



Senior Scientist, PK-PD Modeler

Position Code: 21068-18B

Summary Description

This position participates as a member of the preclinical DMPK team and is responsible for developing and executing PK-PD modeling and simulation (M&S) strategies in a collaborative environment with colleagues in translational, regulatory, safety, and preclinical and clinical pharmacology. This individual will apply state of the art M&S methodologies to support lead optimization, clinical candidate selection, FIH and later stage clinical dose selection.

Key Responsibilities

- Develop/apply state of the art PK-PD modelling techniques to guide advancement of drug candidates across development phases (discovery through early clinical development).
- Initiate and monitor outsourced M&S activities as required.
- Actively participate as PK/PD lead on project teams developing small molecule immunologically focused therapies.
- Contribute to regulatory documents (e.g. IND, IMPD, IB) and attend meetings with regulators as required.
- Participate along with diligence team colleagues in the evaluation of in-license opportunities.

Experience & Education

- PhD, PharmD in Pharmaceutical sciences, Pharmacology, Toxicology or related discipline.
- At least 10 years of hands-on experience with development and application of M&S in a drug-development environment.
- Expertise in a specific therapeutic area and ability to demonstrate successful application of M&S tools in that area.
- Expert user of NONMEM, Phoenix-NLME, R/S-Plus or related software with requisite programming skills.
- Demonstrated skills in development of novel modeling approaches that incorporate factors such as receptor affinity, binding kinetics, and diurnal flux in response.
- Hands-on experience with PBPK model development and implementation is a plus.
- Publication record highlighting application of original PK-PD modeling strategies to guide advancement of drug candidates from discovery through early clinical development.
- Excellent leadership and written/oral communication skills with ability to lead team through influence and collaboration.
- Familiarity with regulatory guidance/expectations applicable to M&S.

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