

Job Description: Director, Clinical Operations

About us

RQ Biotechnology Ltd is a UK-based virology company whose mission is to discover and develop long-acting monoclonal antibodies (LAABs) against seasonal influenza with the goal of providing immediate, powerful and long-lasting protection against the risk of severe viral disease. We have recently initiated pre-clinical development of our product candidate and are looking to recruit an experienced clinical operations director to support the advancement of this asset into first-in-human and proof of concept studies.

About the role

The Director, Clinical Operations, will have oversight for one or more clinical trials. Responsibilities will include leading the cross-functional study team and working collaboratively with the company, CROs and external vendors to plan, set-up and execute clinical trials. The individual will help establish GCP compliance processes at RQ Bio in preparation for entering the clinic, which will involve capturing, analyzing and reporting metrics on trial performance and adherence to plans (e.g., timelines, enrollment, data cleaning progress, budget metrics, etc.). The role will report to the Chief Medical Officer.

Success in this role will require strong teamwork and communication skills, as you will work closely with cross-functional teams across all levels of the organisation. Given the dynamic nature of a small biotechnology company, you will be comfortable working in a lean environment, balancing strategic oversight with hands-on operational execution, as well as having a curious and proactive mindset to seek advice and take ownership of areas for improvement. The role would suit a candidate seeking to combine strategic leadership with hands-on operational involvement typical of an early-stage biotech environment.

Role profile

- To own and drive clinical operational strategy.
- Develop, update, maintain and drive adherence to clinical trial plans, timelines and budgets.
- Oversee CRO selection, negotiate contracts, scopes of works and maintain oversight of external vendors and investigative sites. Be the primary point of contact for clinical CROs, external vendors and investigative sites, ensure effective communication.
- Ensure success of clinical trials and alignment with corporate objectives. Manage study budgets, track expenditure and financial performance, build processes for managing change orders.
- Take responsibility for building and maintain ICH GCP compliance processes. Ensure adherence to SOPs and regulatory requirements. Carry responsibility for regulatory audits and inspections.

- Create and maintain the sponsor Trial Master File including creating, maintaining and filing all relevant sponsor documents so that the sponsor is inspection-ready at all times.
- Identify issues in a timely manner and drive their resolution in an effective and timely manner. Develop and implement risk management strategies to ensure trial delivery.
- Drive, oversee, contribute and complete the writing and submission of key documents such as clinical trial protocols, investigator brochures, clinical trial applications, etc.
- Contribute to a collaborative and high-performing team culture, ensuring effective cross-functional communication and co-ordination.

Essential skills and experience

- Extensive experience in clinical operations (typically around 10+ years), including experience managing CROs in full-service outsourcing models.
- Healthy volunteer first-in-human trial experience.
- Comprehensive knowledge of clinical operations, from concept protocol through to clinical study reporting.
- Up-to-date knowledge of GCP and applicable global regulations and guidance for clinical development.
- Proven interpersonal, written and verbal communication and organizational skills. Enthusiasm and ability to work within a small biotech environment.
- Ability to travel as needed for site visits, CRO audit and oversight, internal team meetings, etc.
- Degree in biological sciences.
- Fluent in English.

Desirable skills and experience

- Infectious diseases therapy area experience is an advantage (phase 2 or 3).
- Relevant experience working at, or collaborating with, biotech companies.
- Experience of supporting regulatory (FDA, MHRA, etc.) inspections/audits of sponsor and/or sites will be an advantage. Ability to translate findings into corrective actions plans that mitigate risks to the company, to safety and data integrity.

Working arrangements and benefits

- The position can be hybrid, with an on-site presence required for at least 1 day per month at RQ Bio's team meetings in Cambridge, England. Occasional after-hours work may be required, especially when dealing with business partners across time zones.
- We offer a competitive salary, commensurate with qualifications and experience, and a benefits package including pension and health insurance.
- Candidates must have the right to work in the UK, or eligibility to obtain it.

RQ2601



- We believe diverse teams are the most innovative, and welcome applications from all backgrounds and identities.

To apply, please email your CV and brief cover note to careers@rqbiotechnology.com quoting reference RQ2601.

Our Candidate Privacy Notice can be found on the careers section of our website.