Regulatory Affairs Manager

Neuralight is on a mission to help hundreds of millions of people suffering from Neurological diseases. We are looking for a talented, experienced, and ambitious **Regulatory Affairs Manager** to join our team!

The Regulatory Affairs Manager will facilitate the regulatory affairs within the company as a part of the clinical & regulatory affairs department. This will include the preparation and submission of regulatory agency applications, reports, or correspondence and a review of all regulatory agency submission materials to ensure timeliness, accuracy, comprehensiveness, or compliance with regulatory standards. The ideal candidate possesses a broad base of regulatory experience and a high level of technical depth applicable to medical devices and software design, along with QMS experience.

In this role, you will work in a hybrid environment that strives on learning and growing as professionals and individuals.

You will:

- Report directly to The Head of Clinical & Regulatory Affairs.
- Lead Regulatory Affairs activities and management of external consultants, with expertise in the requirements of regulators and other agencies such as the FDA. This also includes responsibility for global regulatory submissions, preparation of documents, submission, and maintenance of Breakthrough designations, 510(k)s, De Novo, etc.
- Be responsible for writing and developing technical files, device history files, device master records, clinical reports etc.
- Partner closely with Clinical Affairs regarding the clinical development programs needed to support regulatory strategy and submissions to health authorities, assist in determining clinical feasibility of new products, and all required documentation related to developing and implementing new products.

You have:

- At least 3 years' experience in Regulatory Affairs of medical devices, working at or with FDA-cleared medical device companies. Must have hands-on experience in writing, developing and implementing comprehensive Regulatory Affairs processes, documents, procedures, and strategies.
- Experience in a software company or in a Start-up medical device experience, as well as working in a fast-paced development environment is an advantage.
- Understanding of International Conference on Harmonization (ICH) and Good Clinical Practices (GCP) requirements, regulatory compliance, and reporting.
- Experience with coordination, writing documents, and direct submission activities for a variety of regulatory approvals such as breakthrough designations, 510k clearances, De Novo, PMA, Pre-Sub Packages.
- Experience in developing systems to support Document Control, Design Control, Internal Audit.
- Diverse validation experience software/systems, and computer systems.
- Willingness to travel as required (up to 10%).

You are:

- Adaptable, flexible, independent, and resourceful, also willing to roll-up-sleeves and multi-task to thrive in a growing environment.
- Someone with outstanding communication skills (verbal and written) and excellent listening skills.
- Someone with high attention to detail and pace – thorough, quick, and makes self- and team-accountability as a top priority.

APPLY HERE

About NeuraLight:

NeuraLight is a VC-backed venture on a mission to transform the lives of billions of people impacted by neurological disorders by digitizing neurological evaluation and care.
Our AI-driven platform integrates multiple digital markers to accelerate and improve drug development, monitoring, and precision care for patients with neurological disorders.
The technology driving the platform includes proprietary Machine learning algorithms which automatically extract a host of digital oculometric markers from facial videos captured with a standard smartphone or webcam.
NeuraLight's founders are repeat entrepreneurs and industry veterans (including both the co-founder of Chorus.ai and the founding CTO of Flatiron health) leading a 30-strong team, supported by renowned neurologists and 2 Nobel laureates as well as a stellar Scientific Advisory Board, and have raised $30.5M to date.

Our Core Values:

We are on an urgent mission

- Both as a team and as individuals we are driven by a mission to transform neurology and save and improve people's lives.
- The stakes are high, and we understand we need to take risks and be bold. We avoid stagnation, make decisions as soon as possible, and do our best to make progress, and deliver quickly and effectively.

We are psychologically safe

- We encourage everyone to speak up, be vulnerable and take initiative with ideas, questions, concerns or mistakes.
- We respect everyone and take their thoughts and opinions seriously.
- We celebrate each other as individuals and professionals, we are an empowering team.

We enjoy the ride

- We believe the journey is not less important than the goal, so we do our best to enjoy the ride.
- We are proud of what we do and celebrate our successes, we exude optimism in face of the serious and long-haul challenges we face.