Quality Manager

THE COMPANY

Orthoson span out from the University of Oxford in mid 2019, to develop a novel surgical spine procedure using injected, then ultrasound cavitated particles to perform minimally invasive surgery down a needle. The company's method for intervertebral disc repair will meet a major unmet need by creating a minimally-invasive alternative to highly-invasive spinal fusion and disc replacement procedures.

The product is a complex class III medical device including a high intensity therapeutic ultrasound device and injectable, in-situ curing implantable hydrogel for use in the operating theatre for treatment of the spine for low back pain.

In 2021 we completed an £8.0M Series A funding round to take the company through first-in-human clinical trial.

THE ROLE

Day-to-day and leadership responsibility for the Quality Management System. The successful candidate will work as part of a team with the CTO, function leads, reporting directly to the CEO and ensuring the following:

⇒ development, implementation, support and maintenance of processes, documentation, requirements and eQMS

⇒ design, testing, documentation and compliant technical file creation to the standards required for regulatory approval in the USA, UK and the EU.

MAIN RESPONSIBILITIES & KEY TASKS

⇒ **Creation & Management of OrthoSon's Quality Management System (QMS)**

- Create, implement and manage OrthoSon's QMS.
- Timely implementation of ISO 13485-ready processes leading to successful audit according to the plan.
- Maintaining and updating OrthoSon's Quality Manual.
- Ensuring that all SOP's, work instructions and quality records are current, up to date and implemented.
- Ensuring that all employees are trained in OrthoSon's QMS, ensuring compliance and maintenance of training records.
- Support and coach the team as required to achieve compliance.
- Develop KPIs and report on compliance with both process and standards as required.
- Support supplier audits.
- Work with or lead, external consultants where required.
- Conduct regular reviews of any revisions to relevant quality standards.

⇒ **Preparation of Documentation to Support OrthoSon's Clinical Trials Regulatory Submissions**

- Lead the planning and preparation of regulatory submissions to Ethics Committees and Competent Authorities including the MHRA and the FDA.
- Supervision of document preparation and writing appropriate link documentation for the files.
- Assistance in writing key reports, undertaking gap analysis and identification of missing documents.
- Supervision of the compilation of the documentation required for regulatory submission.

⇒ Supervision of OrthoSon's Technical Reports

- Implement an eQMS including document control and a compliant database for the company's technical reports.
- Ensuring that all reports are reviewed, approved and signed off.
- Developing templates for documentation.

This list is not exhaustive and the person will be expected to be flexible toward working in a hands-on, small-team environment.

ESSENTIAL EXPERIENCE

⇒ Compiling technical documentation for class II and/or class III medical devices.

⇒ Interpreting the regulatory requirements for medical devices in the EU and/or USA.

⇒ Maintaining an ISO 13485 quality management system.

⇒ Managing a wide range of projects simultaneously utilizing excellent organizational skills.

⇒ Scientifically or technically trained, with proven experience in quality and regulatory affairs for medical devices.

DESIRABLE EXPERIENCE

⇒ Providing regulatory support for new product development and/or early stage medical device companies.

⇒ Carrying out internal audits of ISO 13485 quality systems .

BEHAVIOURS

⇒ Can-do attitude, with the demonstrable ability to find compliant solutions to business problems where possible.

⇒ Communicate efficiently and effectively both verbally and in written form with cross-functional stakeholders such as technical, regulatory, clinical and commercial, etc.

⇒ Interface with a broad range of functions within an organization.

⇒ Develop and foster positive long-term relationships with suppliers and other key stakeholders by building and maintaining rapport

⇒ Take a flexible approach on a day-to-day basis and perform tasks outside of one's job description

⇒ Exhibit a high degree of professionalism and integrity both in internal and external stakeholders.

WHAT WE OFFER IN RETURN

⇒ A competitive salary, commensurate with qualifications and experience.

⇒ The opportunity to work in a dynamic and rapidly growing team

To apply please send your CV, together with a covering letter to: suzanne.algie@orthoson.com. You will be contacted if we would like to consider you for this role. All applications are considered on their own merit.

For more information on OrthoSon Ltd please see our web site.

NO AGENCIES PLEASE