JOB DESCRIPTION

MEDICAL WRITER

JOB SUMMARY: Responsible for designing and preparation of Protocol, Case report form, Informed consent form and other protocol related documents in consultation with Group-In charge and Investigators, interdepartmental and intradepartmental communication, obtaining approval of protocols from the sponsor and IEC (Independence ethics committee).

BASIC SKILLS AND ABILITIES: Demonstrate ability to prepare and design the protocol and coordinate with other departments, IEC and sponsor. Build and maintain effective working relationships with all functional units across all Cliantha sites and sponsors.

MINIMUM EDUCATION TRAINING AND EXPERIENCE REQUIRED: A minimum of Bachelors degree in science, basic knowledge of GCP, regulatory guidelines or equivalent education unless demonstrated competence through work experience.

SUPERVISED BY: Team leaders and Head of the department

PRINCIPAL DUTIES AND RESPONSIBILITIES:

Note: These statements reflect the general description of the position and are not intended to be an all inclusive list of tasks to which employee may be assigned.

A. 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.

B. Coordination with study personnel and other departments for protocol related issues for finalization of protocol.

C. Approval of protocols from Ethics committee in consultation with Principal Investigator and Sponsor.

D. Responsible for updating the protocol related concerns to investigator(s), sponsor and IEC

E. Preparation and revision of related SOPs.

F. Conforms to training schedule for own position and maintains awareness of SOPs contents according to company requirements.

G. Stays current with the ongoing changes in the pharmaceutical regulatory environment, i.e. FDA, GCPs, GLPs, etc.