



Job title	<i>Quality Engineer</i>
Reports to	<i>VP, QA/RA</i>

Duties and responsibilities

- Provide quality assurance support for engineering for both sustaining and innovation project work
- Assist in creation of, and/or review of software verification and validation protocols
- May act as an independent reviewer during design reviews
- Will participate in system, hardware and software Risk Management (hazard analysis and failure mode and effect analysis)
- Statistical analysis of data and metrics for both department and management review
- Develop, implement and maintain quality system procedures and forms
- Experience with corrective and preventive action
- Experience with complaint handling and investigation
- Provide guidance and instruction to engineering and manufacturing personnel on quality system and quality assurance requirements and documentation
- Additional duties, as assigned.

Qualifications

- ASQ certification required
- Prefer a degree in Engineering (electrical, mechanical or biomedical) or the sciences
- Minimum of 3 years work experience as a quality engineer in a class II or III medical device company (3-5 years preferred), working knowledge of FDA GMP requirements in 21 CFR 820, especially design controls relating to systems and electro-mechanical assemblies and firmware.
- Working knowledge of ISO 13485
- Working knowledge of ISO 14971
- Working knowledge of ISO 60601
- Working knowledge of ISO 62304
- Working knowledge of FDA Guidance on Software Validation
- Working knowledge of ASTM, IEC, IEEE and other standards for medical devices
- Prefer 2-3 years' of experience with electromechanical devices that include hardware, firmware, computers, gui and software.
- Prefer experience with imaging equipment and software
- Prefer experience with algorithm software
- Must have strong communication skills, both verbal and written.
- Must be an excellent communicator and able to work "hands on" with development engineers.

Working conditions

- Full time position. Typically M-F 9am – 6 pm

Physical requirements

- Must speak/read English (fluently)
- Frequently required to stand; walk; kneel; climb, stoop; and, reach with hands and arms
- Ability to lift/move 35 pound items

Direct reports

N/A
