**Job Title:** Quality Manager
**Location:** Thatcham
**Job Type:** Full-Time
**Sector:** Medical / Life Sciences
**Reports To:** TBC

### ****Overview:****

We are seeking a proactive and detail-oriented **Quality Manager** to build, lead and maintain our Quality Management System (QMS) in accordance with **ISO 9001** standards and regulatory requirements. Based in the UK, the successful candidate will play a critical role in ensuring compliance across our core operations, including **HTA licensing**, **UK Responsible Person (UKRP) representation**, and **satellite facility oversight**. This is a unique opportunity to join a forward-thinking organisation at the forefront of the medical sector.

### ****Key Responsibilities:****

#### **Quality Management System (QMS)**

* Develop, implement, and continuously improve the company’s **ISO 9001:2015 QMS**, ensuring all processes are compliant, efficient, and well-documented.
* Lead internal and external audits; manage corrective and preventive actions (CAPAs).
* Liaise with external certification bodies, auditors, and regulatory agencies.

#### **UK Responsible Person (UKRP) Consulting**

* Manage the company’s **UKRP services**, ensuring client compliance with UK medical device regulations.
* Act as primary point of contact for clients and regulatory bodies on UKRP matters.
* Maintain up-to-date knowledge of MHRA guidance and industry best practices.

#### **Human Tissue Authority (HTA) Licenses**

* **Full lifecycle management of the organisation’s following HTA licences**;
	+ **Storage and import license** – ensure compliance with all storage, traceability, and record-keeping requirements for imported human tissue.
	+ **Research license** – ensure all research activities are conducted within HTA guidelines, with appropriate consent and ethical approvals.
* Lead inspections and audits from the HTA; implement any required improvements.
* Train staff on HTA standards and ethical handling of human tissue.

#### **Satellite Facilities Oversight**

* Ensure satellite sites operate in compliance with the QMS, ISO 9001, and HTA standards.
* Conduct regular quality audits and assessments at satellite locations.
* Provide training and support to satellite site staff on regulatory compliance and best practice.

### ****Qualifications & Experience:****

* Bachelor's degree in a life science, quality management, or related discipline (or equivalent experience).
* Proven experience in a quality management role within the **medical, life sciences, or healthcare sector**.
* In-depth knowledge and hands-on experience of **ISO 9001:2015** QMS.
* Experience working with or under **Human Tissue Authority licensing frameworks**.
* Understanding of **UK medical device regulations** and UKRP requirements.
* Strong communication and leadership skills, with the ability to influence and train teams at all levels.
* Audit and risk management expertise.

### ****Desirable:****

* Lead Auditor certification for ISO 9001.
* Experience with MHRA inspections or submissions.
* Familiarity with ISO 13485 (Medical Devices) or GxP environments.

### ****What We Offer:****

* Competitive salary and benefits package
* Opportunity to shape quality strategy in a high-impact medical organisation
* Supportive and collaborative working environment
* Continuous professional development

Our Values

People - Hiring and developing the best people who are passionate about what they do. Respecting diversity in all people interactions, within and externally to the company.

Integrity and Accountability - Always doing the right thing for our people, customers, distribution partners and patients. Being accountable for our performance and decisions, while consulting with colleagues to seek alternative opinions.

Knowledge - Delivering genuine value through our market sector knowledge and functional expertise.

Customer Focus - Always considering our customers in everything we do. Delivering a first-class client experience, providing the best service, and the highest quality commercial expertise throughout the customer journey.

Growth Mindset and Curiosity - Continually look to better ourselves and the business, and supporting each other on this journey.

Commitment to Continuous Improvement - Having high expectations and striving to perform better every day for the benefit of our customers and people.