

**Position: Medical Writer**

<b>Department</b>	Medical Writing
<b>Basic qualification required</b>	B.Pharm / M. Pharm, M.Sc
<b>Brief JDs</b>	<p><b>Job Description:</b></p> <ul style="list-style-type: none"> <li>• Responsible for preparation/review of the Study Synopsis.</li> <li>• Responsible for preparation/review of the Study Protocol.</li> <li>• Responsible for preparation/review of the Investigator's Brochure.</li> <li>• Responsible for preparation/review of ICD, assent form and subject diary.</li> <li>• Responsible for preparation/review of the clinical study report and other dossier related documents.</li> <li>• Responsible for interacting with KOL for inputs for Protocol writing, Data monitoring committees, and other regulatory requirements.</li> <li>• Regular interactions with sponsor's team for preparation of stussdy related documents, presentations, etc.</li> <li>• To prepare/review departmental SOP under the guidance of the departmental Head/QA.</li> <li>• Preparation/review of documents for regulatory submission like executive summary, and presentation for expert committee meeting.</li> <li>• Preparation/review of Non-clinical Overview (Module 2.4), Clinical Overview (Module 2.5), Module 2. 7 and briefing doctunents.</li> <li>• Design and development of manuscript.</li> <li>○ Coordinate with business development, clinical data management and clinical operations teams for timely closure of medical writing inputs.</li> </ul> <p>Any additional responsibility given by Head of the Department/Management</p>