

Aurigene is a development stage biotech company engaged in discovery and clinical development of novel and best-in-class therapies to treat cancer and inflammatory diseases, and a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd. Aurigene is focused on precision - oncology, oral immune checkpoint inhibitors, and the Th-17 pathway. Aurigene currently has several programs from its pipeline in clinical development and multiple compounds at different stages of pre-clinical development. Aurigene has partnered with many large and mid-pharma companies in the United States and Europe and has 15 programs currently in clinical development. Aurigene is a profitable company that has continuously invested in its people resources, infrastructure, and expertise over the years.

Position	Clinical Research Associate / Sr. Clinical Research Associate
Department	Clinical Development
Location	Bangalore
Desired Profile	M. Pharm /M.Sc. with 2-8 years Exp.
Job Description, Key Skills and Competencies:	 Perform site selection, initiation, monitoring and ensure trial close out and retrieval of trial materials. Work with sites to adapt, drive and track subject recruitment and retention plans. Create and maintain appropriate documents related to site management, monitoring, visit findings and action plans. Administer protocol and related study training to assigned sites and establish regular lines of communication. Evaluate quality and integrity of study site practices related to proper conduct of protocol and adherence to applicable regulations. Manage the progress of assigned studies by tracking regulatory and local Ethics Committee submissions & approvals, recruitment & enrolment, case report form (CRF) completion & submission, and data query generation & resolution. Respond to company, client and local regulatory on requirements and audit under supervision of Project Manager. Collaborate and liaise with team members for project execution and support. Maintain and keep trial of Master Files as ready reference for audit, inspections and performs administrative tasks (such as expense reports) updated. Assists project team to prepare project publications, tools and share ideas/suggestions with team members. Perform additional study tasks as assigned by the Project Manager. (e.g. visit report review, CRA performance review, lead CRA calls etc.). Require effective clinical monitoring skills.

	 Knowledge of ICH-GCP, new drug, clinical trial rules and other applicable regulatory guidelines. Understanding and demonstrate application of GCPs and applicable SOPs.
	Competencies:
	Communication Skills
	Interpersonal Skills
	Team Player
Company Overview	Please visit http://www.aurigene.com
Apply Now	Please send your profile at <u>careers@aurigene.com</u>