

## **Director, Clinical Pharmacology Rockaway, NJ**

The primary purpose of this position is to manage and direct the clinical pharmacology and biopharmaceutics aspects of development projects. Major objectives are to develop Phase I (clinical pharmacology/ biopharmaceutics) program strategies, manage all aspects of Phase 1 trials, and prepare/assist in the preparation of research reports and regulatory documents (INDs, NDAs, CTDs) to report Phase I study results to regulatory agencies.

### **About Warner Chilcott**

Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare, gastroenterology, dermatology and urology segments of the U.S. and Western European pharmaceuticals market. It is a fully integrated company with internal resources dedicated to the development, manufacturing and promotion of its products. We have established strong franchises in women's healthcare and dermatology through our marketing techniques and specialty sales forces. We believe that our proven product development capabilities, coupled with our ability to execute acquisitions and licensing transactions and develop partnerships will enable us to sustain and grow our business.

The individual will be responsible for the following activities:

- Prepare/assist in preparation of Phase I study strategies for development projects
- Design Phase I studies (clinical, pharmacokinetic, statistical aspects)
- Manage Phase I study budgets – from bid process to contract research organizations (CROs - clinical, bioanalytical, pharmacokinetic/statistical), develop study budget, track invoice approval against budget.
- Manage study execution to conform to project timelines for all Phase I studies
- Prepare Phase I study protocols, reports and IND/NDA/CTD study summaries
- Identify centers suitable for performing clinical pharmacology studies in healthy volunteers and patients
- Identify CROs suitable for conduct of bioanalytical sample analysis
- Coordinate/Manage clinical study monitor's activities in support of Phase I studies such as the conduct of pre-study, site initiation and monitoring visits
- Monitor eligibility, enrollment, data consistency and safety in Phase I studies

- Work closely with medical director to relay safety results to the relevant Warner Chilcott departments
- Work with the clinical study monitor and data management services to develop paper and electronic data collection, analysis and reporting documents
- Coordinate and monitor study sample shipment
- Review bioanalytical methods and the bioanalysis of study samples to ensure compliance with relevant guidances, best practices and SOPs
- Review bioanalytical data and communicate with the laboratory to resolve discrepancies
- Conduct preliminary and/or validated pharmacokinetic analysis on bioanalytical data and report results to management and project teams
- Act as primary contact in negotiations with CROs for Phase I study agreements and work with management to gain approval of study contracts
- Initiate and maintain regular communication with external CROs to ensure that they understand Warner Chilcott's commitment to conducting work in accordance with GCPs, regulatory guidances, internal SOPs and other quality standards.
- Participate in the review of project proposals, analysis plans, summary reports and any other documents provided by CROs
- Manage the process to archive clinical study documents
- Forecast and track study timelines, budgets, materials and resources
- Provide information (written and oral) as requested for assigned projects
- Ensure clinical pharmacology studies meet development requirements within appropriate cost, time and quality restraints
- Conduct reviews of published scientific and regulatory literature to ensure relevant therapeutic knowledge and be able to provide background information on developmental projects and competitor products
- Provide support to Quality and Regulatory during regulatory inspections of clinical and bioanalytical CROs
- Represent the clinical pharmacology department at project team meetings and provide the project management department and project teams with development updates, timelines and budget projections
- Prepare and compile clinical pharmacology/biopharmaceutics sections of regulatory documents including INDs, NDAs, CTDs, and scientific publications

## **Qualifications**

- PhD in pharmaceuticals/pharmacokinetics, chemistry, or related science, 10+ years experience in clinical pharmacology /biopharmaceutics/clinical pharmacokinetics or equivalent combination of education and experience:
- Good planning and organizational skills coupled with effective negotiation and communication abilities.

- Good communication skills (written and verbal)
- Effective negotiation and communication abilities
- Knowledge and understanding of the fundamentals of pharmacokinetics/biopharmaceutics and ability to apply those to the implementation and interpretation of clinical pharmacology studies
- Knowledge of FDA guidances on bioanalytical method validation, bioavailability/ bioequivalence studies and 21 CFR320.
- Knowledge of governmental Phase I study regulatory requirements in US, UK, Canada
- Good knowledge of word processing (Word), pharmacokinetics (WinNonlin), statistics (SAS), data management (Excel), project management and statistical computer packages

Candidates must be authorized to be employed in the United States. Candidates should be willing and able to travel as necessary. Candidates must be organized and have excellent oral presentation and communication skills. Candidates must also successfully pass a drug test and background check.

Warner Chilcott realizes that our success as an organization is dependant upon our people. We seek aggressive, success oriented and adaptable associates. Please apply at [jobs@wcrx.com](mailto:jobs@wcrx.com) and reference "DirPK" in the subject.