

Job Description

Job Title: QA Specialist – Vendor Management

Reporting to: Head of Quality Assurance

Location: 4 Warner Dr, Springwood Industrial Estate, Braintree, 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 Quality Assurance Specialist – Vendor Management will provide the required support to team members to ensure that supplier and service provider activities are performed according to the required standards and procedures. The Quality Assurance Specialist – Vendor Management will also support the wider Quality department to develop, maintain, and continually improve a fit for purpose Quality Management System (QMS) and provide practical quality Subject Matter Expertise and oversight on the design, commissioning, and continuing validation and qualification of the CGT Catapult Braintree facility.

The Quality Assurance Specialist – Vendor Management will also ensure that the CGT Catapult Braintree facility, via proactive engagement, meets the standards and expectations of all key stakeholders, including regulatory authorities and all internal and external stakeholders and Collaborators. The role shall be responsible for supporting, monitoring and reporting on the operation of the QMS against agreed key performance indicators.

Key Accountabilities:

- To work within a multi-disciplinary team to take a leading role in the implementation and establishment of suitable governance processes to assure adequate documentation, which ensures that processes are maintained, improved, and monitored.

- To be a QA Subject Matter Expert in relation to new vendor assessment, risk identification, vendor governance, audits, liaison, and periodic review.
- Qualification of 3rd Party providers following a risk focused process.
- Ownership of the Audit Programme, responsible for oversight, scheduling and process improvements.
- Provide support to the supply chain and logistic teams to assure compliance within warehousing, transport, and logistical operations.
- Conducting audits to ensure regulatory and Company requirements are met.
- To support the generation and roll out of training on vendor management across the CGT Catapult Braintree facility, with targeted training per role/function.
- Continual improvement and ownership of Vendor related processes.

Other Quality duties:

- Promote the awareness of quality requirements throughout the Company and educate team members in quality related activities.
- Support the maintenance of processes, including GMP document control, education, and training, needed for successful operation, monitoring, and improvement of the QMS.
- Participate in Quality events such as Deviations, Change Controls, Audits and Risk Assessments for various roles such as – Owner, SME or QA Approval
- Statistically analyse data and develop reporting tools that demonstrate the performance of the PQS at Monthly Quarterly and Annual intervals and provide regular reporting to ensure its continuing suitability, adequacy, and effectiveness and review and propose improvements as required.

Experience:

- Experience working with GMP quality systems in a Phase III and/or commercial pharmaceutical manufacturing of biologicals, vaccines, cell or gene therapies manufacturing facility.
- Experience working as a quality professional in biologics and preferably cellular and/or gene therapies.
- Experience of working in a small organisation with a pragmatic attitude.
- Experience of standard Microsoft packages.

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.
- Resilient, with the ability to manage multiple and varied tasks and prioritise workload within a fast-paced professional environment
- Excellent attention to detail and strong organisational skills.

- Ability to create plans that demonstrate appropriate due diligence and take into account the potential changing circumstances and possible difficulties.
- Applies specialist skills, technical knowledge or practical experience to solve complex problems and issues adhering to regulatory frameworks/policies/processes (e.g. alignment to GMP, H&S etc).
- Puts new ways of working/ methodologies into practice, embracing ways to improve best practice.
- Understands who they are communicating to and uses the most effective methods to engage that audience; gains alignment across stakeholders through effective communication and navigation of the organisational structure.
- Holds themselves and others accountable by acting with integrity and fostering trust in everything they do (e.g. demonstrating reliable delivery, keeping commitments etc).
- Excellent interpersonal, written and verbal communication skills.
- A positive attitude towards learning, personal and professional development.
- Keeps up to date with professional knowledge, expertise and best practice.
- Strong computer literacy skills.
- Willingness to travel.

Education / Qualifications:

- Educated to Degree level in a life sciences discipline
- Member of the Chartered Quality Institute – Chartered quality professional (desirable)