Aurigene Oncology
Conquering Cancer

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.

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| **Position** | Assistant Clinical Project Manager / Clinical Project Manager – Clinical Development |
| **Location** | Bangalore (Office based) |
| **Desired Profile** | • Degree in life sciences or relevant discipline with over 5 years of experience in managing clinical trials and related operational aspects.<br>• At least 2 years of experience as a Clinical Project Manager or at least 3 years as an APM (Assistant Project Manager). |
| **Job Description, Key Skills and Competencies:** | ● Act as a Project Lead for the assigned clinical trials while supervising CRAs in their functions of monitoring and administration of clinical trials.<br>● To manage service providers, CRO and Vendors, collect quotes (budget proposals), summarize & present the same to the management team.<br>● Provide support with regulatory authority applications and approvals.<br>● Manage the clinical trials which have been assigned by the Clinical Manager or Head, Clinical Development.<br>● To assure appropriate site selection, proper site set up, notification/ submissions to regulatory or Ethics Committees (ECs) and execution of Clinical Trial Site Agreements (CTA).<br>● Develop and maintain the clinical trial operational plans including timelines, budget, and resource requirements within a therapeutic area and in adherence to organizational SOPs.<br>● Develop and construct content for risk mitigation plans to ensure clinical trials are conducted on time and within budget.<br>● To generate a Project Management Tracker/Plan listing the tasks related to study planning, conduct and closeout.<br>● Review and contribute to Clinical Protocols, Investigator's Brochures (IBs), Case Report Forms (CRFs), Informed Consent Forms (ICFs), Pharmacy Manuals, Laboratory Manuals etc. from an operational perspective.<br>● Assure proper project kick-off meetings and ensure the availability of study progress reports for the extended team.<br>● To assure proper Investigational Medicinal Products (IMPs) management.<br>● Participate in patient identification activities and the development of patient recruitment plans and backup plans.<br>● To identify, recruit, and approve clinical investigators in collaboration with Medical Monitor and Clinical Operations leadership.<br>● Ensure that all supportive study-related documents like Monitoring Plan, Study Reference Manual, Laboratory Manual, Pharmacy Manual, CRF Completion Guidelines, etc. are completed. |

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| | ● Ensure that all monitoring activities and processes are completed in compliance with internal company SOPs and GCP/ICH/regulatory guidelines and all internal and external resources are well trained.<br>● Assure the proper reconciliation of the TMF, appropriate Site Closeout, and archival of the study documents.<br>● To recommend and implement innovative process ideas that impact clinical trials and/or clinical program management. |
| **Company Overview** | Please visit http://www.aurigene.com |
| **Apply Now** | Please send your profile at careers@aurigene.com |