

SCIENTIST, ANALYTICAL METHODS/QUALITY CONTROL

Description

The Scientist's key responsibilities are to develop, transfer, and execute analytical methods to support CGMP Quality Control testing (in-process, lot release, and stability). This individual will transfer and/or develop analytical methods and standard operating procedures for use in a CGMP environment, and to perform analytical qualification / validation along with product testing to support CGMP Operations. The Scientist will be responsible for the maintenance and troubleshooting of instrumentation, including but not limited to UPLC/HPLC, CE (electrophoresis systems /gel and capillary), HIAC, KF and more. The Scientist will support direct interaction and management of the vendor representatives and service contracts for all lab equipment and instrumentation. The position requires knowledge and understanding of both standard and state-of-the-art analytical instrumentation and technologies, and this individual will be expected to recommend the same to meet the company's goals and improve its efficiency. The Scientist will also serve as a member of project teams, in a leadership role as needed, which will require substantial interaction and communication with client company representatives. The ability to communicate technical information, both verbally and written, and to work efficiently to meet defined timelines is crucial. This position will require direct interaction with staff in both Research & Development and Manufacturing, and may supervise Quality Control Associates or Quality Lab Assistants from time to time.

Requirements

We are seeking an individual with pharmaceutical manufacturing experience in analytical sciences or quality control. Candidates with a Bachelor's or Master's degree in biochemistry, analytical chemistry, life sciences, or a related field, should have 8-10 years of industrial experience. Candidates with a Ph.D. should have 2-4 years of industrial experience after post-doctoral work.

Essential requirements include:

- Experience in the analysis of various parenteral protein formulations including monoclonal antibodies, peptides, etc.
- Experience in the analysis of various small molecule parenteral formulations
- Transfer and qualification of analytical methods along with writing of Lab Procedures (Methods) for use in the support of process development and/or CGMP (in-process, lot release, stability) testing.
- Responsibility for the maintenance of analytical instrumentation and QC lab equipment
- Experience in the development and management of scientific project timelines
- Experience working and communicating within multi-disciplinary teams, especially with clients and subcontractors

The following experience is highly desirable:

- Transfer of various types of analytical methods from research and development setting to CGMP labs.
- Execution of analytical method qualification / validation protocols for UPLC/HPLC and capillary electrophoresis methods, in support of both large and small molecule parenteral finished product manufacturing.
- Management or participation in support of CGMP Drug Product stability testing programs. Including the design and writing of stability programs per client requirements and management direction.
- Supervision of scientific/technical staff and management of scientific/technical functions