



## Clinical Pharmacologist

Location: Beijing/ Shanghai

Report to: Scientific Advisor ED&CP-AP

Language: English, Chinese

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Company : Roche R&D Center (China) Co. Ltd.

### Primary Responsibilities and Accountabilities:

- Both build new and apply known disease and drug models as stated previously. This will be based on clinical trial information inside Roche as well as the literature
- Design and analyze cross-trial pharmacokinetic-pharmacodynamic analysis to understand who responds to treatment and who is exposed to risk.
- Simulate new situations (e.g., trial design, efficacy-safety in new populations) based on prior data and models.
- Provide quantitative analysis for the Asia-Pacific market including dose-response, trial design, dosage form performance and new patient subpopulations (e.g., pediatrics, elderly)
- Provide Clinical Pharmacology expertise to p-RED project teams for drug candidates discovered by China R&D.
- Evaluate understand pre-clinical package data for EIH studies, design, conduct, analyze SD and MD EIH studies and mechanism of action studies) .
- Provide local China and other Asia Pacific Countries, clinical pharmacology input for local Phase I/II support for global projects and Lifecycle Teams.
- Serve as a China liaison with Global Clinical Pharmacologist for the assigned projects.
- Lead or contribute to cross-functional working groups in the context of project teams and/or clinical pharmacology activities.
- Develop the timely, scientifically sound, business-required clinical pharmacology studies to support early stage (Phase I-II) and late-stage studies or NDA approvals in China and other Asia Pacific Countries.
- Prepare in a timely manner and with high quality the relevant documentation (protocols and amendments, CSRs), or the clinical pharmacology component of other high level documents such as INDs, IDBs, NDA/PLA expert reports, Chinese package inserts).
- Deliver high-quality evaluation and interpretation of clinical pharmacology data (pharmacokinetics, pharmacodynamics, safety, dose/concentration response).
- Interact with investigators with regard to scientific issues.
- Be responsible for the integrity of Clinical Pharmacology studies conducted by pRED from protocol design, execution, data analysis and final study report perspective is at the best global level.
- Adopt efficient and effective global local clinical pharmacology study working process and experience and implement them in China, in alignment with the global organization (p-RED).



- Deliver portions of the NDA documentation, responses to Asia Pacific Regulatory Agencies questions, and preparation of materials for use in presentation, for all interactions with regulatory authorities with regards to clinical pharmacology issues.
- Contributes to appropriate budget and manpower planning for the assigned activities.
- Prepare or contributes to primary publications for the assigned products.
- Support the assigned product during the launch phase as demanded by the business organizations.
- Provide technical coaching and mentoring to the junior scientists to grow in the field of Clinical Pharmacology or Clinical Pharmacology studies.
- If deemed appropriate, providing group lectures, individual coaching or constructive feedback to colleagues who are new to the concept of Clinical Pharmacology in Asia-Pacific project teams.
- Interact with pre-clinical research and development scientists in China or in Global to provide reliable clinical pharmacology expertise and advice to the research teams in China and AP.
- Participate in evaluation of the Clinical Pharmacology Unit or Clinical Pharmacology CROs, if needed.
- Provide support to train Data Managers, PK/PD Lab managers, Clinical Monitors for the Clinical Pharmacology studies.
- Participate and represent clinical pharmacology on due diligence team
- Participate and contribute to the ED &CP Asia Pacific or Global Department initiatives.

#### **Professional and Technical Requirements:**

##### **Minimum:**

- PharmD, PhD, or MD in clinical pharmacology, or an area relevant to clinical pharmacology, with relevant clinical and pharmaceutical industry experience in the planning and conduct of clinical trials (preferably early human studies in a pharmaceutical industry setting).
- Relevant expertise in nonlinear mixed effects modeling of clinical trial data focused on population PK-PD modeling
- Demonstrated ability to conceive, plan, conduct and analyze sparse samples related to efficacy and safety
- Demonstrated ability to analyze high intensity phase 1 -2 PK-PD trials for dose selection
- Develop disease models (empiric or mechanistic) based on prior knowledge
- Simulate clinical trials (e.g., first in human, proof of concept)
- Publication of these studies in peer reviewed journals
- Appropriate computer software experience (including WINNONLIN or other similar PK analysis tool, MS Word, Excel, PowerPoint, etc)
- Work globally with colleagues in Clinical Pharmacology and M&S, TRS.
- In-depth knowledge of the global drug development process.
- Capability to learn. the China regulatory requirement and process.
- Able to represent Roche interact with regulatory authorities.
- Hands on approach to daily work.
- Able to work in a quickly changing, not fully structured internal and external environment

##### **Desired:**

- Experience with advanced data analysis skills (e.g., create and employ disease-drug models, simulate clinical trials, analyze phase I-III trials with respect to concentration-effect-subgroup analysis.\_.
- Outstanding hands on track record in driving negotiations with both internal and external stakeholders.



- Recognizing as an experienced expert within Clinical Pharmacology community through challenging project breakthrough work, or significant contribution to a therapeutic area or drug development process.
- Successful track record for interfacing with major government agencies, such as US-FDA or CPMP or EMEA.
- Desire to actively "coach" and to collaborate.
- Speaks and writes fluent English & Chinese.