Quality Assurance & Regulatory Affairs Associate



- **Specialist Sector:** Medical Devices
- **Location:** Cambridge
- **Availability:** One Month
- **Salary Expectations:** £30,000 - £40,000 depending on package and shares/equity

Skills

- Medical Devices
- Quality Assurance
- Regulatory Affairs
- ISO 13485
- QMS

Bio

Early?career Quality & Regulatory Associate with two years' focused experience in medical device compliance, QMS management, and technical documentation under **ISO 13485, EU MDR, and FDA 21 CFR 820**. Skilled at compiling comprehensive technical dossiers including risk management files, clinical evaluation reports, GSPR checklists, and PMS/PMCF documentation, and experienced in registering devices in EUDAMED. Proven in conducting internal audits, leading CAPA investigations, managing vigilance reporting to regulatory timelines, and supporting design changes and device testing to relevant ISO standards. Strong at delivering regulatory training and driving cross?functional collaboration to improve audit readiness and reduce repeat non? conformances.

Practical biomedical engineering background with an **MSc in Biomedical Engineering** and hands ?on experience in commissioning, maintenance, and technical support for clinical equipment. Demonstrated ability to streamline processes, enhance compliance, and support successful regulatory submissions through disciplined documentation, risk management, and stakeholder engagement. Comfortable working in clinical and manufacturing environments, committed to

continuous professional development in medical device regulation and process validation, and adept at translating technical detail into clear, auditable quality systems.