

Biotech Company: Clinical Medical Director (MD required)

Our client is a fast paced, fast growing global biotechnology company in Massachusetts. We are seeking high energy individuals who are ready for this exciting opportunity and the chance to further establish your career. If you have current pharmaceutical/biotech clinical experience and an MD this may be the next best step for you! We are looking for dynamic leaders who want to work in a cutting edge environment and want to create impact in a company working to make a difference. For immediate and confidential consideration, please send a Word version of your resume and note the site you saw the posting.

We are searching for an Associate / Medical Director to join the Clinical Development team to assist with the advancement of several programs currently in the drug development process.

The Medical Director serves as Medical Monitor for Clinical Trials, ensuring compliance with GCP regulations and monitoring the safety of enrolled subjects. Generally works on multiple trials or more than one program at a time comprised primarily of Phase II and Phase III studies. In this position you provide program level clinical support across multiple programs in the area of cystic fibrosis.

Top Candidate Qualities:

- MD required.
- 5+ current years of Clinical Development in the pharmaceutical industry is required.
- 1-2 years of basic or clinical research experience in an academic setting with publications in peer reviewed journals.
- Board certification in Internal Medicine or a similar medical specialty required. Preferred qualifications include sub-specialty training in internal medicine, family practice, pediatrics, pulmonary medicine or allergy.
- Excellent communication skills; and ability to work collaboratively in a team-based matrix management environment with minimal supervision.
- Possess a full understanding of applicable US and EU regulations and of the drug development process.
- Have a working knowledge of biostatistics and pharmacokinetics.
- Experience in filing and defending US IND's, or similar ex-US regulatory submissions.

Job Responsibilities Include:

- Act as the Medical Monitor for clinical trials.
- Develops clinical protocols, investigator's brochures and clinical development plans (in coordination with the Clinical Program Manager) with emphasis on scientific and safety matters, with minimal guidance.
- Represents company to outside medical / scientific experts in the development of the clinical protocols, solicitation of input and opinion, and presents at conferences and symposiums.
- Utilizes novel and creative methods to resolve clinical development problems independently.

- Acts as liaison between clinical development department and internal regulatory affairs for assigned programs.
- Be a direct participant in clinical trials.
- Contribute to the production of regulatory documents such as IND filings, IND annual reports and EU regulatory submissions.
- Be the primary company liaison to academic medical experts and investigators.

Excellent compensation offered, with bonus and full benefits. Relocation available.