Director, Clinical Scientist Lead, Medical Writing, and Publication

(Job: -15-21BA)

About Ambrx:

Ambrx Inc., is a clinical-stage biopharmaceutical company focused on developing Precision Biologics using an expanded genetic code. Ambrx technology uses an expanded genetic code to incorporate synthetic amino acids into protein, all completed within a living cell. These synthetic amino acids enable the creation of Precision Biologics, an exciting new class of therapeutics with broad application and potential. This includes next-generation antibody drug conjugates (ADCs), bispecifics, and targeted immuno-oncology therapies for cancer as well as smart cytokines to modulate the immune system, and long-acting therapeutic peptides for metabolic and cardiovascular disease.

This role is to support various clinical research and lead the medical writing tasks associated with drug development. Scope of work will include tasks associated with the execution, monitoring, and reporting of clinical trials, in addition to medical writing (protocol related document writing, regulatory writing), publication, and medical communication.

(S)he will lead the medical writing, publication, and be a key member of the clinical team in the design and execution of clinical studies.

Responsibilities:

- Activities which support the execution, monitoring, and reporting of clinical trials.
- Provides scientific and clinical leadership to the cross-functional clinical trial team
- Leads the development of clinical study documents (e.g., protocols, informed consent documents, case report forms).
- Support activities related to the start-up and execution of new clinical trials.
- Performing clinical data review and assist in the preparation of clinical safety presentations and reports.
- Set up data review activities. Tracking of safety events, review of new SAEs, and composing Adverse Event Narratives.
- Collaborate and serve as primary liaison between external partners for scientific advice
- Support preparation of the clinical content of drug safety documents and reports such as the investigator brochures, DSURs, and other regulatory response documents.
- Assist with managing other vendor activities such as laboratory, histology or imaging. In collaboration with Operations, identifying clinical sites and CROs that will participate in trials.
- Interact with staff responsible for the design, set-up, execution, analysis and reporting of these studies.
- Review incoming data from the study for accuracy and completeness. Participate in the review and interpretation of clinical trial data to enable timely internal decision-making and external communication with investigators and regulatory agencies.

- Applies knowledge of regulatory medical writing and therapeutic area/investigational product to support pipeline projects
- Leads the preparation and assure the accuracy of the clinical study report and any external publications.
- Interprets data and applies knowledge of regulatory/compliance/scientific requirements to document preparation

Qualifications

- MD, PharmD, or PhD preferably with a scientific background in oncology or a related field, and 6-10 years industry experience is required.
- Experience with Ph 2 and Ph 3 studies in oncology indications is preferred.
- Excellent medical writing and verbal English communication skills.
- Ability to survey and interpret the scientific literature related to the assigned projects is required.
- Strong organizational skills and the ability to work well in a dynamic environment with cross-functional team and be able to prioritize and respond to changing needs of the business.

To be considered as an applicant, please submit your resume/CV referencing the specific position of interest and position code to careers@ambrx.com. Applicants whose qualifications and experience most closely match the requirements of the position will be reviewed. Candidates will only be contacted for evaluative discussions. Ambrx offers competitive compensation & benefits.