

Job Description

Job Title: Senior Quality Control Scientist – Microbiology

Reporting to: Head of Quality Control / Analytics

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

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. It creates 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, in collaboration with academia, industry and healthcare providers to develop new technology and innovation.

The CGT Catapult works with Innovate UK.

Purpose of Role:

The Senior Quality Control Scientist – Microbiology will support the activities of the CGT Catapult Braintree's GMP Quality Control Laboratory and associated infrastructure. Reporting to the Quality Control Lead, this role will help ensure that the CGT Catapult Braintree Manufacturing Innovation Centre meets the standards and expectations of all key stakeholders, regulatory authorities, potential Collaborators, and all external stakeholders.

Key Accountabilities:

The Senior Quality Control Scientist – Microbiology will be responsible for undertaking QC activities at CGT Catapult Braintree within Microbiology, ensuring the testing of starting materials, reagents, intermediate and finished products, and sterility testing, as required to support the site plan:

- Use in-depth knowledge of Microbiology to transfer and validate Microbiological Procedures for Quality Control (QC)
- Conduct laboratory analysis and result reporting to assure the QC service provision associated with the testing of starting materials, raw materials, excipients, in-process and final product sample testing, is maintained in line with the requirements of each Collaborator and external stakeholder.
- Work with the wider QC and QA teams, suppliers, and service providers, to assist in the development and maintenance of GMP compliant QC Laboratory services.
- Lead/ownership of laboratory activities associated with QC, including stock control, experimental design, planning and reporting.

- Ownership of the review and reporting of process trending charts for QC processes.
- Line manage and mentor QC Scientists and QC Technicians within the QC team.
- Strong interaction with the Analytical Sciences team at CGTC Braintree
- Working closely with the QC Lead to ensure successful delivery of project outputs, including work breakdown structures and project plans to ensure delivery.
- Working with CMO's, technology providers and organisations to ensure that Cell and Gene Therapy Catapult is a true world leader in its manufacturing technology development capability

Microbiological Testing:

- Lead routine microbiological testing and method validation activities.
- Provide interpretation and guidance to the CGT Catapult Site Leadership Team as required, of analytical test results, trends, and other areas of interest.
- Coordination of workload to ensure the availability of results to meet the site manufacturing and release schedule.
- Provision of expert advice to Collaborators, and other external stakeholders, as required.
- Strong ability to interpret analytical data.
- Participate in microbiology related training and qualification.

Regulatory Compliance:

- Provide support to ensure the CGT Catapult Braintree QC provision operates to a high standard and complies with cGMP and other appropriate regulatory standards.
- Provide support to ensure all QC laboratory equipment is maintained, and is 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.
- Ensure archiving of both written and electronic data in accordance with company procedures and regulatory requirements.
- Provide support to ensure the CGT Catapult Braintree site and its associated service providers complete all documentation and records accurately, contemporaneously, and to a consistent GMP standard.
- Provide support to ensure the traceability of all reagents, materials, equipment, standards etc. is maintained for all GMP sampling and testing activity.
- Lead 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:

- Demonstrable experience gained within in a biological analytical testing laboratory or an aseptic (bio) pharmaceutical manufacturing environment.
- Demonstrable experience of writing and reviewing GMP documents.
- Demonstrable experience of looking critically at own and others work practices and procedures and identifying and implementing any needed improvements.
- Demonstrable experience of motivating teams, whilst training and acting as a role model for employees associated with the GMP QC laboratories.
- Demonstrable experience in interacting with clients and other client/external stakeholders.
- Demonstrable experience in writing Microbiological Procedures, Validation Plans and Reports.
- Proven knowledge of cutting-edge solutions to address challenges of high throughput sample handling and method validation initiatives.
- Proven ability to engage constructively with colleagues and stakeholders at all levels across different departments to deliver objectives.
- Minimum 2-5 years' experience in the application of EU GMP to QC operations.

Knowledge / Skills / Competencies:

- Ability to lead a team when required to achieve project milestones.
- Ability to represent the QC team at cross-functional project meeting
- Experience in planning and executing projects, utilising the most appropriate technology available to ensure future clinical and commercial success.
- Highly motivated, pragmatic and practical to support the mission of the Cell and Gene Therapy Catapult to accelerate the development of a commercial cell and gene-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.
- High level interpersonal, communication (oral and written) skills.
- A "roll your sleeves up" hands-on attitude towards varying work assignments.
- Resilient, with the ability to manage multiple and varied tasks and prioritise workload, with a strong attention to detail.
- Flexible and pragmatic, able to learn quickly and respond flexibly to project needs and priorities.
- Project ownership and pride in its delivery.
- Flexibility towards work assignments and new learning.
- 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.
- Accurate with strong attention to detail.
- 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.
- Proven diplomacy skills with diverse groups of internal and external stakeholders.
- Accepts own mistakes - prioritises team over personal goals.
- High degree of motivation, problem solving skills and innovative thinking.
- A good team player with a hands-on approach, and adaptable to new challenges.
- Experience of standard Microsoft packages.
- A positive attitude towards learning, personal and professional development.
- Keeps up to date with professional knowledge, expertise and best practice.
- Willingness to travel.

Education / Qualifications:

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