Head of Quality

The Position:
Bolt Biotherapeutics has an exciting opportunity for an experienced Quality leader to lead and grow Bolt's Quality organization. You will be responsible for developing and executing quality and compliance programs in support of our expanding pipeline of novel biotherapeutic agents. As Director, this role is expected to effectively lead and guide a team of Quality staff and partner with cross-functional teams to ensure that activities are conducted in compliance with regulatory requirements and established internal procedures.

Specific responsibilities include but may not be limited to:

- Promote Quality throughout the company and execute Quality roadmap.
- Direct a wide variety of activities to ensure compliance with Quality systems, Quality procedures, Quality policies and applicable regulatory requirements to facilitate compliance with regulatory agencies and business requirements.
- Phase appropriate Quality oversight in alignment with regulatory GMP expectations and established Quality Agreements.
- Effectively communicate strategy, methodology, progress, and challenges to stakeholders and partners, including senior executives.
- Responsible for supervision of designated staff to ensure effective execution of roles and responsibilities; overseeing professional development, and conducting performance reviews
- Directs compliance audits as required.
- Reviews and approves regulatory submissions.
- Interfaces with regulatory agencies as required representing the company to authorities and regulatory inspectorates.
- Reviews, approves, and directs implementation of changes to controlled documents and processes (e.g., SOPs, Specifications, Methods, etc.) as needed.
- Represents company as host of regulatory GMP inspections at applicable contract sites and supports inspections at CMO facilities.

Job Requirements include:

- Bachelor's degree in science and 12+ years of relevant experience in pharmaceutical/biotechnology Quality.
- In-depth knowledge of quality systems and how quality systems are designed and operated to satisfy regulatory requirements in commercial GMP operations.
- Excellent working knowledge of cGMP requirements, FDA /EMA regulations and ICH guidelines.
- Understanding of regulated biotechnology processing.
- Excellent written and oral communication skills and the ability to proactively prioritize and accomplish multiple tasks simultaneously.
- Strong analytical and problem-solving skills.
- Ability to work independently, and cross-functionally, and develop/maintain strong partner relationships both, internal and externally.
- Ability to influence teams and to balance scientific judgment and compliance to cGMP when a risk-based approach is appropriate.
- Limited travel may be required, including domestic and international (5 - 10%)

Who We Are:

Bolt Biotherapeutics, based in the San Francisco Bay Area, is a publicly traded 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.