SHL MEDICAL

Quality Assurance Engineer

Job Overview

This position is to provide quality oversight to assure design, development, manufacturing and post-market of SHL product are compliant to applicable regulations, standards, and SOPs. QA engineer ensures the delivery of high quality product which meet the regulatory requirements and customer expectations.

Main Responsibilities

- Lead / participate in project related quality activities (e.g. design control, change control, product release) and provide quality consultation to the team.
- Demonstrate customer focus, cross-functional cooperation skills, and sound quality judgement.
- Complete the evaluation and detailed investigation on the observed nonconformities during manufacturing process.
- Present accumulated quality data to customers and management.
- Identify trends of quality data with the usage of statistics and quality improvement tools to prevent quality issues.
- Ability to effectively communicate and interact with foreign customer, team members, and various technical disciplines.
- Support external quality inspections and execute internal and supplier audits.
- Complete assigned tasks on time with minimal supervision (self-motivated).

Required Skills & Qualifications

- BS degree above or equivalent technical work experience.
- Clear / logical thinking with strong organization and communication skills
- Proficient problem solving skills.
- Working knowledge of Microsoft Office.
- Experience in the medical device industry is preferred.
- Knowledge of regulatory compliance: GMP (good manufacturing practice), QSR (quality system regulations), and ISO 13485 is preferred.
- CQT (certified quality technician), CQE (certified quality engineer) is a plus.
- Six sigma green belt or black belt is a plus.