

JOB DESCRIPTION

Job Title	Medical Writer
Department	Clinical Operations
Major Responsibilities	<ul style="list-style-type: none"> • Work closely with the Clinical Study Managers, Director of Clinical Development and Operations and Principal Investigator to ensure that Clinical documents are produced to the standard required by FDA/ICH guidelines. • Write Phase 1 and Bioequivalence study protocols, Informed Consent Forms and final study reports. • Interact with the Ethic Review Boards with respect to clinical study protocols and Informed Consent Forms. • Conduct all work in compliance with Standard Operating Procedures (SOP's) and all FDA guidelines. • Contribute to the development of document templates & relevant SOPs.
Reports to	Director of Clinical Development and Operations
Communications	<ul style="list-style-type: none"> • Liaisons with the Director of Clinical Development and Operations, QA, Clinical Study Managers, Principal Investigator and Ethic Review Board.
Requirements	<ul style="list-style-type: none"> • Minimum university degree, B.Sc. (i.e. Life Sciences) and /or at least 2 years of clinical experience as Medical Writer in a Clinical Development environment • Experience in CRO environment preferably in conduct of Phase I and Bioequivalence studies • Good interpersonal skills, good communication skills. • Attentive to details, good initiative and able to work with changing priorities.

This job description should not be constructed to imply that these requirements are the only duties, responsibilities and qualifications for this position. Employee may be required to follow any additional related instructions, acquire job skills and perform other related work if deemed necessary.