

Job Description

Job Title: Quality Control Lead

Reporting to: Head of Quality Control

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

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 Control Lead will support the activities of CGT Catapult Stevenage Manufacturing Innovation Centre (S-MIC) GMP Quality Control Laboratories and associated infrastructure. Reporting to the Head of Quality Control, the QC Lead will help ensure that the CGT Catapult S-MIC meets and operates to the standards and expectations of its key stakeholders; regulatory authorities; and both potential and existing Collaborators.

The Quality Control Lead will possess managerial skills, regulatory knowledge and experience in the cell and gene therapy sector to ensure effective management of the quality control function.

Key Accountabilities:

- Oversight of Quality Control Service Support – including environmental monitoring, microbiology, testing of raw material, in-process material tests, and final product testing etc.
- Establish, review, and monitor key performance indicators and trend tools to measure performance of Quality Control, including personal performance.
- Ensure the Quality Control function meets all Regulatory, Quality, HS&E policies, and procedures such that employees, visitors, and the environment are protected from significant risk.

- Focus on continuous improvement opportunities for the Quality Control function and create a proactive, continual improvement culture within Quality Control, always driving the concept of 'audit ready'.
- Work within the CGT Catapult S-MIC multi-disciplinary team and matrix environment to ensure successful delivery of CGT Catapult and Collaborator projects.
- Liaise with Collaborators and other CGT Catapult teams to ensure resources are used efficiently & effectively.
- Establish links with outside parties to benefit the CGT Catapult S-MIC Quality Control processes including identifying, evaluating, and adapting innovative technologies where appropriate.
- Be a Subject Matter Expert for the Environmental Monitoring and Biosafety testing at CGT Catapult S-MIC
- Maintain a portfolio of Pharmacopeia tests into Quality Control.
- Assist in the development of Quality Control equipment and analytical method validation protocols and reports specifically associated with Biosafety testing e.g.: detection of mycoplasma by PCR, detection of Endotoxin, detection of microbial contamination by direct inoculation, detection of microbial contamination by BacT/Alert.
- Provide oversight of Quality Control analysis to assure the Quality Control service provision associated with biosafety testing of excipient, in-process and final product sample testing is maintained in line with the requirements of each Collaborator.
- Review and approval of Biosafety assays and support Environmental Monitoring results.
- Assist in the review and reporting of process trending charts for Quality Control activities.
- Support Out of Specification investigations, providing subject matter expertise on investigations of Quality Control result excursions.
- Leadership and line management supporting a growing team of Quality Control Specialists and Technicians.
- Overseeing Quality Control scheduling and resource allocation ensuring efficient operation.
- Management and closure of Quality Records (Non-conformance, CAPAs, Change Controls) pertaining to the Quality Control department.
- Emphasising and maintaining a strong GMP knowledge base and work ethic within the CGT Catapult S-MIC team.
- Technical training and coaching of the Quality Control team.
- Support the management with project delivery and project management.
- Act as the Quality Control representative for management of Collaborator requests, contribute to Additional Input Agreements and liaise with Collaborators and Project Managers.
- Provide support for aseptic process qualifications, such as aseptic gowning, good aseptic practices, and media fills etc.

QC Sample Management & LIMS Management

- Work with the Quality Control Lab Compliance Manager to monitor the Sample/Stock Management function to ensure the Quality Control team

provides a timely, effective and efficient service for the collection (from manufacturing modules and other classified areas), transportation, storage and lifecycle management of Collaborator and CGT Catapult derived microbiology and environmental monitoring samples requiring testing.

- Oversight of the raw material sampling activity and ensure it is undertaken to GMP and in accordance with Collaborator requirements.
- Support the continued use of the QC department electronic laboratory information management system (LIMS) in accordance with the requirements of GMP.

Regulatory Compliance

- Provide support to ensure the Quality Control department operates to a high standard and complies with cGMP and other appropriate regulatory standards.
- Provide support to ensure all Quality Control laboratory equipment is maintained fit for purpose (qualified and calibrated appropriately and with the appropriate degree of periodicity).
- Generate, review, and approve cGMP documentation such as Standard Operating Procedures, Analytical Test Methods, Analytical Test Qualification protocols and reports etc.

Experience:

- Demonstrable experience in managing research and development projects in an academic or industry environment to delivery.
- Experience working in microbiology or in an aseptic (bio)pharmaceutical manufacturing environment, operating according to GMP, at similar responsibility level for minimum of 3 years.
- Experience of writing, executing, and reviewing GMP documents and processes, including validations, autonomously for a minimum of 2 years.
- Experience of working in grade B/C cleanroom in a GMP facility for at least 2 years.
- Experience of working with relevant laboratory test platforms including operation and troubleshooting e.g. MALDI-TOF, FACS, ELISA, Endotoxin testing, Sterility testing, qPCR, ddPCR, Cell viability testing etc. in a commercial setting would be desirable.
- Experience in interacting with the regulatory authorities is desirable.
- Experience in interacting with clients and collaborators is essential.
- Experience of managing a team of Quality Control professionals.

Knowledge / Skills / Competencies:

- Highly motivated and pragmatic with a practical approach to supporting 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 and emotional intelligence with ability to build relationships.

- Resilient, with the ability to manage multiple and varied tasks and independently prioritise workload within a fast-paced professional environment.
- Flexible and able to learn quickly and respond to project needs and priorities.
- Project ownership and pride in its delivery.
- 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 internal and external stakeholders.
- 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.
- Good public speaker with strong external and internal scientific credibility.
- Proven coaching/mentoring ability.
- Good presentation skills.
- Expertise in pharmaceutical microbiology.
- Accepts own mistakes - prioritises team over personal goals.
- Driven and proactive - goes above and beyond the call of duty to achieve company results.
- Leads and inspires colleagues.
- Support the Head of QC to deliver strategic aims, goals, and targets.
- Understands innovation and the impact of disruptive technologies as well as drivers of change and new ways of working across industry, processes, people, and culture.
- Understands financial strategies including scenarios, risk management, to avoid resource wastage.
- Strong influencing and leadership skills. Understands influencing, stakeholder management.

Education / Qualifications:

- Masters or Bachelor's degree in Microbiology, Biotechnology, Molecular Biology, or related discipline.