

Job Title: R&D Chemist I

Department/Division: Laboratory

Reports to: Analytical Sr. Scientist

Grade:



Job Summary:

Duties/Responsibilities:

- Provide analytical support to a designated range of products enabling revenue growth, increased laboratory capability, and enhanced lab quality compliance.
- Ensure all feasibility work, analysis, validation, stability, industry trials, and development are performed on time, meeting QbD standards and meet all regulatory requirements.
- Analytical support for all KPIs for the laboratory and operations.
- Analytical support scale up activities for all projects to commercial scale.
- Analytical development, optimization and scale up of all dosage forms.
- Create and review technical documents including analytical method development reports, method development/validation protocols and reports, standard operating procedures in compliance with regulatory requirements.
- Perform bench work such as HPLC, GC and dissolution.

Education and Experience:

- Bachelor's degree in relevant science field with minimum 1-3 years' experience.
- A minimum 1-3 years' experience in a cGMP or cGLP laboratory environment required.
- Knowledge of analytical techniques including HPLC. (GC, FTIR and dissolution experience a plus)
- Experience using chromatographic software (Empower 3 – strongly preferred).
- Excellent analytical, technical writing, communication and data management skills to present data to internal technical and project teams & potentially to clients.
- Proven scientific and technical ability to design and execute experimental studies as well as statistically analyze data, author and review protocols and reports.
- Must be able to think critically and troubleshoot typical analytical (HPLC) instrumentation problems.
- Knowledge & experience with cGMP, cGLP, USP and the regulatory requirements for pharmaceuticals.
- Highly motivated and self-driven individual with ability to work independently, and multi-task, adhere to aggressive timelines in support of department and company objectives.

Preferred Skills/Abilities:

- 2-3 years' experience in the FDA drug/pharmaceutical industry
- Demonstrated in-depth scientific knowledge & experience in analytical method development, & validation
- Experience in the development of pharmaceutical dosage forms and polymeric drug delivery systems with emphasis in transdermals.

- Experience in statistical data analysis and QbD principles
- An understanding of polymer science, analytical development, drug and formulation characterization, optimization and scale-up

The above job description does not constitute a contract of employment, and Tapemark may exercise its employment-at-will rights at any time.

Employee Signature

Date