Trice Medical

TENEX HEALTH | Tenex Health is now a part of Trice Medical

DESIGN ENGINEER (DE)

The Design Engineer (DE) is responsible for helping with the design efforts to create medical devices and their accessories through Feasibility & Planning, Design & Development, Verification & Validation and Transfer to Manufacturing. This position will work closely with other engineering team members, marketing, sales, operations, and physicians. Duties and responsibilities include, but are not limited to:

- Lead/Support Product development efforts (project specific) through all phases of design (e.g., feasibility through transfer to manufacturing).
- Create and manage solid models, assemblies, and drawings using SolidWorks and SolidWorks Vault (PDM).
- Establish and implement validation requirements for products, test methods, and manufacturing processes.
- Write design and process validation protocols and reports.
- Plan and write Clinical Assessments and Usability Validations.
- Write Hazard/Risk Analysis (per ISO 14971) and FMEAs (Design and Use).
- Create Bills of Materials. Support their entry into Sage ERP system.
- Lead project document control efforts in the entering of documents into the Visual Vault and maintaining solid models not resident in the Visual Vault (e.g., SolidWorks Vault).
- Create and maintain FDA compliant Design History Files (DHF).
- Support quality system compliance with FDA QSR and ISO 13485, and regulatory submissions.

JOB REQUIREMENTS

- 4-6 years' experience in design and development of complex, single-use, sterile medical devices.
- Must have a minimum B.S. Biomedical or Mechanical Engineering.
- Strong proficiency with developing complex devices in SolidWorks.
- Ability to use hand tools to create prototype/proof of concept devices.
- High degree of initiative and self-motivation with a strong sense of accountability.
- Ability to work effectively in a team environment and build strong working relationships.
- Ability to effectively problem-solve through critical thinking and root-cause analysis with minimal direction and make decisions with confidence.
- Excellent organizational skills and attention to detail.
- Strong communication skills, both oral and written.
- Ability to prioritize, multi-task and adapt to change.
- Working knowledge of quality systems regulations i.e., FDA QSR, ISO 13485, is required.
- Candidates who have prior experience with manufacturing processes (e.g., CNC machining, injection molding, rapid prototyping) will be given higher considerations.
- This position requires up to 15% travel.