magnusmedical

**Senior Quality System Specialist**

Magnus' Senior Quality System Specialist will work on setting up and maintaining an effective quality management system. This role will also support the continuous improvement and maintenance of document control, change control, training, CAPA and internal audit program to ensure the product safety, performance and overall regulatory compliance. This role will report to the Senior Quality Control Manager.

**Roles and Responsibilities**

- Maintain and support all company-controlled documentation as part of the Quality System including hard and soft copies; drawings, specifications, lab notebooks, Design History Files, corrective/preventative action, internal audits, and Device History Records
- Understand and demonstrate the ability to perform complex document control processes
- Provide expertise on end-user assistance in the Engineering Change Order (ECO) processes and of the Product Lifecycle Management System
- Serve as the Product Lifecycle Management System back-up administrator
- Analyze document changes for correctness and completeness
- Ensure the correct and timely implementation of document control requests
- Verify own work, check format and compliance with company templates
- Create, maintain and improve document control systems and templates
- Ensure proper implementation of documentation procedures
- Conduct, maintain and provide support for training programs by initiating and updating training plans/programs in collaboration with managers, as needed
- Work on assignments that are complex in nature where judgment is required in resolving problems
- Make recommendations for continuous improvements of the quality system and support implementation
- Maintain external standards library offsite storage program
- Provide support and manage back room for internal and regulatory audits and inspections as required (i.e. CA, FDB, FDA and ISO)
- Scan and clean documents in preparation for electronic and offsite storage archiving

- May be required to cross train in other areas with the Quality Department to support workload required (i.e. Supplier Quality, Quality Inspection, CAPA, Complaints)
- Maintain trained status for, and comply with, all relevant aspects of the Quality Management System to ensure product and support regulatory compliance
- Lead special projects and work on additional responsibilities as needed

**Skills and Qualifications**

- Minimum of 7 years of document control experience in the medical device or related industry
- Bachelor's degree or equivalent combination of related education and experience required
- Advanced knowledge and understanding of Document Control and Quality Systems, standards, practices, and principles
- Knowledge and understanding of applicable GMP regulations and standards
- Advanced proficiency with Google and Microsoft Suite (i.e. Word, Excel, Visio, PowerPoint, etc.) and Adobe
- Experienced in internal and external audits
- Effective written and verbal communication skills
- Effective time management and interpersonal skills
- Ability to perform detail-oriented work with a high degree of accuracy while multitasking
- Ability to work independently as well as collaboratively in a team environment, including liaising with other departments
- Ability to work proactively and effectively in a fast paced, high change environment
- Flexible; adapts work style to meet organization needs
- Demonstrate initiative and resourcefulness
- Assumes responsibility and accountability for results
- Committed to self-development and professional growth with the ability to solicit feedback from others

**Salary Range: $68,000 - $96,000 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.

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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