Associate Director/Director, Clinical Research (MD)

Reports to: Chief Medical Officer

Classification: Exempt

Summary:
Responsible for medical guidance to all aspects of product development, as well as data interpretation and reporting.

Essential Functions and Job Responsibilities:

- Provide medical expertise to the clinical operation team, medical affair team, and if necessary the pre-clinical team
- Assumes responsibility for all scientific aspects of conceptualizing, planning, and executing clinical studies
- Manage the clinical research component in the preparation/review of regulatory documents and various reports
- Ensure adherence to regulatory requirements of study conduct and industry standards of Good Clinical Practice
- Coordinate the collection and analysis of clinical data for internal analysis and review
- Manage the preparation and/or review of data listings, summary tables, study results, study reports, and clinical NDA sections
- Conduct ongoing and periodic clinical data review of assigned clinical studies
- Monitor clinical safety and address safety signals
- Provide medical/scientific input into the development of statistical analysis plans, review of tables/listings/figures and interpretation of data, including safety narratives and safety reports
- Manage and assist in the preparation of meeting materials for scientific meetings, including presentations and abstracts
- Maintain and expand medical knowledge in relevant fields
- Complete other responsibilities as assigned

Minimum Qualifications:

- MD or MD/PhD, medical specialty preferred
- Significant experience of medical practice will be a plus
- Minimum 3 years of experience required in pharmaceutical industry
- Relevant industry experience in clinical research with understanding of Good Clinical Practices
- Ability to think analytically and strategically to formulate, develop, and execute clinical plans.
- Strong leadership skills with an ability to set vision, lead change, and mentor others.
- Excellent scientific written and oral communication skills.
- Comfort with engaging internal and external experts, as well as study investigators, in constructive scientific and clinical dialog around study design, study conduct, and interpretation of clinical results.
- Well-developed sense of integrity, strong work ethic, scrupulous attention to detail, clear ability to establish and maintain timelines, and persistent commitment to ensuring a high level of quality.