Job Description
Medical Writer

JOB SPECIFICATION:	
Qualification & Competencies	A bachelor's or master's degree – in Biotechnology, Pharmacology, Pharmacognosy/Phytochemistry, or a health science field is a standard prerequisite for Medical Writers. - Capable of working independently with minimal supervision and also as part of a team - Skilled with standard computer programs including the MS Office suite (Word, Excel, Powerpoint) - Possess superior analytical and organizational and time management skills - Good Inter-personal & communication skills (Written and Verbal) - Thorough understanding of the drug development process with sound knowledge of ICH-GCP - Comprehensive writing skills with good command of written and spoken English - Self-motivation and ability to work independently
Experience:	0-2 years relevant clinical research experience
Qualities:	**Ready to learn new things, out of box thinker, Have to go-getter attitude, who wish to grow together with a start-up company**
Job Location:	Shaligram Lakeview, Nr. Vaishnodevi Circle, Khoraj, Gandhinagar – 382421

JOB RESPONSIBILITIES:

- Prepares, edits, and finalizes protocols, investigator brochures, synopses, regulatory documents, and related clinical documents, such as abstracts, posters, presentations, and manuscripts
- Participates in scientific communication planning, including the development of strategic medical communication plans
- Partners with the study biostatistician to engage early with the study team including participation in the review of mock and/or blinded tables, figures, and listings (TFLs), and narrative planning for relevant documents
- Works closely with the study team to ensure that results and messages in clinical documents accurately reflect the data in TFLs and other information sources.
- Schedules and conducts document-related meetings including the preparation of pre-meeting agenda, key data points for discussion, and post-meeting minutes
- Collaborates with clinicians, clinical scientists, biostatisticians, to interpret study results and ensure study results and statistical interpretations are accurately and reflected in relevant documents
- Manages the document review process ensuring conflicting and/or ambiguous comments are clarified and appropriately addressed
- Works closely with the study team to reach a consensus on timelines for deliverables
- Completes documents according to agreed-upon timelines and follows up with the study team as needed to meet internal and external timeline commitments, and to ensure SOP and regulatory compliance
- Understands the functions and roles within the study team and aligns with them in the delivery of documents to meet project-related goals and to meet external results disclosure obligations
- Manages all aspects of outsourced or internal CSR production and ensures project delivery
- Ensures that medical writing deliverables conform to International Conference on Harmonization (ICH) and other relevant regulatory guidelines
- Creates and maintains standard operating procedures and work instructions for preparation and maintenance of compliant medical writing deliverables
- Ensures documents are generated following agreed internal processes and standards, are submission-ready, and are appropriately stored in the agreed document management system
- Ensures that appropriate documented quality control (QC) checks are performed on medical writing deliverables, responds to findings, and recommends quality process improvements
- Suggests or identifies changes, modifications, and improvements to the document preparation processes and templates to improve quality, efficiency, and productivity
- Align with department management to set a strategy for meeting department goals.