

The ExeVir logo, consisting of an orange stylized 'X' shape with a dark blue dot at the top left of the 'x'.

HEAD OF NONCLINICAL DEVELOPMENT

Role

Reporting to the Chief Scientific Officer, the Head of Preclinical Development will be responsible for leading the R&D of ExeVir Bio's pipeline. The individual will develop strategic and operational plans to efficiently progress the company's research projects from early discovery to pre-clinical proof-of-concept, lead candidate selection and subsequent nonclinical development studies to generate the nonclinical data packages required to support IND applications and the initiation of FIH studies. The Head of Preclinical Development will lead a team of scientists, associate scientists and laboratory technicians and oversees the design and conduct of all nonclinical studies/activities, including antibody discovery and characterization of the pharmacodynamic, pharmacokinetic, non-clinical safety and toxicological properties required to progress pipeline candidate compounds to clinical candidate declaration.

The role requires strong leadership skills, strategic insight and a background in antibody discovery and nonclinical development, with experience in study design, data evaluation, preparation of study reports and other written documentation of preclinical data and contributing to regulatory documents such as IB, IND applications and/or scientific advice briefing books. This position offers the opportunity to contribute strategic thinking, scientific knowledge as well as project and people management skills to a collaborative and dynamic team in a small start-up company. Efficiency, enthusiasm, reliability and pro-active mindset are a must to thrive in this fast-paced, challenging environment where all must take a hands-on approach to get things done.

Responsibilities

- Oversee the preclinical strategy for the complete R&D portfolio
- Responsible for translating ExeVir Bio's research goals into actions and accomplishing the company's research targets
- Lead the research collaborations with the partners and actively initiate new contacts and interactions with potential new research partners
- Develop strategies for the conduct of early discovery, preclinical proof-of-concept and IND/CTA-enabling preclinical studies/activities to meet the company's research objectives

- Lead a team of scientists, associate scientists and laboratory technicians through project oversight, day-to-day management and support of their personal development
- Work with cross-functional colleagues in the project teams to develop strategies and maintain project timelines to reach the company's targets
- Oversee the selection and management of contract research organizations (CROs) to support non-clinical activities
- Support clinical studies for biomarkers (translational medicine) and assay set ups
- Review preclinical study reports
- Expert understanding of current regulatory guidance and regulatory requirements in drug discovery and non-clinical development
- Write the nonclinical sections of regulatory documents (IB, IND, scientific advice briefing books, etc.)
- Develop presentations and present ExeVir's nonclinical data at internal and external meetings as well as scientific conferences
- Develop presentations and data sheets for presentations to ExeVir Bio's board of directors, potential investors and partners when needed
- Develop and maintain an extensive knowledge and understanding of the competitive landscape of all prophylactic/therapeutic antibodies in the disease area's of ExeVir's pipeline and potential new pipeline candidates
- Writing of scientific publications
- Keep up to date with the newest developments in the field and implement novel technology and/or assays

Education / Experience

- PhD in Bio-engineering, Virology, Pharmacokinetics, Pharmaceutical Sciences, Toxicology, Pharmacology, Bio-chemistry or closely related discipline.
- 10+ years of experience in drug discovery and preclinical development

Technical Skills and Competencies

- Extensive industry experience with biotech or large pharmaceutical companies
- Proven experience of managing and coordinating CROs/vendors
- Experience with preparing INDs and CTAs
- Knowledge of the scope and extent of Pharmacology, ADME, Toxicology and CMC studies/activities required to optimally conduct first-in-human studies and rapidly transition to clinical POC studies
- Structured and highly organized with a pro-active, hands-on attitude
- Contributed to successful transitions of drug candidates into clinical development resulting in favourable clinical outcomes
- Comfortable in a small company environment that is fast-paced, challenging and where all leaders must take a hands-on approach to get things done
- Quick learner and problem solver
- Ability to evaluate key business / scientific challenges and complete complex, ambiguous initiatives having cross-functional impact
- Ability to apply advanced analytical thought and judgment
- Ability to influence others with or without authority at all levels of the organization

- Proactive, innovative, with good problem-solving skills
- Ability to work cross functionally
- Excellent written, presentation, and verbal communication skills
- Ability to evaluate key business / scientific challenges and complete complex, ambiguous initiatives having cross-functional impact
- Excellent written, presentation and verbal communication skills in English

If interested, please email your application to jobs@exevir.com