

Analytical / Method Development Chemist

Job Function Summary:

Pharmaceutical oral solid dose manufacturer seeking an experienced Analytical Chemist with proven skills to design, develop, validate and verify analytical methods for the testing of Raw Materials, Finished products, Stability and Process Validation.

Required Experience:

- Experience in method development, validation, verification, and transfer activities for pharmaceutical raw materials and finished products; based on USP, FDA, and ICH guidelines.
- Analysis of Active Pharmaceutical Ingredients, Excipients, and Finished Drug Product according to company established Standard Operating Procedures (SOP's), Current Good Manufacturing Practices (cGMP's), Good Laboratory Practices (GLP's), Good Documentation Practices (GDP's), FDA/DEA/OSHA regulations.
- Knowledge of USP/NF monographs.
- Ability to communicate effectively with coworkers and clients.
- Writing and executing protocols, reports, and test methods related to raw material and finished product testing.
- Proven ability to work independently, as well as within a team.
- Proficiency in operating routine laboratory equipment and experience with the following laboratory instrumentation/equipment related to method development:
 - HPLC/UPLC
 - Gas Chromatography (GC)
 - Malvern Mastersizer
- Experience with the following laboratory instrumentation/equipment:
 - FT-IR Spectrophotometer
 - Dissolution (Apparatus I and II)
 - Differential Scanning Colorimeter (DSC)

Preferred Skills

- Proficient in Empower 3
- Effective communication skills
- Self-motivated and ability to work independently with minimal supervision
- Ability to organize projects and complete timely
- Ability to execute method transfers from R&D to QC, as well as site transfers of drug substance and drug product
- Provide technical expertise to support laboratory investigations

Education

- Minimum requirement of a BS degree in analytical chemistry, organic chemistry, biochemistry, or food science with course work in analytical chemistry plus 3 or more years laboratory experience.