

## **Job Description**

**Job Title:** Quality Assurance Specialist

**Reporting to:** Head of Quality Assurance

**Location:** Gunnels Wood Road, Stevenage, Herts, SG1 2FX

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The Cell and Gene Therapy Catapult (CGT Catapult) is an independent innovation and technology organisation committed to the advancement of cell and gene therapies with a vision of a thriving industry delivering life changing advanced therapies to the world. Its aim is to create powerful collaborations which overcome challenges to the advancement of the sector.

With over 400 experts covering all aspects of advanced therapies, it applies its unique capabilities and assets, collaborates with academia, industry and healthcare providers to develop new technology and innovation.

The Cell and Gene Therapy Catapult works with Innovate UK.

### **Purpose of Role:**

The Quality Assurance Specialist will be responsible for ensuring the standards of the Quality Management System (QMS) at CGT Catapult Stevenage are maintained in a fit for purpose state of control, and improved, for a multi-purpose, multi-client facility. This will involve maintenance and improvement of associated procedures for controlling key quality and business processes in addition to helping develop the measures and governance structures to be employed to maintain visibility on the processes and interactions within and across them. The Quality Assurance Specialist will also be responsible for managing the Quality interactions between CGT Catapult and our Collaborators and will be the primary Quality point of contact for a defined Collaborator.

Reporting to and with the guidance of the Quality Assurance Lead, this role will ensure that CGT Catapult Stevenage, via proactive engagement, meets the standards and expectations of two key stakeholders: the regulatory authorities and Collaborators.

### **Key Accountabilities:**

- To work within a multi-disciplinary team to take a tactical role in the design, implementation, and establishment of suitable governance processes to assure the consistent GMP compliance of the CGT Catapult Stevenage GMP facility for cell and gene therapy.

- Participate in the preparation for and the management of regulatory agency and Collaborator inspections.
- Provide general Quality subject matter expertise for the facility operations.
- Provide compliance support by providing advice and facilitating the escalation of compliance issues through the appropriate routes.
- Promote the awareness of quality requirements and support the evolution of the quality culture throughout CGT Catapult and to train employees in quality related activities where appropriate.
- Maintain processes, including GMP document control and training, needed for successful site compliance to the QMS.
- Participate in the review the performance of the QMS at planned intervals and provide regular reporting to ensure its continuing suitability, adequacy and effectiveness and propose improvements.
- Participate in the execution of a GMP internal audit programme including the identification and implementation of appropriate corrective actions and a process to track their completion.

### **Experience:**

- Demonstrable experience in an Operational Quality Assurance role providing product impact assessments as part of QMS processes.
- Demonstrable experience in sterile manufacturing processes, ideally ATMP's or biologics (Desirable).
- Previous exposure to R&D interfacing environment (Desirable).
- Demonstrable experience in interacting with the regulatory authorities (Desirable).
- Experience in interacting with clients and Collaborators (Desirable).
- Demonstrable experience working as a Quality Specialist (or equivalent) in biologics and preferably cellular and/or gene therapies.
- Previous exposure experience in delivering continuous improvement activities to develop GMP quality systems.
- Experience working independently towards goals and working collaboratively as part of a cross functional team.

### **Knowledge / Skills / Competencies:**

- Highly motivated, pragmatic and practical to support the mission of the Cell Therapy Catapult to accelerate the development of a commercial cell-based therapy industry in the UK.
- Desire to establish a high-profile career within cell and gene sector and the personal drive to help push the sector to be a commercial success.
- Sound knowledge of MHRA / EMA and FDA regulatory environments and requirements.
- Familiar with global standards related to quality e.g. ISO 9001.
- Confidence and ambition to provide pragmatic and considered GMP advice.
- High level interpersonal, communication (oral and written) skills.
- Accurate with strong attention to detail.
- Able to evaluate complex situations and find solutions for them in a professional manner.

- Project ownership and pride in its delivery.
- Having a passion for delivering excellent customer service.
- Flexibility towards work assignments and new learning.
- Ability to manage multiple and varied tasks and to prioritise workload within a fast-paced environment.
- Ability to work well under pressure, to work independently and to be able to take the initiative when completing tasks.
- Ambitious, collaborative, driven.
- Comfortable operating autonomously once goals and objectives are set.
- Able to evaluate complex situations and find solutions for them in a professional manner.
- Ability to quickly establish credibility and build rapport and trust.
- Proven ability to engage constructively with colleagues at all levels across different departments to deliver objectives and to respond to a wide range of customer and management needs.
- Ability to quickly establish credibility and build rapport and trust.
- Proven diplomacy skills with diverse groups of internal and external stakeholders.
- A positive attitude towards learning, personal and professional development.
- Keeps up to date with professional knowledge, expertise and best practice.
- Experience of standard Microsoft packages.
- Willingness to travel.

#### **Education / Qualifications:**

- Educated to Degree level in a life sciences discipline.
- Member of a professional organisation e.g. RSC, SOB, CQI etc. (Desirable).