

## **Senior Scientist, US Characterization Team, Analytical Development**

### **About Shire:**

Newly combined with Baxalta, Shire is now the leading global biotechnology company focused on serving people affected by rare diseases and other highly specialized conditions. These diseases are often misunderstood, under-diagnosed, and potentially life-threatening.

Our 22,000 employees come to work every day with a common purpose: to develop and deliver breakthrough therapies that enable people with life-altering conditions to live their lives to the fullest.

At Shire, we are dedicated to expanding, building and sustaining leadership across our key therapeutic areas through our extensive portfolio of products, innovative pipeline and collaborative approach to working with diverse partners around the globe. We strive to earn and keep the trust of our patients, their families and physicians, and all others who support and advance their care.

Working together, the possibilities for our patients, healthcare partners and employees are unprecedented, with significant growth potential for our shareholders.

### **Position Overview:**

We are seeking an expert in structural characterization of biologics to contribute to the US based Characterization team within the Analytical Development group at Shire.

### **Primary Duties:**

- As an expert in structural characterization of biologics, contributes as part of a team of scientists to the design and implementation of mass spectrometric based solutions and other relevant characterization tools for the qualitative and quantitative analysis of proteins and glycoproteins in a compliance-based environment.
- Additional expertise/knowledge in biophysical techniques and in vitro/in vivo activity and functional assay development is a plus.
- Identifies, strategizes, prioritizes and manages own activities to bring agile resolution to a variety of problems of moderate scope and complexity to support company products in alignment with organizational objectives. Provides mentoring to junior team members and contributes to setting objectives and group priorities.
- Understands and applies advanced scientific principles, theories, concepts, practices and standards to process and product development. Keeps current with scientific knowledge in areas of expertise. Provides input to the development of new scientific knowledge.
- Besides protein mass spectrometry, applies in-depth knowledge in a number of potential analytical areas to characterization efforts, including HPLC (such as RP-HPLC, SEC, IEX, UPLC with UV, Fluorescence, MALLS detection), CE (free solution CZE, CE-SDS, cIEF), and biophysical techniques. Independently guide method development for elucidation and monitoring of structure of proteins and glycoproteins (primary, secondary and higher order structure), peptide

mapping and quantitation of process- and product-related impurities. Knowledge and experience with glycan analysis will be a plus.

- Previous experience in designing and implementing structure/function studies and comparability studies is highly desirable.
- Works with management to review progress and strategy in meeting team and project objectives.
- Demonstrates independent judgment in technique and method selection, protocol and study design and execution, data analysis and use of standard practices and procedures for a variety of problems of moderate scope and complexity to meet assigned objectives.
- Documents and reviews data as per established company guidelines and SOPs. Authors documents such as protocols, memos, data summaries, reports and procedures and contributes to publications and relevant CMC sections of regulatory filings.
- Presents issues and results at department and project team meetings. Presents at external meetings or publishes in peer-reviewed journals.

Education and Experience:

- PhD in Analytical Chemistry, Biochemistry, Chemistry, Pharmaceutical Science or related field with a minimum of 3 years relevant Postdoctoral or industry experience in product and process development (*preferred*), or
- MS in Analytical Chemistry, Chemistry, Biochemistry and pharmaceutical or related discipline with a minimum of 6 years relevant industry experience in product and process development, or
- BS in Analytical Chemistry, Chemistry, Biochemistry and pharmaceutical or related discipline with a minimum of 10 years relevant industry experience
- Primary technical expertise should be in protein mass spectrometry. Technical experience in multiple analytical technologies is highly desirable. Knowledge of theories, concepts, principles and techniques of relevant scientific areas is also highly desired.
- Excellent communication, interpersonal and organizational skills. Proficient with standard computer applications, including software for MS data analysis. Proactive at keeping current with literature and latest technologies. Ability to work well both independently and in a team environment. Ability to prioritize work and multitask. Conducts work in compliance with cGMPs, safety and regulatory requirements.

To immediate consideration, please apply using this link:

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