulatory submissions to US and global health authorities, including Investigational New Drug (IND) applications and Biologics License Applications (BLAs)
- Ensures key messages are clear and consistent within and across documents
- Contributes strategically and scientifically at the project and/or study team level

- Provides editorial or review support (or coordinates external resources) for other types of documents, such as abstracts, manuscripts, posters, and presentations for scientific meetings and journals
- Collaborates with cross-functional team members, e.g., Clinical Pharmacology, Toxicology, Research, Clinical Development, Regulatory Affairs, Quality, etc., to ensure accurate and timely completion and delivery of high-quality, scientifically-sound documents
- Demonstrated ability to communicate and write clearly, concisely, and effectively; strong aptitude for compilation, analysis, and presentation of data
- Ability to work independently and collaboratively, as required, in a fast-paced, matrixed team environment consisting of internal and external team members
- Ensures a consistent style of document presentation to maintain quality and ease of review, and adherence to company standards
- Procures and manages external medical writing resources, e.g., contract research organizations, document quality reviewers, and freelance medical writers, etc., as needed
- Contributes to the development and standardization of templates and related processes, including updating, revising and developing relevant SOPs and internal best practices

Requirements and Qualifications:

Advanced degree, e.g., PhD, PharmD or MD, with 5+ years medical writing experience in biotech/pharmaceutical industry. Demonstrated experience in preparing manuscripts, grant submissions, protocols, study reports, investigator brochures and regulatory documents, including regulatory submissions to the US Food and Drug Administration (FDA). Demonstrated ability to incorporate pre-clinical data into clinical and regulatory documents. Analytical thinker with excellent problem-solving skills and the ability to adapt to changing priorities and deadlines. Excellent planning, organization and time management skills including the ability to support and prioritize multiple projects. Excellent attention to detail, including fact checking, logical flow, parallelism, formatting, and document structure. Ability to complete high quality documents under tight timelines. Demonstrated internal and external stakeholder management and project management experience. Demonstrated ability to represent and advocate for Medical Writing and influence without direct authority.

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