Research Investigator, Analytical Development

SUMMARY OF POSITION

The successful candidate will be a highly motivated individual ready to work within a science-focused, collaborative, multidisciplinary drug substance and drug product development environment.

The Research Investigator position will have demonstrated experience to support analytical methods development/validation, characterization, lot release and stability testing. The successful candidate will also be responsible for knowledge development to facilitate fundamental product and process understanding, and the advancement of innovative approaches to the support of drug development. Support for drug candidates across all stages of development and, as needed, within our commercial product portfolio will be required.

MAJOR ACTIVITIES AND RESPONSIBILITIES

Temporary reporting to the Senior Director, Pharmaceutical Development, Research Investigator will:

- Responsible for performing laboratory tasks to support the development, optimization and validation of analytical HPLC methods.
- Design experiments for the characterization and testing of API.
- Design and perform experiments for the qualification/validation of analytical methods and their transfer to quality control and contract laboratories.
- Support drug product formulation, evaluation of prototypes, process development and validation.
- Serve on departmental, interdepartmental and project teams.
- Write formal reports for inclusion in regulatory filings and support the generation of appropriate responses to questions from regulatory authorities.
- Adhere to all relevant compliance requirements.

ORGANIZATIONAL STRUCTURE

Temporary reporting to the Senior Director, Pharmaceutical Development.
QUALIFICATIONS AND BACKGROUND REQUIREMENTS

Educational Requirements

- BS in Analytical Chemistry, Biochemistry (or relevant discipline) and minimum of 6 years of pharmaceutical laboratory experience required; or
- MS in Analytical Chemistry, Biochemistry (or relevant discipline) and minimum of 4 years of pharmaceutical laboratory experience required; or
- Ph.D. in Analytical Chemistry, Biochemistry (or relevant discipline) and minimum of 2 years of pharmaceutical laboratory experience required

Professional Work Experience

- Must have strong experience with analytical HPLC methods development and troubleshooting
- Comprehensive hands-on knowledge of analytical testing and characterization.
- Laboratory experience with and knowledge of analytical methods such as HPLC, MS, NMR and other modern analytical techniques.
- Problem-solving and troubleshooting skills.
- Strong capabilities in experimental design and execution and data interpretation.
- Ability to work independently.
- Strong verbal and written communication skills.
- Strong interpersonal skills.
- Knowledge of cGLP / cGMP, FDA, EMA and ICH guidance’s and industry standards for analytical development and characterization.
- Familiarity with the USP and other compendia.

Skills/Knowledge in one or more of the following areas is a plus:

- Laboratory experience with and knowledge of bioanalytical techniques such as SDS-PAGE, DIGE, Western Blot, CE-SDS, ELISA, qPCR, Cell-based bioassays, BIAcore, cIEF, etc.
- Skills in statistics and statistical analysis of data.
- Skills in DOE, QbD.
Compensation

A competitive compensation package will be presented to the right individual including base salary, bonus, and equity.

Location

This position will be based at 1 Cedar Brook Drive, Cranbury, NJ, 08512.

How to apply

For immediate consideration, please email your most recent ms-word resume and cover letter to: Careers@amicusrx.com