



CLEARPOINT®

NEURO

Senior Quality Engineer – Solana Beach, CA

Department: Quality

Basic Functions:

About the Job at ClearPoint Neuro (CLPT):

ClearPoint Neuro's mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders with pinpoint accuracy. Applications of the Company's current product portfolio include deep-brain stimulation, laser ablation, biopsy, neuro-aspiration, and delivery of drugs, biologics, and gene therapy to the brain.

We are seeking a Senior Quality Engineer for our San Diego, CA office who will be responsible for product design assurance, continuous improvement of processes and oversight of global device registration.

Duties and Responsibilities:

- Support new product development projects and sustaining design and process changes
- Support continuous improvement projects
- Implementation of changes to QMS processes
- Registration and organization of devices in new geographies
- Compiling data for and presenting at periodic quality reviews and management reviews
- Review of quality records
- QMS alignment with new or updated regulations
- Support quality tasks including CAPA, NCMR and complaint assessment
- Support external and regulatory audits, and execute internal audits for regulated products to assess the effectiveness of the QMS
- Other special quality related projects / responsibilities as needed.

Skills & Qualifications:

Experience:

- 3+ years of experience in medical devices or related highly regulated field
- Advanced experience in statistical analysis
- Experience supporting external audits
- Familiarity with global regulatory requirements
- Excellent written and verbal communication skills
- Good follow through and closure of responsibilities / tasks
- Logical decision making and thought processing
- Strong team player, using both internal and external resources to execute activities
- Communicates opinions, facts and thoughts with clarity, transparency and honesty
- Sets clear and high expectations and holds self and others accountable for decisions and results achieved.
- Seeks multiple perspectives and listens openly to others' points of views
- Enables and demonstrates the courage to speak up on issues and risks
- Demonstrates ownership of results within (and beyond) area of responsibility
- Looks for opportunities for continuous improvement
- Demonstrated understanding of quality management system elements and interactions
- Strong public speaking skills / presentation experience
- Self-driven with strategic, tactical, and analytical mindset

Education:

- Bachelor's Degree in Mechanical Engineering, Biomedical Engineering, or equivalent.

Contact: careers@clearpointneuro.com to apply