

## **Job Description**

**Job Title:** Quality Control Scientist – Microbiology

**Reporting to:** Head of Quality Control

**Location:** 4 Warner Drive, Springwood Industrial Estate, Braintree, Essex  
CM7 2YW

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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 four hundred 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 Control Scientist – Microbiology will support the activities of the CGT Catapult Braintree's GMP Quality Control Laboratories and associated infrastructure. Reporting to the Quality Control Lead – Microbiology, the Quality Control Scientist – Microbiology will help ensure that the CGT Catapult Braintree Manufacturing Innovation Centre meets the standards and expectations of its key stakeholders, regulatory authorities, and potential Collaborators/external stakeholders.

### **Key Accountabilities:**

The Quality Control Scientist – Microbiology will ensure –that activities are conducted including Environmental monitoring / microbiology testing of starting materials, reagents, intermediate and finished products as required to support the site plan:

- Conduct laboratory analysis and result reporting to assure the QC service provision associated with viable environmental monitoring, starting material, raw material, excipient, in-process, and final product sample testing is maintained in line with the requirements of each Collaborator/external stakeholder.
- As required work with other QC personnel, QA, suppliers & service providers to assist in the development and maintenance of GMP compliant QC Laboratory services.
- Assist in the review and reporting of process trending charts for QC processes.

#### QC Sample Management & LIMS Management:

- Actively participate in the collection (from manufacturing modules and other classified areas), transportation, storage and lifecycle management of microbiological samples requiring testing either externally or to be performed within the CGT Catapult Braintree facility.
- Support the microbiological testing of incoming materials, as required.
- Support the implementation and operation of a suitable electronic laboratory information management system (LIMS) for use in an appropriate timeframe and in accordance with the requirements of GMP.

#### Microbiology:

- Provide interpretation and guidance to the Site Leadership Team, and nominated Qualified Persons, as required.
- Coordination of workload to ensure the availability of results to meet site manufacturing and release schedule.
- Provision of expert advice to clients and other Collaborators/external stakeholders, as required.
- Conduct microbiology test validations and method qualifications.
- Provide support for process qualifications, such as aseptic gowning, good aseptic practises and media fills etc. as might be required.
- Participate in microbiological related training and qualification.

#### Regulatory Compliance:

- Support to ensure the QC function operates to a high standard and complies with cGMP and other appropriate regulatory standards.
- Support to ensure all QC laboratory equipment is maintained fit for purpose (qualified and calibrated appropriately and with the appropriate degree of periodicity).
- Generate and review cGMP documentation such as Standard Operating Procedures, Analytical Test Methods, Analytical Test Qualification protocols and reports etc.
- Ensure archiving of both written and electronic data in accordance with company procedures.
- Support to ensure the CGT Catapult Braintree site team and associated service providers complete all documentation and records accurately, contemporaneously and to a consistent GMP standard.
- Support to ensure the traceability of all reagents, materials, equipment, standards etc. is maintained for all GMP sampling and testing activity.
- Participate in Out of Trend, Out of Specification and Deviation management events associated with QC activity and act as Collaborator/external stakeholder liaison to report and manage such events to an appropriate and compliant conclusion.

**Experience:**

- Experience in microbiology or in an aseptic (bio) pharmaceutical manufacturing environment.
- Proven experience of writing and reviewing GMP documents.
- Proven experience of looking critically at own and others work practices and procedures and identifying and implementing any needed improvements.
- Proven experience of motivating teams, whilst training and acting as a role model for staff associated with the GMP QC laboratories.
- Experience in interacting with clients and other client/external stakeholders.

**Knowledge / Skills / Competencies:**

- Highly motivated, pragmatic and practical to support the mission of the Cell and Gene Therapy Catapult to assist in the acceleration of 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.
- 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 prioritise workload with attention to detail.
- Comfortable operating autonomously once goals and objectives are set.
- Excellent interpersonal, written and verbal communication skills.
- Ambitious, collaborative, driven.
- 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.
- A positive attitude towards learning, personal and professional development.
- Keeps up to date with professional knowledge, expertise, and best practice.
- A good team player, with strong organisational skills.
- Willingness to travel.

**Education / Qualifications:**

- Bachelor's degree in Microbiology or related discipline
- Member of a recognised professional body (Desirable)