Director – Analytical Chemistry

Exemplify BioPharma, Inc. is a global partner research organization (PRO) based in New Jersey, USA. We are a team of biopharma industry experts focused on delivering end-to-end Chemistry, Manufacturing and Controls (CMC) throughout the drug development and regulatory market application processes. Using a unique combination of program management, coupled with our New Jersey based process development laboratories we are ideally positioned to deliver CMC success to partner organizations. We are talent based team and our key asset is our experience, multidisciplinary expertise and proven track record. We strive to bring tangible value to our partners through provision of strategic, tactical and technical leadership to solve complex problems focused on reducing program timelines and costs.

Position & Responsibilities

Exemplify BioPharma is seeking a Director, Analytical Chemistry to lead the CMC Analytical Development team at our R&D laboratory located in Cranbury, New Jersey. The ideal candidate will have 10 years' experience and a proven record of sustained laboratory achievement and innovation.

- Lead, develop, train and coach a high performing team of analytical chemists.
- Direct and manage the analytical development for small molecule drug substance and product including GMP starting materials, process intermediates, in-process controls, stability testing and cGMP release testing.
- Oversee the daily scientific activities including method development and validation, in-process control and routine sample analysis, including review of experimental results and reports.
- Participate in decision-making process with senior management on budgeting, planning, and implementation.
- Provide training and technical guidance to scientists to ensure the quality of work and timely completion of projects as required.
- Represents the analytical chemistry function in integrated project teams and partners with representatives from key CMC functions such as process chemistry, formulation development, quality assurance, regulatory affairs, manufacturing and supply chain.
- Provides ideas, laboratory support and supervises scientific efforts to solve complex project related problems, including novel chromatographic method development for co-eluting impurities, structural elucidation for unknown impurities, potential genotoxic impurity assessment and solutions to specific process development challenges.
- Leads technology transfer activities for his/her projects as appropriate from clients to Exemplify and to partner CRO/CMOs.
- Liaises directly with key clients providing technical and overall project updates.
- Prepare timely documentation (project reports, development reports, etc.).
- The professional in this position will lead and mentor scientific teams to support early and late CMC development.

Qualifications and Experience

A Ph.D. degree in analytical chemistry or a related discipline with 10 years of hands-on and progressive leadership experience in analytical chemistry within the biopharmaceutical industry.

Thorough understanding of the drug development cycle and analytical development for small molecules for drug substance and product from IND through commercialization.

Direct experience with HPLC, GC, MS, FTIR, NMR and wet chemistry method development, validation and cGMP release testing.

Experience with drug substance and product stability and compatibility studies.

Ability to interpret and apply ICH guidance, cGMP, GLP, regulatory requirements and leverage industry best practices.

Experience with preparation and review of CMC regulatory submissions is a plus.

Excellent interpersonal and leadership skills and abilities

Highly motivated, organized, and detail-oriented with demonstrated project management skills.

Strong written and verbal communication with a “can-do” problem solving style.

Hands-on individual with a collaborative personal style and the ability to work well in a fast-paced team and collaborative environment.

This is an exceptional opportunity for motivated candidates who wish to be exposed to all aspects of CMC drug development in a fast moving, collaborative and learning environment.

Application

If you are interested in applying for this exciting opportunity at Exemplify BioPharma please e-mail a cover letter and resume to careers@exemplifybiopharma.com