Position: Medical Writer
Location: Worcester, MA
Reports to: SVP & Head of Clinical Development

Join our team! At Mustang Bio we are driven by people. The patients we serve and the team we are building are the driving forces behind our mission to deliver life-changing first-in-class cell and gene therapies to patients with genetic diseases and aggressive forms of cancer.

Summary:

Mustang Bio is seeking an organized, motivated, and collaborative individual for our medical writing team. The medical writer will partner cross-functionally with client teams in Clinical Development, Clinical Operations, Biostatistics, Regulatory, and Program Management in planning and preparation of high-quality clinical and regulatory documents. The medical writer may produce protocols, publications, clinical study reports, investigator brochures, narratives, and regulatory module documents to support IND/CTA/BLA filings, according to regulatory agency guidelines, to support drug development under brisk timelines and in accordance with regulatory guidelines where applicable.

Responsibilities:

- Prepare, edit, and finalize protocols, investigator brochures, synopses, regulatory documents, clinical study reports (CSR) and related clinical documents, such as abstracts, posters, presentations, and manuscripts according to agreed-upon timelines
- Understand the functions and roles within the study team(s) and aligns with them in the delivery of documents to meet project-related goals and to meet external/regulatory results disclosure obligations
- Complete documents and follow up with the relevant study team as needed to meet internal and external timeline commitments, and to ensure compliance to internal SOP
- Ensure that medical writing deliverables are in accordance with International Conference on Harmonization (ICH) as well as other relevant regulatory guidelines (FDA/EMA, etc.) and local policies and regulations
- Schedule and conduct document-related meetings including the preparation of pre-meeting agenda, key data points for discussion, anticipated outcomes, and post-meeting minutes
- Manage the document review process ensuring conflicting and/or ambiguous comments are clarified, scientifically sound, and appropriately addressed
- Ensure that appropriate documented quality control (QC) checks are performed on medical writing deliverables
- Ensure documents are submission ready and are appropriately stored in agreed document management system
- Collaborate with cross functional team members including clinicians, clinical scientists, biostatisticians, and translational/analytical scientists to interpret study results/key messages and statistical interpretations to ensure they are accurately and clearly reflected in relevant documents, including tables, figures, and listings (TFLs) and narrative planning
- Manage all aspects of outsourced or internal CSR production and ensures project delivery.

- Create and maintain internal style guide, standard operating procedures (SOPs), and work instructions for preparation and maintenance of compliant medical writing deliverables
- Suggests or identifies changes, modifications, and improvements to the document preparation processes and standard writing templates in order to improve quality, efficiency, and productivity

Qualifications and Experience:

- Minimum of BS or equivalent, MPH, MS, PharmD, PhD or MD in field relevant to clinical research preferred. Prior experience in oncology or cell/gene therapy desirable
- Minimum 3 years of experience with PharmD, PhD or MD, 5 years with MS or 8 years with BS
- Must be able to interpret scientific and clinical knowledge to develop relevant medical/scientific materials for clinical trials
- Demonstrates excellent writing and organizational management abilities
- Highly experienced in use of eCTD templates
- Familiarity with the requirements for preparation of key clinical and regulatory documents, including ICH and US regulatory requirements; working knowledge of ex-US regulatory requirements is desired
- Working knowledge of document management systems
- Strong working knowledge of clinical operations, HIPAA rules, and ISO regulations
- Knowledge of good document management practices
- Experience in a matrixed work environment

Additional Desirable Qualifications, Skills and Knowledge:

- Ability to anticipate and resolve problems
- Ability to lead cross functional efforts and teams
- Proficient in clinical data interpretation
- Excellent oral and written communications
- Ability to multitask and work independently in a faced paced team working environment
- Ability to work collaboratively within a team setting