Quality Control Manager

Summary:

This newly created position will work with contract manufacturing organizations (CMOs) to ensure that appropriate quality standards are met during production and prior to the release of our products. This position will collaborate closely with cross-functional within CMC and Quality department. The successful candidate will be a self-starter with the ability to work under limited supervision, and who is seeking to be part of an innovative team.

Responsibilities:

Reporting to the Director, Quality Control, responsibilities include, but are not limited to:

- Manage the development and validation of analytical test methods for intermediates, drug substance and drug product in accordance with ICH/FDA/USP/Ph. Eur. Guidelines
- Author, update, and revise CMC regulatory filing sections to support regulatory filings
- Manage the generation, execution and technical review of analytical data, laboratory documents, method validation protocols, method validation summary reports, and method development reports
- Ensure compliance with current GMP's in a manufacturing environment such that the products are assessed to agreed-upon specifications in a timely manner in order to support in-process, lot release and stability testing
- Implement and maintain a GMP compliant stability program including protocol writing, stability planning and set-up, stability sample inventory and distribution for testing, stability report writing, and stability data trending
- Manage stability studies executed at CMOs
- Champion, lead and participate in continuous improvement activities for the quality control operations.

Qualifications:

- BS (with at least 5 years of experience) or MS (with at least 3 years of experience) in Immunology, Molecular Biology, Biochemistry or related discipline.
- Experienced in executing analytical and chemistry test method validations.
- Experienced in protein and small molecule chemistry methods, including reverse phase and size exclusion chromatography, UV-Vis spectroscopy, SDS-PAGE, HIC, cell based assay, and ELISA. Experience in QC stability testing and regulatory/pharmacopeia requirements.
- Excellent oral and written communication skills, auditing skills, and proven ability to work autonomously and manage effectively in a matrix environment.
- Familiar with MS Office and statistical analysis software.
- High attention to detail, excellent organizational skills and the ability to work on multiple projects with tight deadlines.

Who We Are:

Bolt Biotherapeutics, based in the San Francisco Bay Area, is a clinical-stage biotechnology company developing Boltbody™ Immune-stimulating Antibody Conjugates (ISACs), a new class of immuno-oncology therapeutics that have eliminated tumors following systemic administration in preclinical studies while also developing immunological memory, which may lead to more durable clinical responses for patients. This is a unique opportunity to join and build, with like-minded colleagues, a company that will transform the lives of individuals with cancers.

We are an Equal Opportunity Employer offering a competitive salary and benefits package. Applicants should be legally entitled to work for any employer in the US. Note to Employment Agencies: Please do not forward any agency resumes. The company will not be responsible for any fees related to resumes that are unsolicited.