Job Description

Job Title: Regulatory Affairs Manager

Reporting to: Head of Regulatory Affairs

Location: 12th Floor Tower Wing, Guys Hospital, Great Maze Pond, London, SE1 9RT

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 Regulatory Affairs Manager at CGT Catapult will act as a regulatory representative for CGT Catapult programmes.

- Implement optimal regulatory strategies for each programme in agreement with the Head of Regulatory Affairs/Senior Lead Regulatory Affairs, Chief Clinical Officer (CCO) and key stakeholders
- Compile and submit regulatory submissions, ensuring that they are delivered to agreed time, cost and quality standards
- To support the development programmes in place in CGT Catapult, providing expert advice to ensure the programmes are developed in a way which meet regulatory and quality requirements
- Implement optimal regulatory strategies for each programme in agreement with the Head of Regulatory Affairs/Senior Lead Regulatory Affairs, Chief Clinical Officer (CCO) and key stakeholders
- Compile and submit regulatory submissions, ensuring that they are delivered to agreed time, cost and quality standards
- To support the development programmes in place in CGT Catapult, providing expert advice to ensure the programmes are developed in a way which meet regulatory and quality requirements

Key Accountabilities:

- With the Head of Regulatory Affairs and/or Senior Lead Regulatory Affairs, develop an agreed CMC/ regulatory strategy and implementation plan for each programme

- Prepare regulatory documents (briefing documents, GMO submissions, CTAs, INDs, amendments, safety reports, annual reports, etc.) to meet business needs and agreed time, cost and quality standards
- To liaise closely with relevant departments of CGT Catapult and external Collaborators to ensure proposed developments (manufacturing and analytical) are fit for purpose and suitably planned whilst ensuring the development programme will meet regulatory and quality requirements
- Ensure appropriate regulatory due diligence is carried out on all incoming propositions and external facing proposals
- Maintain up to date knowledge of development in regulations, guidelines, CMC, GCP and GMP requirements for cell and gene therapy products
- Develop and maintain constructive working relationships with regulatory agency and health authority contacts, contributing to strategies to influence regulators as required towards appropriate risk evaluation and management
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Experience:

- Approximately 3-5 years or more regulatory affairs experience, ideally with 1-2 years in a cell and/or gene therapy environment or, at a minimum, with some experience in the regulation of biologic or biotech products
- Proven experience of working independently in the drafting and delivery of high-quality regulatory documents

Knowledge / Skills / Competencies:

- 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
- Knowledge of US regulatory frameworks (Advantageous)
- Working knowledge of EU GMP and tissues and cells legislation (Advantageous)
- Proven ability to evaluate and implement efficient regulatory strategies and manage complex regulatory issues including areas of biotechnology, biological therapies and preferably, cell and gene therapy
- Ability to lead the quality and regulatory aspects of the development strategy for assigned CGT Catapult Programmes
- Demonstrable regulatory leadership of CTA /IND processes as well as experience of scientific advice meetings with Regulatory Authorities is an advantage
- Proven ability to consistently deliver to time, cost and quality standards
- Can be counted on to deliver tasks, planning effectively and managing time to cope with the unexpected
- Applies technical expertise/practical experience and shares knowledge with others to continuously improve; provides opportunities to involve others in projects by listening, collaborating and influencing to create wider impact
- Proposes solutions and seeks advice to gets things done.
- Builds trust and credibility with others through clear communication, pursues and secure buy-in from a range of people
- Understands the importance of working together and aligns abilities and goals with those of the team

- Navigates ambiguity well and learns from experiences; demonstrate resilience when coping with challenges
- Actively seeks to understand, question and listen to others to improve effectiveness to benefit the team and division
- Open to feedback and confident to deliver constructive feedback with the intent of learning and developing themselves and others
- High level interpersonal, communication (oral and written) skills and emotional intelligence
- A “roll your sleeves up” hands-on attitude towards varying work assignments
- Project ownership and pride in its delivery
- 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
- High degree of motivation, problem solving skills and innovative thinking
- 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:

- Higher degree or at a minimum graduate in a life science subject.

CGT Catapult is committed to providing an equal, diverse, and inclusive work environment where everyone’s contributions are valued. We celebrate differences, empower, and inspire everyone, because when everyone is included, everyone wins. In 2024, we received bronze accreditation from Inclusive Employers.