magnusmedical

Senior Principal Quality Engineer

Magnus' Senior Principal Quality Engineer will be responsible for setting up and maintaining an effective quality management system. This role will also provide engineering guidance and oversight on the appropriate controls and essential deliverables during the full life cycle of the medical device at Magnus Medical to ensure the product safety, performance and overall regulatory compliance. This role will report to the VP of Regulatory and Quality.

Roles and Responsibilities

- Setup and maintain the company's quality management system(QMS) compliant with FDA 21 CFR Part 820 and other applicable regulations
- Create or update the quality policy/manual, procedures, instructions, forms and records to meet regulatory requirements as needed
- Lead quality activities to support the product development starting from requirements definition through development, V&V, design transfer to commercialization
- Lead/Support the risk management program and maintain the Risk Management File (risk management plans, reports, hazard analysis, FMEAs, etc.) per ISO 14971
- Lead the design control in development of the hardware and software to ensure the completion of all deliverables such as Design History Files (DHF), Device Master
- Record(DMR), Verification & Validation Plans and Reports, etc.
- Manage the quality operations such as IQC, MRB, CAPA, DHR review, product release
- Provides engineering guidance to production control including test fixture qualifications and process validation
- Participate in supplier selection, qualification, collaborate with new suppliers to develop the process validation strategies
- Proactively communicates quality issues to suppliers as needed through supplier corrective action requests and perform supplier audit as needed
- Support the regulatory activities, including FDA 510(k) and Technical File creation
- Prepare and approve Engineering Change Orders
- Manage the complaint handling and resolution of all product performance complaints and patient-related events in a manner that complies with regulatory requirements.
- Ability to effectively work with all levels of internal staff and external contractors and suppliers
- Additional responsibilities, as assigned

Skills and Qualifications

- M.S. in Engineering or another technical discipline, or equivalent experience.
- 10+ years of related experience, including working with a Class II or III medical device with hardware and software
- Strong knowledge and understanding of, and experience working in compliance with 21 CFR 820, ISO 13485, and ISO 14971. IEC60601 and IEC62304
- ASQ Quality certifications (CQE, Auditor, etc.) or RAPS Regulatory Affairs Certificate
- Medical device product development experience in full-lifecycle
- Knowledge of medical device regulations, standards, guidelines, directives, global and domestic standards as applicable.
- Able to resolve the internal and external quality related issues and drive the continuous improvement in a fast-paced startup environment
- Able to create and execute training for team members on quality processes and systems
- Collaborative team player in supporting and executing cross-functional team decision
- Capable to manage quality projects with internal and external resources
- Experienced in QMS audit as both auditor and auditee
- Strong analytical and problem-solving skills with excellent attention to detail
- Good written and verbal communications skills

Salary Range: $160,000 - 210,000 Annually

Company Statement

Magnus is a venture-funded medical devices startup based in the San Francisco Bay Area, led by industry veterans, and committed to development of novel neuromodulation technology for personalized treatment of psychiatric and neurological disorders.

With clinical data in hand showing large effect sizes in a high-need indication, we have recently closed our Series A financing and have nearly three years of runway.

We are deeply committed to integrity, kindness, and communication, and these principles govern how we will build our team and operate the company.

Magnus is an equal opportunity employer. We value diversity and are committed to creating a positive, inclusive environment for all employees.

Contact

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