

Job Description

Job title	Analytical Development Senior Scientist
Department	CMC
Employee Type	Regular, Full Time, Exempt
Working Location	San Diego, CA
Report to	VP of CMC

Summary

Ansun has an exciting opportunity for a highly motivated individual to fill a Senior Scientist position in the CMC organization in San Diego, CA. The Analytical division of the CMC organization is responsible for all aspects of CMC analytical development required to progress biologics candidates from discovery into and through clinical development stages. In this lab-based role, the candidate will utilize knowledge and experience of physicochemical and biological characterization of traditional biologics such as recombinant proteins and advanced therapeutics such as cell and oncolytic virus therapies, to develop Ansun's pipeline products. The candidate will also be involved in the bioanalytical assay development for the pipeline products in preclinical and clinical studies. The candidate will develop innovative assay and characterization tools to guide and ensure the development of a high yield and high quality production process for various therapeutic modalities.

Primary Responsibilities

Accountable for the development, coordination and execution of method development, optimization, transfer and validation of analytical and bioanalytical assays including but not limited to the Identity, Purity, Quantity and Potency assays and characterization methods supporting Drug Substance and Drug Product for research, preclinical and clinical use.

Accountable for the management of contracted analytical and bioanalytical testing to meet the needs for quality, compliance and business imperitives including tracking, submitting reports and supporting data.

Organizes and prepares analytical and quality control components of CMC regulatory filings including descriptions of test methods, qualification/validation summaries, specifications, specification justifications and test results.

Provide responsive, timely and high integrity assay service function for research and development and ongoing stability studies.

Ensure Analytical instruments are operating correctly with minimal downtime with good use practices, routine maintenance, troubleshooting problems and obtaining outside service.

Any other duties as assigned

Qualification / Education / Experiences / Skills

* BS and above in Chemistry, Analytical Chemistry, Biochemistry or related discipline.

* Degree and relevant pharmaceutical/biotechnology development experience: 3 years with Ph.D., 6 years with MA, 8 years with BS. Position and title will be based on degree and total years of relevant experience in industry and academia.

* Familiarity with ICH guidelines on API, product specifications, stability, assay validation

* Experience in Protein Analytical Chemistry, Biochemistry, Molecular/Cell Biology and Statistics required. Virology and immunology experience and GMP and GLP experience highly desirable. Hands-on development and troubleshooting experience with various analytical and biological assays are required.

*Must have strong written and verbal communications skills.

*Must be capable of working in a fast-paced, collaborative environment and managing multiple concurrent projects with a high degree of independence.

* Must be hands on in the lab, well organized, detail orientated and collaborative.

Special Working Conditions:

Exposure to hazards or disagreeable conditions such as organic solvents, glassware under vacuum, laboratory machinery such as pumps, centrifuges, etc. Working with potentially toxic or pharmaceutically active biological and chemical entities.

Special physical or visual requirements: Lifting containers containing up to 5 gallons of solvent.

Travel: about 5%

Ansun is an Equal Employment Opportunity/Affirmative Action Employer:
Minority/Female/Disability/Veterans/Sexual Orientation and Gender Identity.