# Director of Quality

Vaccitech is a clinical stage T cell immunotherapy company developing products to treat and prevent infectious disease and cancer.

The company's proprietary heterologous prime-boost platform comprises Chimpanzee Adenovirus Oxford (ChAdOx) and Modified Vaccinia Ankara (MVA), two non-replicating viral vectors which safely mimic viral infection in human cells and elicit high magnitude, durable, targeted CD8+ and CD4+ T cell responses to clear foreign pathogens and tumours.

The platform was licensed from the prestigious Jenner Institute for vaccine research at the University of Oxford, which dedicated over 20 years of research to identify and refine the optimal method for CD8+ T cell induction in humans. This platform has generated a robust, largely immunotherapeutic pipeline of seven clinical product candidates for infectious disease and cancer indications, four of which are in co-development with partners and external funding and one which is fully out licensed.

Vaccitech is backed by leading investment institutions, including GV (formerly Google Ventures), Sequoia Capital China, Liontrust (formerly Neptune), Korea Investment Partners and Oxford Sciences Innovation.

Due to exciting expansion across the company, with offices in the UK (headquarter), USA, Italy and Australia, Vaccitech is now recruiting for this new position, which is office based in the UK, fulltime (37.5 hours per week) and a permanent contract.

**Key responsibilities:**

- Input to development plans and programs to ensure appropriate Quality strategies are executed in accordance with the overall development plans;
- Ensure good practices (GxP) are adopted and implemented throughout the organisation;
- Maintain detailed working knowledge of the Quality environment through direct and indirect contact with agencies and industry groups including MHRA, EMA, FDA etc;
- Work with staff, external consultants and advisors to ensure Quality compliance and take accountability for ensuring Vaccitech maintains its 'Inspection Ready' status;
- Provide Quality expertise and oversight internally to project teams and other departments;
- Maintain a constant and current knowledge of global Quality intelligence, advising the business of any potential impacts with regards to changes in regulations and guidelines and recommending appropriate course of actions;
- Prepare and manage the Quality annual budget;
- Maintain and develop the QMS to ensure ongoing compliance with regulatory standards and regulations;
- Manage SOP and policy document control;
- Act in the capacity of Quality Representative for all tasks defined in the quality system documents;
- Delivering Quality training (GCP, GMP, GLP) to staff;
- Managing QMS training for new and existing staff.

- Manage annual External/Contract Service Provider audit programme;
- Manage internal audit programme including audit schedules;
- Perform internal, Contract Service Provider and investigator site audits;
- Manage independent auditors;
- Host regulatory authority inspections.
- Provide senior management with assurances that systems and procedures are in place to identify and manage business and other risks within the quality framework and the company strategy;
- Ensure that the company's statutory and legal obligations are discharged to satisfy current legislation where relating to Quality/GxP;
- Ensuring compliance with GCP, GMP and other regulatory requirements;
- Make sure that Quality systems support optimal day-to-day operations and projects;
- Take responsibility for policies, procedures and Quality systems;
- Maintain and monitor, and record appropriately, all types of Quality risks.

**Essential Knowledge, experience and skills:**

- Proven experience as a Quality Assurance Manager;
- Minimum of ten years' quality assurance experience in a pharmaceutical or biotechnology organisation;
- Degree in a scientific subject;
- Experience in working in a small biotechnology company that has undergone rapid expansion;
- Ability to work in a fast-moving organisation;
- Good communication and interpersonal skills with the ability to communicate effectively with staff at all levels and different cultures;
- Good experience of auditing suppliers and clinical investigator sites;
- Good knowledge of clinical trial and IMP manufacturing;
- Knowledge of MHRA, EMA and FDA standards;
- Knowledge of GCP and GMP mandatory and other good practices desirable;
- A good working knowledge of MS Office including Word, Excel, Outlook and PowerPoint;
- A flexible "can do" attitude;
- Ability to work independently;
- Ability to interact with staff at all levels within the organisation and subcontractors.

The successful candidate will report to the Chief Operating Officer.

Please use the cover letter to highlight how you meet the competencies for the role which will be used along with your CV to assess your application. Please also confirm your current salary and salary expectations.

With your application could you please quote job reference QA001