Head of Regulatory and Quality Affairs

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 **Head of Regulatory and Quality Affairs** to join our team!

The Head of Regulatory & Quality Affairs will lead and facilitate both the Regulatory Affairs activities and Quality Management Systems (QMS) to ensure compliance with regulation and compliance agencies. 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 are an advocate for quality and support best quality management and quality design practices. You will work with development teams to encourage agile design concepts, as well as with the clinical team, in an engaging and positive way.
You will work in a hybrid environment that strives on learning and growing as professionals and individuals.

You will:

- Develop, Coordinate, and implement all practices, programs, and strategy of the organization's Regulatory and Quality Affairs Department.
- **Report directly to The Chief Innovation Officer.**

<u>Regulatory:</u>

- Lead Regulatory Affairs activities and management of external consultants, with expertise in the requirements of regulators and other agencies such as the FDA (FDCA and its amendments pertaining to medical devices), EMA (EAUs), etc. This also includes responsibility for preparation of documents, submission, and maintenance of Breakthrough designations, 510(k)s, EUAs, etc.
- Ensure that quality system requirements for software and medical devices are effectively established and maintained in accordance with regulations and guidelines as applicable.

- Serve as FDA and other RA authorities Management Representative (participation/leading meetings with Regulatory authorities personnel) and response to address compliance issues.
- Responsibility for development of Technical Files, Device History Files, Device Master Record, clinical reports, etc.
- Responsible for global regulatory submissions.

Quality:

- Design and implement Neuralight's Quality Measurement System (QMS), processes, and guidelines.
- Work with the engineering teams to install QMS best practices as part of the development cycle and release processes.
- Serve as the go-to person for clarifying and interpreting regulatory requirements with respect to NeuraLight's software development and release processes.

Additional responsibilities:

- 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.
- Conduct critical assessments via internal audits of all processes and equipment to identify areas of improvement.
- Conduct Management Reviews as scheduled, be responsible for the evaluation and dissemination of company quality standards, initiatives, guidelines.
- Maintain Quality Assurance programs, policies, processes, and procedures to ensure that the performance and quality of products conform to established standards.

You have:

- At least 7 years' experience in Regulatory Affairs of **software and medical devices**, working at or with FDA-cleared medical device companies. Must have hands-on experience in developing and implementing comprehensive Regulatory Affairs & Quality processes, documents, procedures, and strategies.

- Start-up medical device experience and experience 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 in **both leading a big vision strategy while 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.
- High attention to detail and pace – thorough, quick, and makes self- and team-accountability as a top priority.
- Demonstrate executive presence when dealing with complex issues, ambiguity, and making timely, high-quality decisions.

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.

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