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Job Title:	Engineer II
Reports To:	Principal Engineer
Location:	900 Long Lake Road, New Brighton, MN
Date:	2020 December 17

Purpose/Role

Responsible for assisting in the design and development of a range of permanent/implantable medical devices.

Position Description

- Work with Engineering, R&D, and external subcontractors to develop invitro test methods and execute testing used in the verification and validation of designs. This includes the design and fabrication of test jigs and equipment suitable for the characteristics being tested. This also includes the drafting of protocols and reports that adequately summarize the testing performed and are suitable for review by the appropriate regulatory authorities.
- Ability to support preclinical animal studies with other Neovasc employee. This may include gathering the appropriate material for the studies, loading and preparing systems and some interaction with various animal models.
- Participate as part of a team undertaking all phases of the development process – from planning and proof-of-concept activities through to product launch. Will work closely with the project leaders, members of the project core team (manufacturing, quality, regulatory, etc.) and surgeons/customers to define user needs, generate design concepts and prototypes, perform design evaluations (such as tolerance analysis, FEA, simulated use testing, etc) and support development of product validation plans and testing.
- Should demonstrate proficiency in the application of design controls and development processes and possess strong organizational skills to support all aspects of the project management functions including scope definition, budgeting and contingency planning.
- Participate in the operation and upkeep of the test lab and all equipment therein, including the qualification of test equipment along with regular maintenance.
- Ability to prioritize tasks and manage a varied workload, exhibit strong written and verbal skills and interface effectively with project teams, management and physicians.
- Design, build, and/or contract out parts: test jigs and various fixtures.
- Develop and carry out test plans to prove a concept, write reports concluding the findings
- Coordinate logistics for product testing (out-of-house), and communicate with contractors
- Familiar with medical device guidance documents
- Other related duties as required

Qualifications

Education:

- A minimum of a BA/BS degree in Engineering
- A degree in Biomedical Engineering or Mechanical Engineering would be preferred
- A background in Biology, Chemistry and Anatomy is preferred

Experience:

- Some experience (3-5 years) working in an ISO setting, and/or aware of general ISO requirements.

Skills:

- Exposure to polymeric or biomaterials, injection molding, and/or sterile product
- Experience utilizing computer aided design (CAD) such as Solidworks to develop a product
- Understanding of various types of mechanisms, materials, proper tolerancing, drafting standards
- Demonstrated ability developing creative solutions to solve design problems
- Successful track record or working within a cross functional team bringing products from concept to launch
- Ability to effectively communicate concepts, ideas and knowledge to other individuals, surgeons, customers and/or teams, and work effectively as a team member
- Ability to independently manage responsibilities and to work well in a team environment
- Fine hand assembly work for prototyping, sewing, micro-assemblies
- Familiarity working with external vendors such as machine shops

Please note that only candidates local to the Twin Cities, Minneapolis area, will be considered for this position.