Head of Quality and Regulatory Affairs

Nottingham, UK

SurePulse Medical's mission is to improve the life chances for premature and sick babies. We aim to achieve this by giving clinicians the tools to provide optimal newborn care, as existing monitoring systems were not designed for the unique needs of newborn babies, particularly those who need support at birth.

Our first product, the SurePulse VS, is a CE certified and FDA cleared wireless heart rate monitor specifically designed for use from birth. It is designed to give an upfront, accurate heart rate to guide clinical decision making in the critical moments after birth. We have an exciting pipeline of products building on the VS platform.

SurePulse Medical Ltd is a medical device start-up based in Nottingham. We are looking for a highly-motivated Quality and Regulatory Manager to join our growing team to help support commercialisation of the next generation of innovative medical monitoring systems. You will have the opportunity to make a real impact in ensuring the commercial success of the company.

Reliability is a crucial part of our product and company ethos and you will therefore have strong attention to detail and a passion for excellence. You will have strong interpersonal skills and be able to communicate clearly and effectively. You'll demand the highest standards from our suppliers.

The candidate will handle quality and regulatory affairs within SurePulse Medical. The candidate will maintain and support the company's existing QMS process and procedures to ensure compliance with UK, EU and USA regulatory regimes. This involves the generation of new processes and procedures and to maintain the current ones. It will also involve generating and helping resolve and track all non-conformances via the CAPA process. Alongside the technical team, the candidate will interpret regulatory requirements for new and existing product, identifying what relevant standards, tests and documentation are required, and liaising with service providers where necessary.

With ownership of the QMS and all aspects associated with it, the candidate will be required to help undertake internal audits and represent SurePulse in external audits.

We are looking for someone with an exceptional combination of creativity and structure. You won't just tolerate regulatory frameworks but thrive in them, enjoying the challenge of merging strict regulatory requirements with efficient and effective quality processes.

Responsibilities.

- Support the improvement of existing and new QMS processes and procedures to meet business and regulatory needs.
- Run and support internal and external auditing.
- Provide support documentation and relevant standards for the engineering team with respects to testing and verification of new and existing product.
- Oversee product technical file(s) life cycle and change notes.
- Liaise with regulatory authorities and consultants where required
- Handling of quality and product non-conformances and associated documentation (CAPA process)

Skills and Requirements.

- Understanding of quality and regulatory requirements per ISO 13485, UK (UKCA), EU (MDR), USA (FDA 21 CFR 820 and 510(k))
- Meticulous record keeping skills.
- Experience with the auditing process.
- Well organised and self-motivated to complete tasks and take initiative.
- At least two years' experience within the medical device industry.

Attitude.

- You have a passion for detail.
- You're flexible and willing to engage with feedback.
- You're always learning and looking to advance your skills.
- You're self-motivated, organised and can manage your own projects.
- You get stuff done but strive to produce the best work you can.

- You enjoy being part of a fast-moving team and being a key player in it.

Package.

- Competitive Pay.
- Family friendly flexible hours.
- Informal working environment.
- Employer Pension Contributions.
- Private medical insurance.

Please email a CV and covering letter to careers@surepulsemedical.com
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