JOB DESCRIPTION

Primary Responsibilities	• Overall responsible for organization and conduct of bioequivalence and pharmacokinetic studies in conformance to GCP standards, SOPs, and applicable regulations • To ensure that all professional and technical personnel involved in the conduct of the study have job descriptions and records of training, qualification and experience, which support their ability to undertake the tasks assigned to them • Review medical records and ascertain eligibility of subjects • Prepare protocols, informed consent documents and CRFs for clinical studies • Prepare project plan in co-ordination with designated personnel • Conduct trials with compliance to SOPs and GCP/GLP requirements • Facilitate monitoring and auditing by the sponsor and inspections by the appropriate regulatory authorities. • Liase with Ethics Committee for review of study protocols and informed consent documents • Ensure proper reporting of adverse events to sponsor / Ethics Committee/ regulatory authorities • Ensure reporting of SOP/ protocol deviations in accordance with SOPs

Primary Responsibilities	• Obtain written informed consent from study subjects • Carry out medical examination of volunteers for screening prior to clinical studies or as required • Manage medical emergencies • Account for study drug samples according to GCP guidelines • Prepare final study report of completed studies • Impart GCP and other technical training (including protocol training) to study personnel
Secondary Responsibilities	• Review SOPs and give inputs, as applicable during SOP development / revisions • Maintain awareness in recent trends and newer guidelines in clinical research • To co-ordinate with Quality Assurance Unit in audits and ensure that all the corrective actions are properly incorporated and documented • Respond to Quality Assurance Unit queries