



***Medical Director, Clinical Development***  
Cambridge, Massachusetts

**Job Description**

The Medical Director will provide clinical direction and leadership to the design and conduct of clinical trials.

**Job Duties**

- Oversees implementation of clinical development plans, including research and selection of appropriate clinical endpoints, inclusion/exclusion criteria and protocol design.
- Oversees the conduct of clinical studies in accordance with GCPs, SOPs, FDA and ICH regulations.
- Medical monitor responsibilities for Phase III/IV studies in substance abuse – developing protocols, interacting with investigators to appropriately manage safety and adverse experiences of subjects on study.
- Management and oversight of Safety sub-group within Clinical Development.
- Review of adverse event, serious adverse events in the clinical and safety databases.
- Periodic review of safety data listings to identify trends or issues.
- Contributes to writing and reviewing of clinical study reports, protocols, investigator brochures, safety reports and other clinical documents.
- Review and interpretation of data from clinical studies, including submission of abstracts to scientific meetings, presenting results, and submitting journal articles for publication.
- Interact with senior management, program management and key functional groups about issues affecting clinical programs including timelines and communications of data.
- Participation in regulatory planning and regulatory submissions including but not limited to INDs, IND safety reports, NDAs, NDA safety updates, sNDAs, product labeling package inserts, and other reports as necessary.

**Autonomy**

- Task Execution: Capable of determining appropriate method(s) for completing new assignments.
- Decision making: Assignments are complex in nature and require judgments based on fluent understanding of SOP, GCP.
- Prioritizing/Multitasking: Recommend feasible timelines with assumptions and possible contingencies. Capable of efficiently triaging workload and appropriately delegating tasks to meet or exceed timelines. Able to recommend deadlines or revised timeframes based on workload, resources, and emergent situations.
- Problem solving: Ability to recognize potential adverse situations, propose corrective actions to appropriate teams, and assist in the resolution. Capable of implementing most efficient and appropriate corrective actions
- Supervisory requirements: Capable of making appropriate decisions independently, triages the details of the situations that require reporting to supervisor staff, and show accountability for actions.

**Communications**

- Excellent oral, written, and presentation skills.
- Excellent negotiation skills and ability to work through difficult conversations/situations.
- Capable of presenting a clear message, simplifying the presentation of complex information, and interacting with audiences.
- Regularly serves as team meeting chairperson within the department.
- Excellent information management skills are demonstrated in all forums, internal and external.

- Represent the department in multidisciplinary and corporate meetings and effectively presents messages consistent with the department expectations.
- Represent the company in scientific and business meetings, effectively representing Alkermes and its corporate goals.

### **Ongoing Professional Development**

- Ongoing review of industry and therapeutic publications.
- Attend professional conferences and training courses (therapeutic-specific and clinical research, regulatory, & process improvement related).

### **Department Development Contributions**

- Supervising, mentoring and/or training peers/direct reports, presentation of industry trends or relevant therapeutic interests.
- Appropriately initiate department meetings to discuss specific topics or situations. Identify department needs (programs, SOPs, training, etc), suggest and manage special projects to address such needs.
- Consistently and appropriately initiate process and SOP improvements (Identify inefficiencies and/or problems, suggest & support modifications).

### **Travel Requirements**

Up to 35%

### **Minimum Education & Experience Requirements:**

- An MD, DO or MD/PhD is required.
- Experience in psychiatry, neurology or addiction medicine is a plus.
- The candidate should be comfortable working across multiple therapeutic areas.
- Basic or applied medical research experience in either the pharmaceutical industry and/or academia is essential.

### **Knowledge/Skills Needed:**

- Thorough knowledge and experience with clinical research methodologies (design, statistics and technologies) across a range of therapy areas.
- Detailed knowledge of ICH/GCP and FDA regulations and guidance related to clinical studies.

### **Personal Attributes Needed:**

- Ability to effectively interact with medical experts, regulatory agencies, corporate partners and Alkermes development teams.
- Strong Leadership skills.
- Excellent verbal and written communication skills.
- Flexible but goal oriented work practices.

## ***COMPANY PROFILE***

**Alkermes® (Nasdaq: ALKS) is a world leader in the development of products based on sophisticated drug delivery technologies. We partner with many of the world's finest pharmaceutical companies and we develop drugs for our own account. We seek to apply our technologies to product candidates that solve important health problems and meet true medical needs. Our expertise lies in the development of controlled, sustained-release injectable drugs using our ProLease® and Medisorb® technologies and inhaled formulations based on our proprietary AIR® pulmonary technology.**

**IF YOU WOULD LIKE TO BE CONSIDERED FOR A POSITION WITH ALKERMES,  
PLEASE VISIT OUR WEBSITE TO SUBMIT YOUR RESUME**

**WWW.ALKERMES.COM**

Benefits include: Medical/Dental Coverage, 401(k) with company match, Stock Options, Tuition Reimbursement, Flexible spending accounts, Short and Long term Disability (100% paid), Life Insurance (100% paid), 11 Holidays plus 3 personal days per year, 3 weeks vacation to start, and transportation benefits.

**Alkermes is an equal opportunity employer, relying on the strength of a diverse workforce**