Title: Product Quality Engineer - Risk Assessment

Location: Mysore

Exp: 5+ yrs

Roles & Responsibilities:

- Working on Risk files like RMP (Risk Management Plan), RMR (Risk Management Report) from scratch.
- Identification of Hazards and estimation of risk for each Hazard for medical devices
- Experience in working on Hazard Matrix table.
- Familiarity with ISO 13485 Medical Quality Management System and ISO 14971 Application of Risk Management to Medical Devices.
- Knowledge on ISO 14001, USFDA 21CFR part 820, IEC 62304 (Samd).
- Implementing and verification of risk control measures, Evaluation of Residual risk and RBA
- Hands experience in Design Control (Risk management, Design Review, Process Validation) activities for medical devices.
- Ensures product safety risk management deliverables are created, maintained, and stored in the Risk Management file during product development
- Experience in Risk files like RMP, PHA,DHM, dFMEA, aFMEA, pFMEA, RBA, RMR
- Creation of Risk Management Report and ensure the RM file is complete
- Experience in Requirement Traceability Matrix.

Required Education/Experience:

- Bachelor's degree, Engineering or Science discipline preferred or equivalent work experience 5+ years of relevant working experience in creating risk management deliverables.
- Knowledge of Quality management systems such as risk management, design controls, CAPAs, doc control, etc.
- Strong written and oral communications skills and ability to effectively communicate technical content to a variety of internal and external audiences (e.g. Authorities, customers)

Notice period: Immediate joiners preferred or candidate who can join within 30 days.