

## Director of Clinical Affairs

The Director of Clinical Affairs will lead pre-market clinical research activities for Olfax Medical's emerging pipeline of nasally delivered therapeutics. This is a fully empowered position that will work in close collaboration with executive team members to advance clinical development strategy and manage clinical research activities, regulatory compliance, and publication efforts. The initial focus will be on overseeing clinical and regulatory planning for Olfax Medical's lead pipeline asset, a novel drug/device combination product for acute migraine. Continuing opportunities for clinical development are also expected to emerge for new assets that address central nervous system disorders and leverage Olfax Medical's existing nasal delivery technology. This position is expected to contribute to the assessment, selection, and pursuit of funding to support development of the expanded pipeline.

### Essential Functions

- Create clinical development plans that execute commercial, regulatory, and clinical strategies
- Coordinate with key opinion leaders and medical advisors to create clinical protocols for Phase I - III trials
- Liaison between device development, drug development, regulatory, and clinical partners to prepare medical and scientific input to IND submissions, investigator's brochures, trial reports, regulatory briefing packages, NDA dossiers
- Lead FDA and IRB interactions to obtain approval for drug development programs at various phases - from early development to post-marketing

### Additional Responsibilities

- Conduct scientific and medical research to identify and assess new pipeline opportunities
- Assist in the strategic planning, creation, and submission of funding proposals to the NIH, DoD, and other federal/state agencies
- Actively participate in developing and implementing initiatives to grow and improve the company

### Desired Qualifications, Skills, and Behavior

- PhD in related field or MS with demonstrated equivalent experience and expertise
- Ideally Phase I-III clinical research experience in pharmaceutical / biotech / medtech industry. May also consider academic research and/or pharmaceutical development background that includes foundational understanding of clinical and regulatory research.
- Excellent team working skills and the communication ability to positively encourage and energize others to reach high performance
- Demonstrated proficiency in technical writing
- Values being part of and thrives in a start-up company culture where quality of life, accountability, diligence, resourcefulness, trust, and diversity is paramount
- Proactive, self-motivated, and entrepreneurial individual who has the ability to prioritize and get things done

### Additional Considerations

- This position is work-from-home / remote apart from company management meetings (quarterly)
- Occasional travel to participate in relevant conferences, meet with external experts, and visit partner sites.



### About Olfax Medical

Olfax Medical is a pre-clinical stage pharmaceutical company specializing in nasally administered therapeutics. Our mission is to help patients avoid the harmful and addictive side effects of systemic pharmaceuticals by revolutionizing nasal drug delivery. Founded in 2017, Olfax's product development is based on a simple-to-use, handheld device that accurately delivers medication to the highly vascularized regions of the upper-posterior nasal cavity. In 2022, Olfax Medical was identified as a top-three life science venture in North Carolina and has since secured over \$6.1M in non-dilutive funding from the Department of Defense and National Institutes of Health to develop a novel, intranasal nerve block treatment for headache disorders. Further information about Olfax Medical is available at [www.olfaxmedical.com](http://www.olfaxmedical.com).

### Contact Information

Potential applicants should send a resume and letter of interest to [info@olfaxmedical.com](mailto:info@olfaxmedical.com)