



Example of Staff Engineer, Quality Job Description

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Our company is growing rapidly and is searching for experienced candidates for the position of staff engineer, quality. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

Responsibilities for staff engineer, quality

- Monitors complaint vigilance reporting modules for continuous improvement
- Ensures alignment of department objectives and activities with Business Quality Organization, Q&C, JSC and Enterprise Quality System strategic objectives
- Develops advanced technological ideas and guides their development into a final product, process or business opportunity
- Ensures the accurate and actionable recording of data for the making of decisions to document development work
- Plans and participates in disciplines strategically relevant to the business and/or functions
- Provides advice and mentors junior Associates
- Provide coordination and guidance to cross functional teams to ensure software quality objectives are met for product software, manufacturing software, quality system software, and software technologies included or used in the creation or production of medical devices
- Identify software quality challenges and software quality improvement opportunities
- Reviews and approves project documentation including Software Development Plans, Software Requirements Specifications, Software Design Documents, Software Test Plans/Protocols/Reports
- Conducts audits as member of a quality system audit team

Qualifications for staff engineer, quality

- A minimum of 7+ years of experience in Quality Engineering or Quality Assurance, including data analysis, risk assessment and risk mitigation is required
- Prior experience within an electro-mechanical environment is preferred
- A Six Sigma Green belt /Black belt certification is preferred
- Prior knowledge of medical device regulations such as 21 CFR 820 and ISO 13485 is preferred
- Understanding of continuous improvement methodologies including Lean, Six Sigma, SPC, is desired
- BS degree in Life Sciences or Engineering