

04/09

Daiichi

Edison, New Jersey

Senior Scientist, Clinical Pharmacology

Summary:

This position will support the clinical pharmacology aspects of a compound in late development and for product(s) within Daiichi Sankyo Pharma Development.

Responsibilities:

- Develop clinical pharmacology plans, design and direct clinical pharmacology studies and participate in the management of Contract Research Organizations (CROs) in the conduct of clinical pharmacology studies and the analysis and reporting of clinical pharmacokinetic and pharmacodynamic data. Work with Study Logistics, CROs and other vendors to execute clinical pharmacology studies.
- If medically qualified, also responsible for medical review of additional TM/CP projects, including assessment of subject risk/benefit.
- Review primary data tables, analyze and interpret results, and supervise final review and approval.
- Prepare clinical pharmacology sections of investigator brochures, IND and other regulatory submissions, CTD, and external presentations. Draft and/or review abstracts and manuscripts based on clinical study and on modeling and simulation reports.
- Prepare comprehensive summaries based on extensive literature review of key components of exposure response for various study endpoints of similar compounds in the therapeutic area.

Requirements:

- M.D. or Ph.D. in Pharmaceutics/ PharmD with clinical post-graduate training or M.D. with post-graduate training in clinical pharmacology.
- 3 - 10 years clinical pharmacokinetic experience.
- Strong clinical pharmacokinetic experience with some NONMEM population PK.
- Experience with PK/PD modeling is a plus.
- Experience in the development of clinical pharmacology programs for new chemical entities, directing clinical pharmacology studies and preparation of regulatory submissions would be a plus.
- Excellent organizational, communication and interpersonal skills, as well as effective collaboration and negotiation techniques.
- High proficiency in standard computer software (Word, Excel and Power Point). Proficiency in specialized software for pharmacokinetic data analysis is also desired.

FOR MORE INFORMATION PLEASE CONTACT:

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***Senior Account Representative Career Development
CONTINENTAL CSC***

Fairfield, CT Madison, CT Wilton, CT