SR PHARMACOMETRICS SCIENTIST/DEVELOPMENT SCIENCES

OVERALL RESPONSIBILITY:

Axcella Health is seeking a Pharmacometrics Scientist who is well versed in the application of model-based clinical development strategies, in order to describe and understand the pharmacology of our endogenous metabolic modulators.

The modeling and simulation activities include population PK/PD models, disease progression models, statistical models, physiologically-based PK (PBPK) models, allometric scaling, quantitative system pharmacology (QSP) models, clinical trial simulations, literature meta-analysis, machine learning/deep learning, and other state-of-the-art quantitative techniques.

The candidate will represent the DMPK organization on cross-functional project teams and be an advocate for the use of quantitative approaches to describe the relationship between the known physiology and the observed pharmacokinetics of products.

KEY TASKS AND RESPONSIBILITIES:

- Collaborate with internal and external experts to build population PKPD models for amino acids and contribute to the development of a predictive AXA Development Platform. Our aim is to incorporate drug metabolism and pharmacokinetics knowledge from internal and external sources into a proprietary AXA Development Platform to inform exposure-response relationships and to influence new AXA design.
- Understand and simulate healthy versus disease condition differences to propose dosing regimens for signal seeking studies.
- Undertake diverse scaling approaches to design optimal dosing regimens for pediatric population.
- Conduct biopharmaceutics data analyses (e.g. dissolution performance) with the objective to translate in vitro formulation performance to in vivo formulation performance in humans.
- Organize, execute, and report M&S independently, as well as to present work at cross-functional teams, department meetings, senior management review committees, regulatory interactions, and scientific conferences.
- Plan, write, and review pharmacometrics aspects in relevant clinical documents such as study protocols, analysis plans, clinical study reports, and regulatory documents.
• Serve as a single point of contact for expert advice on modeling & simulation strategy within Axcella. Collaborate with functions inside and outside of Medical Affairs, including the Product Development Team, to translate available data, summaries, and reports into medical communications and educational resources.

SKILLS AND ATTRIBUTES:

• Must have proven experience in quantitative pharmacology and strong hands-on modeling and simulation experience with PK/PD analysis to inform dose selection, safety profile characterization, and product labeling.
• Hands-on experience with population PKPD modeling software (NONMEM, R, SAS, MATLAB, Phoenix, GastroPlus, etc.) is a must.
• In-depth theoretical and applied understanding of PK and PD, in order to describe and understand the pharmacology/biology of amino acids, is required.
• Demonstrated ability to independently plan, organize, and analyze PK/PD data is essential.
• Highly motivated individual with a strong intellectual and technical background in Pharmacometrics discipline.
• Excellent problem-solving, written and oral communication skills.

EDUCATION AND EXPERIENCE:

Degree in pharmacometrics, pharmacokinetics, pharmacology, pharmaceutical science or related field. PhD with 1-5 years, or MS with 8+ years of experience in a pharmaceutical industry setting. Experience in modeling/simulation strategies is highly desired. Title/level dependent on experience.

*If interested, we would welcome a cover letter and CV sent to careers@axcellahealth.com No phone calls please, and only those we will be following up with, will receive a reply.*