Senior Design Assurance & Quality Engineer

Eden Prairie, MN

Job Type

Full-time

Description

Nuwellis, Inc. is a medical device company dedicated to transforming the lives of patients suffering from fluid overload with its Aquadex SmartFlow ultrafiltration therapy.

The Senior Design Assurance & Quality Engineer partners with Marketing, Clinical, Regulatory, R&D and Operations and has the responsibility to provide Quality representation on teams facilitating front-end design, design transfer to manufacturing, and process/product improvements. This position is responsible for product safety and quality in all stages of product and process development and ensuring compliance to design specifications, ISO, FDA, and all applicable regulatory requirements. This position is also responsible for implementation and maintenance of Quality System procedures related to operations, document and record control, customer feedback/complaint handling, and internal and external audits to assure compliance to Quality System Regulations (QSR), ISO, and other applicable requirements.

This is an onsite position, requiring a full-time in-person presence at Nuwellis' corporate office in Eden Prairie, MN.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Provide effective quality engineering support in all aspects of the design and development phases in accordance with all applicable procedures, regulations and standards.
- Review, initiate, and/or approve change requests associated with: design verification & validation, risk management, usability, biocompatibility, shelf life, test method validations, equipment qualifications, sterilization, packaging, and labeling.
- Manage product development processes and procedures.
- Manage design history file organization, deliverables, maintenance and associated procedures.
- Manage the risk management process in accordance with ISO 14971, including risk management plans, hazard analyses, FMEAs, and risk management reports, throughout all product development phases.
- Partner with other functional areas, primarily R&D, in areas such as preparing test plans, data analysis, specifications, risk analysis, and change implementation.

- Interpret and contribute to electro-mechanical systems (electronics, pneumatics) and software design and testing.
- Use statistical tools to analyze data, make acceptance decisions, and improve process capability (Gage R & R, TMV, SPC, DOE). Partner with engineering in test method development and validation.
- Identify, apply, and update engineering, technical, and regulatory standard requirements for medical devices.
- Maintain Quality System, especially compliance with ISO 13485, and QSR 21 CFR 820.
- Assist in management of regulatory agency inspections and certification/accreditation body audits.
- Develop quality plans to ensure corporate and compliance objectives are met.
- Ensure Corrective Actions are comprehensive, effective and timely.
- Maintain working knowledge of existing and emerging regulations, standards and guidance documents applicable to the business.
- Act as Quality liaison and representative with government agencies, their extensions and the business community, as needed.
- Assist in ensuring the company is in a constant state of readiness for regulatory inspections.
- Assure compliance and feedback information is summarized and communicated to Sr. Management in a timely periodic manner.
- Oversight and management of supplier quality to support supplier selection and approval, audits and CAPA.
- Oversee equipment management to including calibration, maintenance and out of tolerance.
- Identify and analyze quality trends and proposes and implements strategies and projects to maximize and optimize overall quality performance.

Requirements

MINIMUM QUALIFICATIONS

- Bachelor’s degree in Engineering or other relevant discipline.
- 5-8 years of experience in medical device quality and/or design assurance.

PREFERRED QUALIFICATIONS & COMPETENCIES

- Experience with software design, verification, and validation.

- Experience in biocompatibility, human factors, electrical safety, hardware, and sterilization industry standards.
- Proficient in driving risk management activities.
- Experience in application of statistical methods to design reliability and process capability.
- Effective verbal and written communication, analytical, and interpersonal skills.
- Able to independently provide technical solutions to a wide range of difficult problems. Solutions are imaginative, thorough, and practicable, and consistent with organizational objectives.
- Able to work or lead cross-functionally and contribute as an effective team player
- Must be able to handle multiple tasks/projects and manage priorities accordingly
- Practical approach to quality and a partnering style with colleagues in all functions of the business
- Ability to respond to common inquiries or complaints from customers, regulatory agencies, or members of the business community.
- Proficient in MS Excel, Word, Power Point.

Salary Description

$115,000-$130,000