SonoMotion

Innovations in Noninvasive Kidney Stone Treatment

Quality Assurance Engineer

Quality Assurance
San Mateo, California

Description
SonoMotion is a venture-backed medical device company developing game-changing ultrasound solutions for the non-invasive treatment of kidney stones. The company comprises of a multidisciplinary team of seasoned, highly motivated professionals committed to fundamentally changing how kidney stones are treated.

Position Overview
The QA Engineer applies engineering and quality assurance best practices to the development of innovative ultrasound medical devices indicated for repositioning and fragmenting kidney stones, from concept and feasibility through design transfer to manufacturing. This engineering position requires a versatile, high performing individual who covers a broad range of responsibility supporting labeling, risk management, human factors activities, device manufacturing and test engineering. Significant opportunity to expand role based on individual aptitude and company needs.

Roles & Responsibilities:
- Support the authoring of the User Manual, Training Protocol, Training Presentation, and related labeling.
- Support the development of risk management documentation, including the Risk Management SOP, Risk Management Plan, Hazards Analysis, Use Related Risk Analysis, and DFMEA.
- Support the development of the User Interface Specification/Requirements, Human Factors Validation Protocol/Report, and related Usability/Human Factors documentation.
- Monitor and improve the manufacturing processes, tooling, and supply chain necessary for the commercial manufacturing of the ultrasound therapy probe and Generator.
- Author and close NCMRs, CAPAs as required per company Quality Management System.
- Administer DHRs, DMR, and DHF to resolve gaps and deficiencies.
- Support formative human factors studies as a notetaker or moderator.
- Contribute to and administer Observation Management (issue tracking) activities.
- Author design verification test protocols and reports.
- Support all Verification and Validation testing activities including software testing.
- Prepare Purchase Orders and Engineering Change Orders as needed
- Perform all activities following FDA 21 CFR 820 and ISO13485 quality system regulations.
- Support type testing of the device per IEC60601-1 and -1-2 safety standards.
- Maintains laboratory equipment, notebook and current training record.

Required Skills:
- Bachelor's or Master's Degree in relevant engineering or scientific discipline, such as mechanical engineering, biomedical engineering, electrical engineering.
- Minimum of 5 years of product development or relevant QA/R&D experience. Software QA experience is desirable.
- Strong Microsoft Office skills with the ability to support automated workflows
- A solid, experienced individual contributor who can work independently.
- Strong documentation skills

- Basic knowledge of statistics in the context of medical device development
- Working knowledge of FDA 21CFR820, ISO13485, ISO14971, and safety compliance regulations desired.
- Cope with fast-paced startup environment with moments of uncertainty, ambiguity, and shifting priorities. Must work well within a team.
- This position requires an In-Office, Full-Time commitment

Interested candidates are encouraged to apply by sending a resume and/or a cover letter to careers@sonomotion.com. SonoMotion is an equal opportunity employer and supports diversity in the workplace. No candidates who require H-1B or F-1 visa sponsorship.