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**Associate Director/Director/Senior and Director,
Pharmacometrics/Modeling and Simulation-
REMOTE**

Hiring organization
CarterMacKay

Employment Type
Full-time

Date posted
September 27, 2021

Description

Director in Modeling & Simulations will combine strong pharmacometric skills with a deep biological understanding. They are responsible for independently determining, planning, and executing M&S analyses for an entire drug development program in close collaboration with cross-functional colleagues within the R&D organization. Specific experience and interest in working in population PK/PD or quantitative systems pharmacology is required. The Director determines, plans, and executes technically challenging analyses by using state of the art Modeling & Simulation methodologies to strongly contribute to critical decision making. The Director will lead M&S projects for an entire drug development program to evaluate study design, dose selection, probability of success estimation, portfolio strategy, pediatric extrapolation etc. In this role, it is expected that they will represent M&S with cross-functional drug development teams, proactively advocate for model-based approaches, and clearly communicate M&S results.

Responsibilities

- Independently determines, plans, executes, and interprets modeling analyses for an entire drug development program aligned with the program strategy
- Closely collaborates with the Modeling & Simulations senior director
- Represents M&S on cross-functional drug development teams, proactively advocating model-based approaches to address development challenges
- By using state of the art Modeling & Simulation methodologies strongly contribute to decision making at critical milestones based on quantitative principles in close collaboration with Biostats, Clin Pharm and other quantitative disciplines
- Represents M&S in preparation for regulatory responses and external regulatory interactions
- Represents the department in company-wide, non-scientific initiatives
- Proactively incorporates and develops approaches and methodologies based on review of relevant scientific literature
- Supervise and mentor junior scientists
- Perform population PK, PKPD-analyses, Clinical trial simulations and other model based analyses on a regular basis
- Coordinate outsourced Modeling & Simulation activities when appropriate
- Strengthen our internal Modeling & Simulation capability on a continuous basis by initiating training activities, evaluating and incorporating new M&S tools as appropriate.
- Demonstrate effective communication and leadership to a broad audience with diverse backgrounds, including senior management

Qualifications

PhD in Pharmaceutics, Clinical pharmacology, or other quantitative discipline with an emphasis Pharmacometric methodologies
Minimum of 8+ yrs of industry experience in the application of Pharmacometrics within the context of drug development.
Expert hands-on skills from population-based PKPD modeling, Clinical trial simulation and optimal design, probability of success calculations, Disease progression modeling, Meta analyses etc.
A solid understanding of fundamental pharmacokinetic and quantitative pharmacology (PKPD) principles.
Excellent programming skills (NonMem, R, Phoenix, SAS and other similar tools)
Demonstrated strong leadership and influencing skills
Excellent collaborative, verbal and written communication skills
Experience from Regulatory interactions and guidelines relevant for M&S

Contacts

For a more comprehensive list over over 25 total openings, please contact Brenda Roseberry directly

Brenda Roseberry

Division Manager-Scientific

Preclinical/Clinical-PK, Pharmacology, Pharmacometrics, Biomarkers

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