



POSITION: Medical Writer

Department	Medical Writing (BA-BE)
Basic qualification required	B.Pharm / M. Pharm, M.Sc
Experience	2 -6 years
Brief JDs	<p>Job Description :</p> <ul style="list-style-type: none"> • Preparation of Protocols, Informed Consent Forms, Case Report Forms, and other protocol related documents as per applicable regulatory requirements in consultation with Group In-charge, Principal Investigator, Biostatistician, Analytical Investigator, and Head of the department. • Coordination with study personnel and other departments for protocol related issues for finalization of protocol. • Approval of protocols from Ethics committee in consultation with Principal Investigator and Sponsor. • Responsible for updating the protocol related concerns to investigator(s), sponsor and IEC • Preparation and revision of related SOPs. • Conforms to training schedule for own position and maintains awareness of SOPs contents according to company requirements. • Stays current with the ongoing changes in the pharmaceutical regulatory environment, i.e. FDA, GCPs, GLPs, etc.