



Job Description

Department	Clinical Trial
Designation	1. Clinical Research Associate – I / II
	2. Sr. Clinical Research Associate
Location	Ahmedabad
Basic qualification required	M.Sc (Clinical Research) /B.Pharm / M.Pharm
Experience	1. Clinical Research Associate – I / II - Atleast 1 – 3 year of Monitoring Experience, 50-150 SMV, 20 SIV/SCV
	2. Sr. Clinical Research Associate - Atleast 4 year of Monitoring Experience, 250-300 SMV, 60 SIV/SCV
Brief JD	Conduct of monitoring visits as per monitoring plan in order to check compliance with study management, protocol & other requirements at all assigned sites.
	Identify and qualify potential investigators
	Perform source document verification as per monitoring plan and ensure that source documents & other trial records are accurate, complete, kept up-to-date & maintained according to applicable SOP's to avoid incomplete records.
	Responsible for identification & collection of necessary documents to be forwarded to Project Manager/ designee, in order to check the feasibility of site/ investigator and approval from authorities.
	Responsible for training of site study team regarding the monitoring plan, recording & maintenance of essential documents and for startup activities & site initiation as per the guidance of Project Manager.
	Responsible for IP accountability and availability, tracking and management of all Clinical Trial related supplies shipped to the sites/ warehouse & accordingly clinical trials supplies vendor management for the study.
	Responsible for site-closeout & follow up activities in order to maintain documents at the site.
	Assist with the audit of an investigational site or central files and liase with Quality Assurance personnel as required to ensure that the study is being conducted in accordance with ICH GCP and applicable regulatory guidelines.