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Head of Pre-Clinical Science

Department: R&D
Hours per week: 37.5
Basis: Permanent

Job Purpose

The Head of Pre-Clinical Science will be responsible for evaluating and directing non-clinical pharmacology and toxicology strategies. This includes the evaluating the pre-clinical proof of concept strategy in order that nonclinical strategies can be executed in line with requirements from regulators and aligned to target product profiles for onward evaluation in the clinic via recommendation and contribution to strategic product development plans.

Key Responsibilities

- Define development of proof of concept animal phase development studies which will be appropriate to translate into nonclinical programmes for all R&D product development
- Develop, execute, and lead a sound science-based nonclinical pharmacology and toxicology development plan which support clinical and product development, and is sufficiently robust that it passes EU and US regulatory requirements.
- Design scientific non-clinical product strategies which comply with best industry practices in pharmacology and nonclinical toxicology.
- Provide insightful and translational recommendations on clinical biomarker
- Maintain a current and broad technical experience/expertise across vaccine and immunotherapy development, knowledge of relevant animal models and build this intelligence into future product development considerations
- Collate, review and approve non-clinical sections in key clinical and regulatory documents (e.g. IMPD, CTD modules 2 and 4, IND/IMPD, study protocol, IB, NDA, BLA, MAA) and ensure timely responses and to regulatory queries in collaboration with regulatory colleagues

Knowledge, Experience & Skills Required

- PhD in toxicology, pharmacology, immunology or related field with demonstrable industry experience
- Extensive hands-on experience designing, conducting, and interpreting results from animal models within an industry setting
- Experience with in vivo immunology/pharmacology with good understanding of DC/T/B cell biology, cytokine function, and overall aspects of how adaptive and innate immune cells interface with other parts of the immune system
- Demonstrated excellence in critical thinking and problem solving skills
- In depth knowledge of ICH, EMEA, MHRA and FDA guidance documents and understanding of Non-Clinical Pharmacology and Toxicology regulatory requirements.

If you are interested in this role, a job statement for this role is available on request.

Please send all applications to:
careers@allergytherapeutics.com

Allergy Therapeutics