Manager, Quality Affairs

About Paradromics

Paradromics is bringing to market the first high-bandwidth data interface between brains and computers. We envision a future where data is medicine and some of the hardest challenges in physical and mental health have been reframed as technical problems with clear solutions. By allowing direct readout and modulation of neural activity, brain computer interfaces (BCI) will act like a modem for the brain, allowing it to connect with restorative digital systems. Our first product will be an Assistive Communication Device for patients with severe combined speech and motor deficits as a result of paralysis.

Job description

As the Manager of Quality Affairs, you will be responsible for developing and maintaining the Quality Systems at Paradromics and for providing Quality Affairs leadership to project teams. You will ensure the implementation of an effective Quality Management System that complies with applicable regulations (including 21 CFR 820) and standards, including design controls, risk management, and supplier quality processes and systems. This position is instrumental in supporting the company's continued growth and future success, and requires an individual with a "can-do," self-starter attitude. This person is excited about working collaboratively with a team and is capable of both diving into hands-on, detailed quality work, as well as stepping back to view the bigger picture and set strategy and direction.

Educational Requirements

- Bachelors Degree in an Engineering, Science or Technical field
- Preferred certification(s) in a Quality-related discipline (e.g., CQE, CQA, CQM, etc.)

Required Skills & Experience

- 7+ years' Quality Systems experience in medical devices. Ideally experience with active electronic devices (e.g. neuromodulation)
- Proven ability to direct, build, develop, and manage teams and to build effective relationships with internal and external stakeholders.
- Expert knowledge of medical device quality standards and regulations, including FDA QSR (21 CFR 820) and ISO 13485.
- Proven ability to support successful external audits (e.g., FDA, EU Notified Bodies, etc.)
- Experience auditing suppliers, including contract manufacturers. Experience in auditing manufacturers of FDA Class III devices a plus.
- Strong knowledge of quality-related aspects of medical device commercialization in the US, including Design Controls, Risk Management, CAPA/root-cause analysis, Verification & Validation (design & process), Complaint Handling, and Document Control.
- Able to develop creative solutions to difficult, complex problems that meet regulations and business needs.
- Able to work effectively in a team environment with a diverse group of people
- Organization and ability to obtain results on several projects simultaneously.
- Must work independently under limited supervision to lead high visibility projects and execute in a timely manner
- Good oral and written communication skills

Qualified candidates should send cover letter and resume to HR@paradromics.com

- Willingness to work in a fast-paced organization with shifting responsibilities.
- Familiarity with common software programs (e.g., Word, Excel and PowerPoint) and GSuite platform

Responsibilities

- Implement, manage, and maintain the Quality System for Paradromics.
- Effectively communicate Quality Affairs requirements and needs to cross-functional teams and all levels of management.
- Be the point of contact for and manage internal and external audits, including regulatory body audits and supplier audits.
- Provide leadership to internal and external teams to ensure Quality System needs are met.
- Develop procedures and tools to ensure effective implementation and use of Design Controls and Risk Management.
- Ensure suppliers adhere to Paradromics' Quality requirements.
- Develop metrics and tools to continually monitor Quality System health.

Paradromics is an Equal Opportunity Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, or national origin.

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