Medical Device Research & Development Engineer

Reports to: R&D Manager	Department: Research & Development

Basic Functions:

Summary of Role at ClearPoint Neuro (CLPT):

ClearPoint Neuro is looking for a high-energy, versatile R&D Engineer to support a varied line of products.

As an R&D Engineer specializing in medical devices for neurosurgery, you will play a crucial role in the entire product development lifecycle. This role will support product development in the business units focused on Neuro Navigation and Neurocritical Care Management. Expected projects range from development on complex electromechanical capital equipment to sterile single-use disposable devices. The role supports programs that lean heavier towards new product development and advanced development, but all engineers support sustaining efforts as needed.

The work spans catheter design, capital equipment design, system engineering, R&D project management, implantables, design for precision plastics and injection molding, microfluidics, sterile packaging, contract manufacturing management, design for manufacture, etc. With a career at ClearPoint Neuro, our new teammate will have opportunities to impact and contribute to programs that synthesize all of these subject areas into medical devices that change the standard of neurosurgical care.

Location: This is a full-time onsite position in Carlsbad, California.

Pay Range: $80K-$110K/year

This range reflects the expected base salary for this role. Final compensation will be based on qualifications, experience, and other job-related factors permitted by law.

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:*** Contribute to 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.

About ClearPoint Neuro:

ClearPoint Neuro is dedicated to treating and caring for neurological disease pathologies and offers products focused on: precision Biologics and Drug Delivery, Neuro Navigation and Robotics, Ablation Therapy and Access, and Neurocritical Care Management. We uniquely provide both established clinical products as well as pre-clinical development services for controlled drug and device delivery.

Responsibilities & Job Functions:

Device Development:

- Seek out and understand clinical need, brainstorm and develop innovative ideas for new neurosurgical devices.
- Conduct literature reviews and stay updated on the latest advancements in the field.
- Use CAD software to create detailed designs and simulations of new devices.
- Order and/or fabricate parts using in-house equipment or 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:

- Strategically navigate Design Controls to optimize effort, budget and schedule.
- **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:

- Take ownership of projects, managing timelines, resources, and budgets to ensure on-time delivery.
- Work closely with quality assurance, regulatory affairs, manufacturing, marketing, and sales teams to ensure seamless product development and address any challenges.

- Develop project plans, monitor progress, and communicate status updates to stakeholders.

Qualifications:

Education:

- Bachelor's degree in Biomedical Engineering or a related field is required.

Experience:

- 2+ years of demonstrated "hands-on" experience in engineering/technical groups.

Technical Skills:

- Working knowledge of applicable medical device standards, including quality systems, biocompatibility, sterilization, electrical safety, usability, and software development.
- Proficiency in CAD software for design and prototyping. ClearPoint Neuro uses SOLIDWORKS.
- Ensure the technical accuracy and quality of engineering analyses, tolerance studies, metrology, assembly processes, and device or system performance.
- Strong understanding of design controls and regulatory requirements.
- Knowledge of structured root-cause analysis and problem-solving methodologies, with strong attention to detail.
- Hands-on experience with prototyping and testing.
- Ability to write clear, comprehensive technical protocols and reports, including statistical analysis.
- Exposure to the following is highly desirable:
    - GD&T
    - Risk Management: DFMEA & PFMEA
    - Minitab or similar statistical analysis software
    - Design for Manufacturing techniques

Interpersonal Skills:

- High level of personal and professional integrity and trustworthiness with strong work ethic and the ability to work with minimal direction.
- Ability to be part of a high-performance team focused on accountability and meeting and exceeding expectations. Across individuals and teams, constructive feedback is both delivered and received, acknowledged and channeled into improved ways of working.
- Proactive and results-oriented, with a positive attitude and a sense of urgency.
- Ability to work independently and manage projects effectively.
- Ability to create and work collaboratively within cross-functional team environments.

Contact: RDcareers@clearpointneuro.com to apply