Analytical Development Scientist / Scientist I

SUMMARY

Bolt Biotherapeutics has an exciting opportunity for a highly motivated scientist to join our drug development team and play a key role in developing new targeted therapeutics for cancer. The candidate will work closely with other scientists with diverse scientific expertise at a new biotechnology company currently located in Redwood City, CA.

RESPONSIBILITIES

This position, reporting to the Head of Analytical Development, Quality Control & Formulations, will be a key contributor in Bolt's Analytical Development, Quality Control & Formulation Group for activities that are performed either internally or contracted externally to CMO's or CTO's. The candidate's responsibilities include the development and implementation of biochemical/biophysical characterization methods. QC method development & implementation, and stability profiling of the Bolt's antibody-based protein drug candidates, with an emphasis on LC/MS methods.

JOB DUTIES

Analytical Development and Characterization

- Development, optimization, and troubleshooting of biochemical and biophysical analytical methods for characterization, including spectroscopy, LCMS, U/HPLC, and gel/capillary electrophoresis.
- LC/MS characterization of Bolt products to elucidate structure:
  - Conjugation sites and distribution
  - Post -translational modifications
  - Primary sequence, glycan profiling, disulfide mapping, intact mass, etc.
- Characterization of Bolt products to support regulatory filings, including CRO-outsourcing of specialized characterization methods including FTIR, NMR, CD, etc.
- Maintenance and troubleshooting of ADQC equipment
- Summarize experimental data and author technical reports
- Participation in method transfer and troubleshooting
- Process Development & Research support

Other

- Effectively summarize and present results at internal meetings
- Liaise with senior management and external partners in technology evaluation and co-development opportunities
- Assist in managing CROs, CTOs, CMOs and external partners
- Author portions of CMC Regulatory Sections
- Manage activities to time lines
- Other duties as assigned

JOB REQUIREMENTS

Required

- BA/ BS, MS, and/or Ph.D. in analytical chemistry, biochemistry, biotechnology, chemistry, or related field
- At least 10 years of relevant CMC experiences (BA/BS), 8 years (MA/MS), 2 years (Ph.D.)
- Experience in LC/MS analysis of proteins
- Experience in characterization of Antibody Drug Conjugates
- Experience in HPLC separation methods such as ion-exchange, reversed phase, HILIC and size exclusion chromatography highly desired
- In-depth knowledge and hands-on experience in analytical method development and characterization of monoclonal antibodies and antibody drug conjugates
- Ability to clearly communicate scientific information, both written and oral

- Ability to demonstrate potential for technical proficiency, scientific creativity, collaboration with others, and independent thought
- Familiarity with ICH guidelines on analytical method transfer, validation and stability
- Familiarity with pharmacopeia (USP, EP, JP) methodology
- Experience with Word, Excel, Power point

WORKING CONDITIONS/PHYSICAL DEMANDS

This is a research position that requires working in a laboratory environment with hazardous chemicals. Protective clothing, gloves and safety glasses are required while working in the lab. Requires the ability to lift containers or instruments (up to 25 pounds) and work standing at a fume hood or lab bench for extended periods.

TRAVEL REQUIREMENTS

Limited travel may be required, including domestic and international (5 - 10%)