JOB DESCRIPTION: Quality Engineer

Location: NeuSpera Medical, Inc. Head Quarters in San Jose, CA

Reporting to: Sr. Director of Quality

JOB SNAPSHOT

Base Pay	Negotiable
Employment Type	Full-Time
Job Type	Working Manager, Engineering
Education	4 Year Degree
Experience	At least 5 years
Manages Others	Yes
Industry	Medical Devices
Required Travel	Occasional

ABOUT NEUSPERA MEDICAL, INC.

NeuSpera Medical Incorporated is an exciting medical device startup company headquartered in San Jose, CA that is committed to bringing forward implantable medical device technology that will improve lives of patients battling with chronic illness.

PRIMARY FUNCTION:

Provide Quality Engineering support to R&D, product development and manufacturing, as well as external suppliers. Key areas of support include risk management/communication, verification/validation activities, inspection technique support, nonconformance and defect resolution, process capability/process improvement, verify, CAPA and change management. This position is expected to take a hands-on approach on all aspects of quality engineering and quality systems.

JOB DUTIES:

- Develop and implement product quality plans, documents and systems by creating product specifications, quality specifications, quality plans, risk analyses, and FMEAs to provide a high degree of assurance that specific design and processes will consistently and continually produce a product that meets specifications and critical to quality attributes
- Support design, test, and inspection method development, and lead method validation activities
- Support manufacturing process development & qualification for new product commercialization and product changes
- Lead supplier development activities by conducting reviews and visiting supplier sites,

assessing suppliers' technical competency and compliance to requirements, and developing and implementing improvements/modes of control within the supplier processes to minimize non-conformances
- Manage Receiving Inspection and provide engineering support to Receiving Inspection by ensuring objective component specification definitions, supplied component sampling plan development, and vendor qualifications
- Perform internal and supplier Quality System audits and CAPAs to ensure compliance with Quality System elements and determine root cause and corrective actions as needed
- Provide guidance on data analysis and statistical tools to conduct or support of trend analysis, root cause analysis, failure investigation, and risk assessment
- Responsible for performing all duties in compliance with FDA's Quality System Regulation (QSR), ISO13485, the Canadian Medical Device Regulations, and all other international regulatory requirements with which NeuSpera complies
- Must be a creative problem solver, quick with ideas, results oriented; and have strong communication skills
- Other responsibilities as assigned

JOB REQUIREMENTS

Quality Engineer

Qualifications and Experience:

- B.S. in an Engineering discipline
- 5 or more years of operations experience, preferably in quality roles at Medical Device start-up companies
- Experience in interfacing with internal Development and Operations teams and with External partners
- Demonstrated increasing job responsibility over the progression of career
- Results driven, collaborative team player capable of working well with others, as well as autonomously with little direction
- Ability to adapt to dynamic situations and adjust as we grow
- Breadth of knowledge over engineering and manufacturing disciplines
- Experience with active implantable medical devices
- Experience with hermetic laser welding and feedthrough assemblies desired.
- Basic understanding of electrical and software engineering

Work Environment:

- Office and Laboratory
- Some travel necessary