Senior Director/ Clinical Pharmacology

Position Code: 23059-18B

Summary Description

This position acts as the primary clinical pharmacology lead providing clinical pharmacology expertise to a multidisciplinary study team. This position is responsible for clinical pharmacology programs for assigned projects and will be the key expert on all clinical pharmacology & pharmacometrics matters relating to assigned projects. This position will work in close collaboration with different functions including non-clinical, Research, Regulatory, BioMetrics and Clinical.

Key Responsibilities

- Responsible for the design and implementation of the Clinical Pharmacology plans using traditional and model informed drug development approaches and will manage the clinical study process from protocol development to final study reporting.
- Evaluate and perform hands-on analysis of clinical PK/PD data; authorize PK clinical study reports
- Contribute to clinical pharmacology strategy and planning for clinical programs
- Ensure timely and accurate communication of study results and interpretation to appropriate internal drug development teams
- Provide PK/PD modeling to support dosing strategies for clinical programs
- Write and edit dose rationale sections of clinical protocols and investigator brochures
- Prepare of the Clinical Pharmacology components of regulatory submissions and will represent the Clinical Pharmacology line at meetings with regulatory agencies and health authorities.
- Maintain a current understanding of PK literature and methodology, as well as the scientific literature related to the specific drug discovery projects
- Ensure appropriate quality of documentation for internal department studies compatible with global regulatory submission requirements

Education & Experience

- PhD, MD, or PharmD with relevant expertise in pharmacokinetics, pharmacology or pharmaceutical science is required; minimum of 7+ years of direct industry experience in conducting clinical stage drug development
- Experienced in developing clinical pharmacology plans and in the preparation of regulatory submissions (including INDs, NDAs, BLAs and/or significant sNDAs/sBLAs).
- Experienced in responding to regulatory questions related to all aspects of clinical pharmacology.
- Knowledge and experience in the application of current practices in the areas of clinical pharmacology, pharmacokinetics, oncology, drug metabolism, bioanalysis, biopharmaceutics, regulatory affairs, and toxicology.
- Population PK/PD analysis and PBPK modeling experience is a plus
- Experience in working as a PI with external CROs with timely delivery of clear and accurate well written study findings
- Strong knowledge of clinical drug development and FDA and ICH guidance documents is essential

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