Associate Director, 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 lead 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 activities to bring agile resolution to a variety of problems of moderate scope and complexity to support company products in alignment with organizational objectives. Supervises a group of scientist with varying backgrounds. Provides mentoring to junior team members and contributes to setting objectives and group priorities.
- Demonstrates strategic leadership in study design and selection of state-of-the-art technologies to solve a variety of problems related to protein structural characterization.
- Designs and leads studies to troubleshoot issues encountered during process development work, and assists in investigations for issues encountered in manufacturing.
- Designs and leads structure-function studies to identify CQAs in the biologics pipeline in order to support a logical analytical control strategy under QbD

- 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.

Qualifications:

- Analytical science, cGMP compliance, regulatory requirements for characterization
- Essential qualities:
    - Leadership of teams of scientists with proven track-record of delivering timely results
    - Development of team members to individual contributors with an exceptional commitment to science
    - Direct experience characterization of biologics (LCMS, electrophoresis, higher order structure) and interpretation skills of other techniques such as NMR, electron microscopy, AUC and biophysical techniques
    - Strong knowledge of ICH and other regulatory guidelines and QbD for analytics
    - Knowledge and experience with product development
    - Experience in reviewing analytical-related CMC sections of IND/IMPD and BLA/MAA regulatory submissions
- Preferred qualities:
    - Knowledge and experience with statistical applications for data evaluation
    - Knowledgeable in European, Japanese, Chinese and US CMC regulatory requirements for Biologics
    - Experience with EMA / FDA /PDMA inspections and compliance experience
    - Publications in peer reviewed journals in the field of characterization of biologics
- Deep and broad knowledge of analytical chemistry of biologics in characterization of complex biomolecules using state-of the art technology from internal sources completed with information/data from external partners to enable strong in-vitro comparability packages and minimize the need for in-vivo (animal or human) data for process scale-up, transfer, etc.
- Exceptional problem solving and troubleshooting skills related to characterization methods
- Proven ability to work efficiently and effectively as a leader of scientists
- Strong verbal, presentation, and written communication skills. Can concisely articulate and deliver effective presentations on complex technical issues to non-technical audience.
- Skills in optimizing and challenging the status quo to reach better results
- Ability to create collaborative and trusting relationships internally and with external partners.
- Requires strong organisational skills and attention to detail for composing and proofing materials, scheduling, establishing priorities, and meeting deadlines.
- Ability to work effectively with Analytical Product owners, Regulatory CMC leads and all other relevant stakeholders
- Other professional competencies include: building authentic relationship, global and cross-boundary communication, excellence in execution, courage to challenge, inspiring and motivating others.

Education and Experience:

PhD in Biochemistry, Chemistry, Biology or related field

Recognized biologics characterization expert with leadership experience of >5 years in industry by leading senior scientific experts, proven successful regulatory agency interaction experience

To immediate consideration, please apply using this link:

https://jobs.brassring.com/1033/ASP/TG/cim_jobdetail.asp?partnerid=25300&siteid=5445&Areq=14890BR