

TITLE: Product Development Mechanical Engineer (Medical Device)

SUMMARY

Flowonix Medical is a medical device company based in the greater Boston area. We are the developer of a class III medical device that is already commercialized, but are looking to develop our next generation of products to ensure continued success. We are seeking a compelling candidate to join the product development team who can develop products and processes that significantly advance Flowonix Medical's clinical and market success. The ideal candidate would display the ability to perform to the below requirements, would show a high level of individual responsibility, and would act with passion and intensity in a VC-funded medical device company that is fast-paced and collaborative.

JOB DUTIES AND RESPONSIBILITIES:

- Ability to design and evaluate medical devices and solve complex challenges that may arise during the development process
- Experience through product development cycle, including design reviews, risk management, human factors, and V&V Plans
- Working with a small team to invent and develop products from early feasibility through commercial release.
- Driving product development through defining, reviewing, and approving product and hardware requirements
- Creating manufacturing documentation, including Manufacturing Work Instructions
- Human factors engineering efforts including development of protocols and reports
- Drafting technical documents including instructions for use (IFUs)
- Working closely with suppliers and subcontractors.
- Working closely with Q/A to develop standards, perform verification and validation testing, perform failure analysis, and to continuously improve the company's products and processes.
- Working effectively within the confines of a regulated, quality-system driven, FDA monitored medical device environment.
- Working closely with clinicians and clinical marketing to understand clinical needs leading that lead to product specifications and risk analyses.
- Maintain Design History Files (DHF) per company procedure. Ensure that DHFs are accurate, complete and well organized.

ESSENTIAL REQUIREMENTS:

- B.S. or M.S. in Mechanical Engineering, or equivalent
- 3+ years of work experience as a hands-on product development engineer. Medical device experience preferred.
- Mastery of fundamental Mechanical Engineering principles.
- A willingness to work hard, with a driven outlook and with a strong desire to succeed as an engineer, as a team, and as a company.
- An inventive aptitude, balanced with discipline and detail-orientation.

HIGHLY DESIRABLE SKILLS:

- Developed products from invention to market release.
- Experience in a small business environment wearing multiple hats.

- Experience with medical device manufacturing.
- Experience with human factors studies
- Experience with medical device quality systems, V&V testing and regulatory filings.
- Experience with product design.