

Job Opening at ScinoPharm Taiwan

2016/03/25

Position information

Job title: Senior Analyst, Quality Control

Location: Tainan, Taiwan, R.O.C.

Company profile: ScinoPharm Taiwan, Ltd. is a drug company developing and manufacturing APIs and formulations to the global pharmaceutical industry with research and manufacturing facilities in both Taiwan and China.

Job overview

Quality Control Lab is responsible for testing intermediate, final and stability product samples to demonstrate that all products meet all standards required for cGMP operations.

Major responsibilities:

- Improve QC analytical methods/specification based on customer request
- Execute/review the testing related to the project batch release
- Modify the analytical testing method/specification per process changing of each project
- Perform QC method validation/qualification and issue the relative reports
- Handle the needed troubleshooting and investigation of plant deviations
- Generate the reports to support customer/internal/authority technical requests
- Prepare the QC technique transfer reports and training subordinates at QC
- Qualify the analytical methods/specification from any pharmacopeia and customers
- Communicate with EP, USP, JP etc. for the monograph issues
- Modify the analytical testing method and specification for final API
- Assistant supervisor to communicate with customer for the method transfer issue
- Supporting to response customer/internal/authority technical requests
- Review and collect all relative analysis data
- Prepare the Annual Product Reviews for QC's OOS, OOE, MD, and DC
- Work on the API and stability sample testing
- Demonstrate technical proficiency in analytical methodology and adherence to cGMP and ICH compliance
- Hands-on analytical instrumentation skills with analytical instruments such as HPLC, GC, etc.

Qualifications/Work experiences:

- Master degree or above in chemistry or biochemistry related studies
- Six to ten years of work experience in a GMP pharmaceutical manufacturing and/or development environment
- Good knowledge of pharmaceutical regulations and GMP compliance
- Good knowledge of the technical principles, concepts and best practices of the analytical techniques used in the chemical analysis of drug substances and raw materials
- Good command of oral and written English
- Demonstrate strong leadership skills through past work history; a team-oriented individual with strong people skills, the ability to develop, train and interact with teams

ScinoPharm is committed to providing Equal Employment Opportunity for all persons. Equal opportunity extends to all aspects of the employment relationship including hiring, transfers, promotions, training, working conditions, compensation, benefits, and other terms and conditions of employment.