Department	Medical Affairs / Clinical
Position	Clinical Trial Specialist
Reports to	Clinical Trial
Location	Whitefield, Bangalore

Position Overview:

We are seeking a highly motivated and detail-oriented individual to join our team as a Clinical Trial Specialist. As a Clinical Trial Specialist, you will be responsible for supporting the planning, implementation, and management of clinical trials conducted by our pharmaceutical company. Your role will involve collaborating with cross-functional teams, ensuring compliance with regulatory requirements, and contributing to the successful execution of clinical trials.

Key Responsibilities:

1. A Clinical Trial Specialist is responsible for managing the planning, implementation, and tracking of the clinical monitoring process, administration of clinical trials and maintaining an overview of ongoing clinical trials.
2. Lead the clinical development plan & Scientific Strategy
3. Overall responsibility of the ongoing studies
4. International Regulatory & Ethical Submissions
5. Regulatory Strategy Development
6. Policy Making for Product Introduction
7. Should be an expert in ICH-GCP guidelines.
8. Assuring compliance with SOPs and local regulations, and CFR, ICH, and GCP guidelines.
9. Management of CROs/CRAs.
10. Inviting proposal, review, and analysis of proposal.
11. Clinical Trial Documentation & creation of important study documents (Protocol writing, Study design, CRF …….)
12. Participate in protocol development, CRF design and clinical study report writing.
13. Conduct feasibility studies: Initiate BA/BE studies, Phase 1,2,3,4 (PMS/RWS/RWE)
14. Do statistical analysis of the generated data.
15. Article writing & Article publications.
16. Medical Monitoring & Surveillance
17. Oversee patient recruitment.
18. Supervise in-house clinical trial staff & Ensure compliance of staff with the organizations Standard Operating Procedures
19. Conduct team meetings and staff training programs.
20. Creating and overseeing the trial budget.
21. Optimize costs and resources to help improve the organizations profitability.

22. Collaborating with Project Manager to set targets for clinical monitoring staff and ensuring the recording of trial in compliance with project goals.
23. Creating and implementing study-specific clinical monitoring tools and documents.
24. Identifying, enlisting, and choosing sites, and coordinating site management activities.
25. Coordinating and supervising clinical monitoring team.
26. Providing Clinical Research Associates with project-specific training and having regular meetings with them.
27. Recording and sharing interactions with clients.
28. Arranging and overseeing site visits.
29. Gathering and examining trial documents.

EXPERIENCE	Fresher (Experience in IND/NDA applications is preferred)
QUALIFICATION	M.Pharm / Ph.D with Clinical Study exposure

KEY COMPETENCIES

- Thorough understanding of the drug development process with extensive knowledge of ICH-GCP
- Extensive knowledge of clinical trial regulations such as those of US FDA, EMEA, DCGI etc
- Influential & assertive communication skills
- Excellent leadership skills
- Good record keeping skills.
- Ability to motivate.
- Self Confidence
- Ability to think Out-of-the-box.
- Problem solving skills.
- Conflict management skills
- People management skills.