Join Our Team as an R&D Engineer for Medical Device Innovation!

Are you 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!

Position: R&D Engineer - Medical Devices

About Us:

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.

Role Overview:

As an R&D Engineer specializing in medical devices for neurosurgery, you will play a crucial role in the entire product development lifecycle. From initial concept to FDA approval and product release, you will be involved in every step of the process. 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.
  - 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**:
  - **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. A Master's degree is preferred.
- **Experience**: Open to new graduates and candidates with a few years of relevant experience.
- **Skills**:
    - Proficiency in CAD software for design and prototyping.
    - Strong understanding of design controls and regulatory requirements.
    - Excellent problem-solving abilities and attention to detail.
    - Hands-on experience with prototyping and testing.
    - Ability to write protocols and reports using good practices, including statistical techniques.
    - Ability to work independently and manage projects effectively.
    - Strong communication skills and ability to work collaboratively in a team environment.

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.

Location:

This is a full-time and permanent position based in Solana Beach or Carlsbad, CA.