

Department	Clinical Development
Position	Clinical Development Manager
Reports to	AVP - Technical
Location	Whitefield, Bangalore

## **KEY RESPONSIBILITIES SHALL INCLUDE:**

- Identify, contact, share CDAs, RFPs, study synopsis & obtain trial related quotations from various CROs and other vendors
- Perform pre-qualification visits to CROs/vendors & generate reports
- Coordinate with global CROs for the conduct of Bioequivalence and Phase trials
- Develop scope of work and define RACI responsibility matrix for the CROs
- Develop/review Master Services Agreement/Contract for the CROs
- Overview / communicate and escalate all CRO related issues with Bioplus management
- Develop/review various Clinical Study Protocols, Plans, SOPs and other Study related documents
- Initiate governance and kick-off meetings, as required
- Coordinate with State and Central Government bodies for necessary approvals
- Coordinate with other departments like Marketing, F & D, QA, QC, RA and Manufacturing teams for timely delivery/completion of a project
- Coordinate for initiation and collation of Regulatory documents and compile the Dossier for Regulatory submission, as required
- Maintain all clinical related study files at Bioplus
- Any due diligence activities, as assigned by the management

<b>EXPERIENCE</b>	• 8 to 10 years sound experience in reputed Organizations
QUALIFICATION	<ul> <li>Ph.D or MD with Pharmacology background</li> </ul>

## **KEY COMPETENCIES**

- Ability to work both independently and within a team structure
- Proven ability to lead, influence and motivate colleagues and external partners
- Strong planning, presentation and interpersonal skills
- Strong work Ethics, Self-motivated, Dedicated & Results orientated
- Excellent in written and spoken English
- Multi Tasker, strong in systems, process to handle multiple projects/sites
- Can do attitude is a must
- Evaluation of strategic option, costs, time and completion strategy
- Strong internal co-ordination skills
- Ability to handle extreme pressure situations
- Excellent aptitude in written and oral English.
- Problem Solver, Self-motivated, Team Leader