JOB DESCRIPTION

Position Title: Associate Director/Director, Pharmacology

Job Summary

The Associate Director/Director, Pharmacology serves as the Clinical Pharmacologist on program teams and execution of clinical pharmacology plans that characterize the ADME and PK/PD of the drug candidate, providing rationale for dose regimen selection and identifying circumstances where dose adjustment should be considered. The position will also be a resource to teams for guidance on all matters related to Clinical Pharmacology and Pharmacokinetics, Pharmacodynamics, and Drug Metabolism.

Responsibilities

- Provides Clinical Pharmacology support along with absorption, distribution, metabolism and excretion (ADME) input and scientific opinion to project teams, line management, and governance bodies.
- Provides clinical pharmacology study efforts (e.g., study design, protocol concepts/protocols preparation, clinical phase oversight, and reporting) within assigned programs to yield high value PK/PD insight for future critical decisions. Analyzes results and interprets and recommends action based on study results.
- Collaborates with Clinicians, Quantitative Sciences and Clinical Operations to ensure appropriate study designs are achieved for successful implementation of data analyses and accomplishment of intended study outcomes.
- Identifies and efficiently resolves program and study-specific issues.
- Works with study and program teams to achieve program goals and provides deliverables in approved timeframes.
- Applies best regulatory practices and drug development precedent to assigned programs.
- Supports regulatory input for drug filings related to clinical pharmacology.

Required Skills and Abilities

- Ph.D. or Pharm.D. in clinical pharmacology, pharmacokinetics, or a related field.
- 3 years of direct industry experience in clinical pharmacology
- Experience in assisting development clinical pharmacology strategy, designing/implementing clinical pharmacology studies, and conducting ADME studies
- Demonstrates thorough understanding of:
    - PK/PD principles, physiology/pharmacology and pathology;
    - Operational and scientific aspects of phase I clinical pharmacology studies;
    - Other relevant scientific disciplines, including ADME and core therapeutic areas
- Demonstrates strong team work in a multidisciplinary environment.

- Possesses excellent communication skills. Can effectively present clinical pharmacology data, development plans and strategies to various audiences and write clear and concise study results, interpretations and summaries for reports and regulatory documents
- Experience in interpreting population PK and PK/PD modeling
- Strong verbal and written communication skills
- Able to facilitate activities across many disciplines represented on drug development project teams
- Ability to work in a fast-paced environment
- Excellent organization and multi-tasking skills
- Strong interpersonal skills and problem-solving capabilities
- Proven meeting planning and team facilitation skills.