

## **Description**

**Job Title:** Scientist, Analytical Development (Biologics)

**Department:** Pharmaceuticals

**Reporting To:** Senior Scientist, Group Lead

**Classification:** Full-Time, Non-Exempt

**This is a 6-month contract, with the possibility of conversion or extension.**

## **What We Do**

BioDuro-Sundia is one of the premier Contract Research, Development and Manufacturing Organizations (CRDMO) globally, with more than 2,200 employees. Our US operations are US headquartered in San Diego, CA. Our 11 global facilities provide integrated solutions and exceptional services to our clientele for challenging preclinical and clinical trial projects. With capabilities spanning Drug Discovery, Development, and Manufacturing, it is no surprise that BioDuro-Sundia is a leading partner of choice.

## **Why BioDuro-Sundia?**

Take the next step in your career and join BioDuro-Sundia today to change lives through the products we help create. Here, you will contribute your talents to meaningful projects that impact the lives of patients around the world and develop as an individual by working directly with a team of seasoned experts and rising stars. Our values of Accountability, Respect, Tenacity, Results and Integrity are embedded in everything we do. No matter what your role may be, BioDuro-Sundia strives to ensure all our employees are empowered and given the necessary tools to lead us in our relentless pursuit of success.

## **Job Overview/Summary**

This role is responsible for analytical development and characterization activities in support of our projects for biologics. You will be assisting in creating the analytical strategy for the manufacturing of biotherapeutics by developing test methods, method transfer, specifications, and good documentation.

It will require experience with SDS-PAGE analysis, gel-based assays, potency assays or/and molecular biology techniques.

## **Essential Functions and Responsibilities**

- Responsible for analytical development and characterization activities in support of our projects for biologics.
- Design method development strategies for SDS-PAGE analysis.
- Work in the lab to execute potency assays, ELISAs, dissolution testing, UV -spectrophotometer assays.
- Execute other routine assays in the lab not limited to HPLC analysis, water content analysis, residual solvent analysis.

- Set analytical strategy, coordinate and perform in-house analytical development and protein characterization, and partner with the senior scientists.
- Provide technical expertise on analytical methods for performance for biotherapeutic drug substances (DS) and drug products (DP).
- Work with QC, and Analytical Scientists to develop, implement and transfer appropriate analytical methods internally.
- Write and review SOPs.
- Validate methods according to ICH guidelines
- Train junior scientists and provide scientific guidance as needed.
- This job description is subject to change at any time.

## **Requirements**

### **Required Qualifications**

- A degree in Analytical Chemistry, Biochemistry, Cell Biology, or related field; a PhD is preferred.
- At least 3 years of experience in analytical development for the pharmaceutical industry;
- Working knowledge of analytical techniques, such as HPLC, GC, UV/Vis, ELISA, Activity, SEC.
- Extensive experience with the analysis of protein therapeutics and a working knowledge of small molecule analytical methods.
- Demonstrated expertise in the independent design and execution of analytical development projects.
- A working knowledge in the interpretation and application of international regulatory guidelines in different phases of drug development.

## **Benefits**

### **Position Benefits**

BioDuro-Sundia employment provides the opportunity to work in beautiful San Diego, California only 5 minutes from the nearest beach. We offer full health benefits, paid vacation and sick leave, an aggressive bonus structure, and market-competitive salaries to all our employees. In addition, BioDuro-Sundia provides employees with free catered lunch Monday through Thursday, and a variety of engaging employee and community outreach events. We strive to reward and promote employees who exhibit our values of Accountability, Respect, Tenacity, Results and Integrity.

### **EOE and Accommodation**

We value diversity and are proud to be an Equal Opportunity and Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, protected veteran status, pregnancy, citizenship, marital status, gender expression, genetic information, political affiliation, or any

other characteristic protected by law. BioDuro-Sundia provides reasonable accommodation in job application procedures for qualified individuals with disabilities and disabled veterans. If you need accommodation in connection with the recruiting process due to a disability, you may use the alternative methods by emailing [humanresources@BioDuro-Sundia.com](mailto:humanresources@BioDuro-Sundia.com). If you are selected to interview for a position, you may also request an accommodation with our team directly.

**Notice to Agency and Search Firm Representatives**

BioDuro-Sundia is not accepting unsolicited resumes from agencies and/or search firms for this job posting. Resumes submitted to any BioDuro-Sundia employee by a third-party agency and/or search firm without a valid written & signed search agreement, will become the sole property of BioDuro-Sundia. No fee will be paid if a candidate is hired for this position as a result of an unsolicited agency or search firm referral.