



Senior Scientist in Analytical Group

Location: Shanghai

Language: English, Chinese

HR Email: shanghai.rdcrecruit@roche.com

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

Primary Responsibilities and Accountabilities:

- Provide full analytical support to formulation group for preclinical and clinical drug product development, including analytical & dissolution method development & validation, technical report & documentation preparation, analytical troubleshooting, release testing, and related specification setting, etc.
- Responsible for drug product stability studies. Activities include experiment design, stability study execution, and generation of experimental summaries & reports.
- Assist preformulation research activities if necessary, including thermal analysis, solid state characterization, and other physicochemical property tests, etc.
- Assist analytical support to process chemistry for drug substance.
- Serve as a resident expert in analytical development to optimize the capability of analytical development group to create innovative and efficient solutions to specific problems utilizing the state-of-the-art analytical technologies and in-depth scientific knowledge and experience.
- Represent analytical group to attend relevant internal and external symposia/conferences for knowledge sharing and scientific presentations.
- Lead internal analytical projects and manage related out-sourcing activities. Work collaboratively with project team and out-sourcing partners.
- Responsible for drafting, reviewing, and implementing of analytical related SOPs or guidelines, as well as maintaining & troubleshooting of all formulation related analytical instruments.
- Supervise 1~2 analytical scientists. Coach junior scientists in implementing innovative solutions for assigned analytical activities; be responsible for performance plan & review, and career development for direct reports.
- May serve as CMC representative in project teams. Coordinate CMC activities related to specific projects.
- Additional responsibilities include new technology evaluation, vendor or out-sourcing partner auditing & evaluation, and other department related activities.
- Other related duties may be assigned to meet team and site objectives.

Professional and Technical Requirements:

- Ph.D. degree in analytical chemistry/pharmaceutical analysis (or closely related field), plus minimum 2 year working experience in pharmaceutical (or chemical) industry.
- Solid knowledge on the state-of-the-art analytical theories and technologies, and hands-on experience in operating, calibrating, maintaining and troubleshooting of a wide range of analytical instruments (HPLC, GC, IR, UV, DSC, TGA, Dissolution etc).
- Demonstrated analytical development knowledge and experience for drug substance, and



especially for drug product development, which includes analytical testing method development & validation, stability studies, impurity profiling, dissolution method development & validation, and related specification setting, etc.

- Current knowledge and hands-on experience in cGMP & GLP. Experience in IND/NDA dossier preparation would be a plus.
- Knowledge and hands-on experience in analytics/purification of Biologics would be a plus.
- Must be an independent researcher; must be able to manage analytical project; must possess strong problem solving and troubleshooting abilities. Must be proactive and self-motivated.
- Mentor associates; possess good interpersonal communication skills. Must be a good team player.
- Coordinate out-sourcing activities.
- Fluent in both written and spoken English; can deliver good presentations in English and Chinese.