**Job Title:** Quality Manager**/**Designated Individual (DI)

**Date: April 2025**

**Reporting To: Matt Woods**

**Hours per Week: 37.5**

**Location: Head Office**

**Main Responsibilities (to be read in conjunction with the role of the Designated Individual, as outlined in “The Regulations” and summarised at the end of the job description)**

* To be responsible as the Designated Individual under the Human Tissue Act (HTA) for the use of tissues within the scope of the Ortho Surgical Skills Centre (OSSC) Human Tissue Authority licence.
* To play a key role in ongoing compliance with a Human Tissue License via the HTA.
* Provide expertise in the planning, set-up and commercialisation of the OSSC lab, meeting all required legislation to the highest standards. Including, but not limited to, ongoing lab management and management of an appropriate Quality Management System.
* Responsible for the writing of SOP’s, risk assessments, audits and compliance documentation for all aspects of the Anatomy Laboratory activities and facilities maintaining HTA standards applicable to all licensable activities carried out within the facility.
* To ensure that suitable practices are used in undertaking the licensed activity, other persons working under the licence are suitably trained and responsible, the conditions of the licence and third-party agreements are complied with and that all information relating to licensable activities is available for tracing donations, current, correct and held securely.
* To ensure the safe retrieval, storage, distribution and use of all human tissue in accordance with HTA regulations. To present evidence of compliance with HTA regulations during the HTA inspections.
* To advise and inform relevant stakeholders of HTA regulations relating to the implementation of new initiatives at the OCG lab.
* To ensure the correct regulations are documented and be the lead on polices in relation to working with human tissue.
* To provide technical management as appropriate in the day to day running of the OCG lab for other technical services staff employed with responsibility for the management and safe running of the lab.
* Take responsibility as the radiation protection supervisor, completing appropriate training.
* To undertake training in accordance with HTA regulations, as and when required.

**Qualifications - Essential**

* Previous experience working in a highly regulated medical device or similar environment and working with the Human Tissue Authority.
* Background in Quality Management with Quality Management System maintenance, improvement and audit management.
* A diploma, certificate or other evidence of formal qualification in the fields of medical or biological sciences, or
* Be otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications and practical experience, and
* Have at least two years’ practical experience which is directly relevant to the activity to be authorised by the licence.

**Qualifications – Desirable**

* Membership of The Institute for Anatomical Science (IAS)

**Skills and Competencies:**

* Proven high level of planning and organisation skills and resource management
* Excellent IT skills and proven ability to use management and financial systems
* Proven skills in the effective management of people in a laboratory environment
* Excellent analytical, negotiation and problem- solving capability
* A commitment to delivering an excellent service to stakeholder/users
* Project management experience
* Experience with orthopaedic/spine surgery

**Knowledge and Experience**

* Practical extensive experience and understanding of HTA regulations and procedures and the implications of non-compliance
* It is expected that DIs have an awareness of all the relevant legislation covering the use of tissues and cells for human application.
* Proven advanced analytical problem-solving skills/capability
* Ability to communicate clearly to non-specialist and senior level audiences
* Extensive practical experience which is directly relevant to the activity to be authorised by the HTA licence

This job description is not exhaustive but outlines the main requirements.

Our Mission

The Ortho Surgical Skills Centre (OSSC) has one mission: to provide an environment for surgical education and professional development. Through our all-in-one offering, we are committed to delivering a best in class customer experience that is tailored to your medical education needs.

Our Vision

Our vision is to become the go-to centre for healthcare professionals and medical device companies to collaborate in a surgical and didactic setting, establishing the benchmark for hands-on learning and education.

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.

**As stated in the** [**Human Tissue Authority guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment (2021)**](https://content.hta.gov.uk/sites/default/files/2021-06/HTA%20guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Human%20Tissue%20and%20Cells%20for%20Patient%20Treatment%20-%20Jan%202021.pdf) **(“The Regulations”), the role of the Designated Individual includes;**

A Designated Individual (DI) must be appointed having qualifications and responsibilities as provided in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the Regulations).

The DI has a statutory duty to secure that:

* The other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activities;
* Suitable practices are used in the course of carrying out the licensed activities;
* The conditions of the licence are complied with;
* Ensuring that licensable activities carried out by third parties are subject to suitable practices and are carried out by suitable persons; and
* The requirements of Regulation13(1) relating to information and confidentiality are complied with.

In addition, the DI has responsibility for:

* Ensuring that the establishment carries out all appropriate control measures as required by the HTA to ensure adherence to the Regulations;
* Keeping a record of the establishment’s activities and submitting to the HTA an annual report on these activities;
* Notifying the HTA of any serious adverse event or serious adverse reaction within 24 hours of discovery;
* Ensuring that the establishment puts in place and updates a quality management system in accordance as outlined in the Regulations;
* Ensuring that the donor selection and evaluation is carried out in accordance with the Regulations;
* Ensuring (in conjunction with the License Holder “LH”) that third party agreements are in place and maintained whenever a third party undertakes one of the licensable activities on behalf of the licensed establishment, or supplies any goods or services which affect the quality or safety of tissues and cells;
* Ensuring that any third party with whom there is a third-party agreement is made aware of, and provided with, copies of all relevant HTA Directions, regulatory alerts or other communications from the HTA without delay;
* Supervising the establishment’s system for verification that tissues and cells meet all appropriate specifications prior to release;
* Approving the documented risk assessment undertaken to determine the fate of all stored tissues and cells following the introduction of any new donor selection or testing criterion or any significantly modified processing step; and
* Ensuring, in conjunction with the LH, that all imports of human tissues and cells from third countries meet standards of quality and safety equivalent to those set down in the Regulations.