



Quality Engineer

Primary Responsibilities:

- Support Program Management and Engineering with customer interface.
- Utilize Corrective/Preventive Action techniques to investigate and implement containment activities, identify problem root cause, report on objective evidence.
- Knowledge of FDA requirements (Part 820- Quality System Regulations)
- 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.
- Develop and implement Statistical Process Control when required.
- Responsible for systems assurance including documentation, testing and inspection, and product and process development. Lead execution of ISO 13485 compliant
- Risk Management processes and tools (e.g. FMEA, CAPA, and Root Cause Corrective Action, FTA).
- 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.
- Equipment Qualification Experience (IQ/OQ/PQ).
- May participate in internal/external audits.

Preferred Skills:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily:

- Must have good communication skills and an ability to work well with and train others.
- Must be familiar with ISO 13485 requirements, processes and procedures.
- Lead and support new product development execution of design control from concept through post-launch phases.
- Support design change activities through product lifecycle.
- Corrective/Preventive Action, Mistake Proofing, and Report Writing
- Microsoft Office; Word, Excel, PowerPoint.



Education / Experience Required:

- Four-year college degree or minimum 7-10 years' experience in related field.

Please send resume to hруса@valtronic.com in Microsoft Word format.

Valtronic Technologies USA, Inc. will only employ those who are legally authorized to work in the United States for this opening. Applicants will receive consideration without regard to race, sex, color, religion, national origin, age, disability, veteran status, genetic data, or religion or other legally protected status. Valtronic Technologies USA, Inc. is an equal Opportunity Employer (EEO) employer and welcomes all qualified applicants.