

Job Title: Quality Engineer



Department: Quality

ESSENTIAL FUNCTIONS:

- Understanding of ISO 13485:2016 requirements, (e.g. FMEA, CAPA, Root Cause Corrective Action, NCR, RMA's and Customer Feedback).
- Create and maintain quality Metrics when assigned
- Execute design controls and analyzes design inputs.
- Develop and implement Data Analysis metrics.
- Leads investigations related to quality problems.
- Ability to define and manage risk-management plan, risk assessment and risk-control tools.
- Facilitate or independently lead non-conforming product investigations, including corrective/preventive actions and product remedial actions.
- Responsible for systems assurance including documentation, testing and inspection, and product and process development.
- Will support Manufacturing, New Product Development, and Regulatory (as applicable) to ensure systems are in compliance with internal and external guidelines and regulations.
- Identify and lead product and systems continuous improvement initiatives.
- Communicate effectively at all levels within Quality, as well as cross-functionally with R&D, Manufacturing, Supply Chain, Customer Service, Sales, and other functions as necessary.
- Able to influence decisions in a cross-functional team setting.
- Knowledge Equipment Qualification Experience (IQ/OQ/PQ).
- May participate in internal/external audits.

QE-NPD Focus:

- Lead and support new product development execution of design control from concept through post-launch phases.
- Support design change activities through product lifecycle.

EDUCATION AND EXPERIENCE:

- Higher education degree or 5 to 10 years' work experience.
- Handle various projects and responsibilities simultaneously and successfully meet deadlines.
- Microsoft Excel//Word, and PowerPoint. Work with other groups or individuals to resolve issues.
- Medical Device experience required to include ISO 13845:2016 including Knowledge of FDA regulations
- Excellent written and oral communication skills.

If interested, please email resume to ksnyder@valtronic.com or call Kathleen Snyder at 440-349-1239 x 143