



**Title:** Medical Director  
**Location:** Cambridge, MA  
**Reports to:** SVP, Clinical Development

**The Role:**

Medical Director will be responsible for providing clinical leadership of clinical development programs, and for the design, execution, and analysis of clinical trials, as well as for supporting Medical Monitoring activities across trials. Role will report to the VP of Clinical Development and will collaborate with other functional members in the organization.

The Medical Director has proven leadership skills and the ability to successfully guide and influence cross-functional teams. The individual collaborates with internal stakeholders such as Clinical Operations, Regulatory Affairs, Translational Medicine, Clinical Pharmacology, Data management, Biostatistics as well as with external collaborators such as study investigators and their staff, Key Opinion Leaders, CROs and vendors. The candidate will be able to work in a highly scientific and vibrant, fast-pace clinical research environment at an organization that is undergoing substantial growth and have the opportunity to lead to a wide spectrum of drug development activities.

**Here's What You'll Do:**

In conjunction with the Vice President of Clinical Development, the Medical Director, will manage all aspects of clinical operations for assigned programs to assure the highest standards (scientific, ethical, regulatory and good clinical practice) of clinical program planning, study design and execution. Responsibilities include:

- Provides oversight of individual clinical trials to ensure that safety concerns and/or adverse events are identified and appropriate responses to such concerns are developed and executed.
- Develops global clinical strategies working in collaboration with internal and external colleagues to fulfill the corporate goals and objectives; overseeing the product development strategy, clinical development plan.
- Leads the design, data collection, review, execution of clinical studies in support of product development, ensuring rigorous and compliant study conduct with current health authority regulations.
- Directs, designs, authors and reviews clinical trial protocols, protocol amendments, informed consent documents, investigator brochures, CRFs, monitoring plans, data and statistical analysis plans, etc.

- Authors and reviews sections of clinical study reports and regulatory submission documents, such as, INDs, CTAs, BLAs, regulatory agency briefing packages, etc.
- Leads the review, analysis and interpretation of clinical-medical safety and efficacy trial data, including Adverse and Serious Adverse Events, clinical laboratory data, and other technical examinations
- Responsible for the scientific execution as required for the initiation, conduct and medical monitoring of Phase 1-3 clinical trials
- Prepares, presents, and defends complex aspects of protocol design and/or medical study data at internal meetings or investigator meetings
- Actively engages in the planning, preparation and participation of regulatory meetings, e.g., Pre-IND-, End-of-Phase 2 meeting, or other regulatory meetings
- Prepares and or reviews clinical sections of required regulatory documents, including briefing documents, Investigational New Drug (IND) filings, Clinical Trial Applications, safety reports, final study reports, and Biologic License Application (BLA) filings.
- Collaborates with external stakeholders such as study investigators and their staff, Key Opinion Leaders, CROs and vendors during all phases of the clinical trial and program.
- Prepares and reviews draft abstracts, presentations, posters, and manuscripts for publication in consultation with other team members/collaborators
- Provides ongoing overview of plans, and updates plans as project needs change, keeping stakeholders and contributors aligned with changes both in the external environment and across Vedanta Biosciences

**Requirements:**

- Requires an MD degree with a minimum of 2-3 years of pharmaceutical/biotech industry experience. PhD or PharmD with equivalent experience and skills will also be considered.
- Ability to develop and conduct complex clinical research programs independently.
- Proven leadership skills and ability to successfully guide and influence cross-functional teams.
- Will be able to develop, author and review Clinical trial protocols, Informed Consent forms, CRFs, Investigator brochures, Clinical study reports, Data Monitoring plans, Safety Monitoring Plans, Development Safety Update Reports, and other regulatory documents
- Has robust experience in the review, analysis and interpretation of clinical-medical safety and efficacy trial data, including Adverse and Serious Adverse Events, clinical laboratory data, and other technical examinations
- Will be able to evaluate safety events (e.g. SUSARs, laboratory observation, etc.) and analyze in conjunction with similar events across clinical trials and programs. Will be able to closely collaborate with the Safety and Pharmacovigilance group and Medical Monitors at the CRO.
- Experience in one or more of the following clinical area(s) is desirable but not a must: Infectious diseases, gastroenterology, immunology, oncology. Prior medical practice is a definite plus.
- Deep understanding of Good Clinical Practices (GCPs) is necessary. Has successfully conducted clinical trials in a GCP/ICH compliant environment

- Has demonstrated the ability to analyze, interpret, and present complex scientific clinical data to both subject matter (e.g. key opinion leaders) and non-subject matter experts and is able to draw medical and scientific conclusions
- Has demonstrated solid understanding of biostatistics, trial planning and sample size generation in collaboration with the biometrics group
- Has basic understanding of clinical pharmacology, microbiology
- Has worked directly with Clinical investigators and is able to provide leadership in protocol-related discussions (e.g. entry criteria of the protocol) with representatives of clinical operations, investigators and investigator trial staff
- Has demonstrated scientific expertise in the presentation and publication process with a track record of publishing peer-reviewed scientific data, e.g., posters, oral presentations, review articles, and manuscripts
- Can work well in a cross-functional team environment which includes representatives of Biometrics, Clinical Operations, Regulatory, Safety, Project Management, Clinical Pharmacology, Clinical supplies, Data Management, etc.

#### **Competency Expectations:**

- A drive to achieve the highest quality of work at all circumstances
- Able to incorporate a broad understanding of industry issues into plans/strategies in order to capitalize on ideas and initiatives that will drive success of the Clinical Organization
- Able to assess the competitive environment (internally and externally) relevant for the implementation of a clinical development plan, and proposes mitigation strategies
- Considers how present policies and practices might be affected by future developments and trends within the global regulatory and compliance landscape and incorporates necessary updates into policies and practices
- Effective in building relationships and networks with others across and beyond Vedanta Biosciences
- Demonstrates ability to enlist input from stakeholders and constituents to make key decisions (e.g. tactics to accomplish goals), while ensuring final decisions are reached quickly and effectively
- Identifies development opportunities for staff, both within and outside of Clinical Operations
- Ability to utilize a variety of software programs such as Microsoft Office products (e.g., Project, Excel, Word, PowerPoint) and clinical database software

#### **Why join Vedanta Biosciences**

Vedanta is pioneering the development of a new class of therapies that act by modulating the human microbiome. Modulation of the human microbiota holds enormous promise to treat a broad range of immune and infectious diseases in ways that are completely different to existing drug classes. Breakthrough discoveries of our scientific team in the field of mucosal immunology have led to the first

rationally designed drug candidates in the microbiome field. Vedanta was founded by PureTech Health and a team of world renowned experts in immunology and microbiology.

We invite you to explore our site to learn more about our company and how our discovery platform enables identification of bacterial consortia with drug-like properties and their manufacture to GMP standards.

## Our Vision:

We are harnessing the human microbiome to enable a new drug modality based on rationally defined bacterial consortia

*Vedanta is committed to equal employment opportunity and non-discrimination for all employees and qualified applicants without regard to a person's race, color, gender, age, religion, national origin, ancestry, disability, veteran status, genetic information, sexual orientation or any characteristic protected under applicable law. Vedanta will make reasonable accommodations for qualified individuals with known disabilities, in accordance with applicable law.*