Senior R&D Engineer (Medical Devices): Carlsbad, California

Reports to: Director R&D	Department: Engineering

Basic Functions:

Summary of Role at ClearPoint Neuro (CLPT):

Are you an experienced engineer that's passionate about designing cutting-edge medical devices that can make a real difference in people's lives? Do you thrive in dynamic, cross-functional environments where you can take an idea from concept to market? If so, we have the perfect opportunity for you!

As a Senior R&D Engineer specializing in medical devices for neurosurgery, you will lead the entire product development lifecycle. From initial concept to FDA approval and product release, you will be responsible for every step of the process including technical development and project management. **This is a full-time and permanent position based in Carlsbad, CA.**

ClearPoint Neuro is a device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine. We uniquely provide both established clinical products as well as pre-clinical development services for controlled drug and device delivery. ClearPoint Neuro is engaged with healthcare and research centers in North America, Europe, Asia, and South America.

Our Mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders.

Duties and Responsibilities:

As a Senior R&D Engineer specializing in medical devices for neurosurgery, you will lead the entire product development lifecycle. From initial concept to FDA approval and product release, you will be responsible for every step of the process including technical development and project management. This includes:

Device Development:

- Brainstorm and develop innovative ideas for new neurosurgical devices.
- Conduct literature reviews and stay updated on the latest advancements in the field.
- Collaborate with clinical experts to understand unmet needs and translate them into design concepts and requirements.
- Use CAD software to create detailed designs and simulations of new devices.
- Order and/or fabricate parts using in-house equipment and external vendors.
- Build and test prototypes to evaluate functionality, usability, and safety.
- Iterate on designs based on test results and feedback from cross-functional teams.

Design Controls:

- **Design Input:** Develop and maintain design requirements, ensuring they meet clinical and regulatory standards.
- **Design Output:** Create and manage comprehensive design documentation, including specifications, drawings, and change records.
- **Design Verification:** Develop and execute test protocols to verify device performance.
- **Design Validation:** Conduct risk assessments to identify potential hazards and implement mitigation strategies. Validate that the final product meets user needs and intended uses.
- **Transfer to Production:** Coordinate with manufacturing to ensure designs are feasible for production and address any manufacturing challenges.
- **Regulatory Approval:** Prepare and review required documentation to ensure designs and processes adhere to FDA standards and other applicable regulations. Work closely with regulatory affairs to address any questions or concerns from regulatory bodies.

Project Management:

- Manage projects including timelines, resources, and budgets to ensure on-time delivery.
- Lead cross-functional teams including quality assurance, regulatory affairs, manufacturing, marketing, and sales teams to ensure seamless product development and address any challenges.
- Develop project plans, monitor progress, manage risks and communicate status updates to stakeholders.
- Proactively identify and address project challenges to maintain alignment with organizational goals.

Leadership and Mentorship:

- Mentor and guide junior engineers to foster professional growth and technical excellence.
- Champion a culture of innovation, collaboration, and continuous improvement.

Qualifications:

Experience:

- 8+ years of experience in medical device design and development, preferably in neurosurgical or related fields.
- Demonstrated experience leading projects through the full product development lifecycle, from concept to regulatory approval.

Education:

- Bachelor's degree and Master's degree in Biomedical Engineering or a related field.

Skills:

- Proficiency in CAD software for design and prototyping.
- In depth knowledge of design controls and regulatory requirements
- Proven problem-solving abilities and attention to detail.
- Hands-on experience with prototyping, testing and manufacturing processes.
- Proficiency in writing protocols and reports using good practices, including statistical techniques.
- Strong project management skills, including resource planning, project scheduling and risk management.
- Strong communication skills and ability to lead cross-functional teams.
- Proven ability to design and develop devices from concept to market.

Other Training and Certifications:

- N/A

What We Offer:

- **Innovative Environment:** Work on cutting-edge technology that has a direct impact on improving people's lives and well-being.
- **Professional Growth:** Opportunities for continuous learning and career advancement.
- **Meaningful Impact:** Lead projects that make a meaningful difference in patient care and quality of life.
- **Collaborative Culture:** Join a team of passionate professionals dedicated to making a difference.
- **Competitive Compensation:** Attractive salary and benefits package.

Contact us at RDCareers@clearpointneuro.com to apply.