JOB DESCRIPTION

Position	**Senior Programme Manager**
Reports to	**Head of Clinical Operations**

Key Responsibilities of Role

Main purpose of job:

To assist with the coordination and oversight of cross-functional activities to support the Vaccitech portfolio of research and development programmes. All activities carried out within allocated time, and agreed costs and in accordance with quality requirements, Vaccitech SOPs, ICH/ GCP guidelines and local regulations.

Key responsibilities include:

- Maintain an understanding of related Vaccitech corporate objectives and key milestones.
- Preparation and maintenance of Target Product Profiles and Clinical Development Plans for assigned programme.
- Preparation and maintenance of programme and study level Gannt Charts.
- Preparation and management of programme and individual study budgets, for both forecasting and financial management of assigned studies/programme.
- Maintain documentation of programme and associated study activities, decisions, actions and risk assessments.
- Management and oversight of all aspects of development programmes in accordance with internal SOPs, ICH GCP, relevant guidelines and all applicable laws and regulations.
- Cross-functional coordination and oversight of all aspects of assigned clinical programme to ensure agreed programme deliverables are met to the appropriate standards of quality e.g. manufacturing, pre-clinical and clinical.
- Responsibility for preparation and co-ordination of study and programme documentation and coordination of document review, e.g. protocols, IBs, IMPDs, DSURs, ICFs, CSRs.
- Selection and oversight of assigned CROs, vendors or contract monitors (CRAs), as appropriate.
- Selection of suitable clinical sites in collaboration with other members of the Vaccitech study team or CROs, as appropriate.
- Periodic co-monitoring with contract CRAs or CROs as necessary for each study, to ensure high quality monitoring and site management.
- Set up and management of clinical contracts, including Clinical Site Agreements.
- Coordination of IRB/IEC and other required study submissions, and provision of essential documents for regulatory review and submission.
- Active management of clinical trials supply requirements in collaboration with 3rd party storage & distribution specialist
- Responsible for Sponsor Oversight File and/or TMF creation, maintenance and review by Clinical Trial Administrator, to ensure 'inspection-readiness' of documentation at all times.

- Active acquisition and furthering of therapeutic area knowledge appropriate to assigned studies.
- Assist with departmental development work e.g. SOP review/writing and process improvements initiatives.
- Develop and maintain relations with all stakeholders including co-workers, sites, vendors and KOLs.

Other Responsibilities of Role

Personal Abilities and Traits:

- Demonstrates personal drive and goal orientation.
- Self-motivated taking personal pride in delivering on personal and corporate objectives.
- Enthusiastic and flexible to change.
- Demonstrates strong organisational and prioritisation skills to manage a diverse workload.
- Able to interact with individuals at all levels of the organisation.
- A highly effective communicator, both orally and in writing with an eye for detail/ accuracy
- Reliable and trustworthy, able to work with minimal supervision.

Qualifications and/or experience required to perform the role

Essential Knowledge, experience and skills:

- BSc or equivalent
- Extensive clinical study/programme management experience of at least 5 years within a pharmaceutical, biotech or CRO company
- Experience in oversight of external vendors (CROs, central labs, imaging vendors, etc.)
- Excellent written and verbal communication and presentation skills
- Excellent organisational and interpersonal skills
- Ability to manage multiple priorities within one or across different programmes
- Excellent working knowledge of GCP and current clinical trial legislation
- Thorough knowledge of the clinical development process, ideally from first in human through to regulatory filing Market Authorisation
- Ability to travel in the UK and abroad periodically if needed
- Ability to work in a dynamic small team environment

Desired skills:

- Experience in virology and/or Infectious Disease studies
- Working with GMO experience
- CRA/monitoring experience
- Experience of EDC and eTMF; comfortable with electronic systems e.g. CTMS