Specialist II/Sr. Specialist, Manufacturing Quality Assurance

Summary:

Bolt is seeking a Manufacturing QA Specialist to help support our growing Quality Assurance organization. This position is responsible and accountable for ensuring Bolt Biotherapeutic's Quality Management System (QMS) is in compliance against applicable GxP regulations, guidance, industry standards, best practices or laws. This entails GxP Quality activities that are performed either internally or outsourced externally to contract manufacturing and testing facilities. These activities include but are not limited to providing Quality oversight of Bolt GxP Contract Organizations (CO), QMS execution to fulfill Sponsor responsibilities, audit management, batch record review, lot release, change controls, deviation/CAPA, and reporting of Quality performance metrics to Quality Management.

This position may also perform review of quality documentation including regulatory submissions, technical reports, source data verification and represent the company on Quality compliance related issues.

Responsibilities:

Oversight, tracking and follow-up of all activities relating to Bolt's Vendor Management program including but not limited to:

Contract Organization Oversight: Perform Quality oversight of COs by attending routine internal and external meetings, CO document review/approval and following up on Quality issues. Representing the Bolt QA organization according to Bolt policies and standards. Conducting Person-in-plant (PIP) support at Manufacturing & Testing contract organizations, as needed.

Quality Management System: Maintain compliance to Bolt QMS and support development of system, such as standard operating procedures (SOP), Forms, Work Instructions and Templates, as appropriate. Provide support on performing Computer Software Assurance/Computer System Validation efforts and implementation of GxP computerized systems, as needed.

Audits: Supports the Audit program by facilitating the audit schedule, agenda, reports, response, follow-up and close out letters are completed within the target due dates. Works with Lead Auditors and vendors to ensure compliance to target due dates. Participate in internal and/or external audits, as necessary.

Vendor Qualification and Management: Conducts vendor qualification, re-qualification and vendor management activities per procedures and Quality Agreements.

Quality Agreement Management: Supports development, review and approval of all Quality Agreements. Facilitates both internal and external parties to amend, review, and approve revisions. This includes compliance to Quality Agreements.

Deviations:

- Leads, reviews and/or initiates internal and external CO Quality deviations or investigations related to manufacturing, testing, storage or shipping GMP materials according to SOP.
- Facilitate Root Cause Analysis activities with the use of problem-solving tools and templates (e.g., cause & effect, SIPOC, fault tree analysis and 5/6 Why's) to determine underlying root cause of failure.
- Review, tracks and confirms all Bolt and external vendor deviations, communication requirements, and action items are completed in a timely manner.
- Follows up with appropriate cross-functional team members and multi-site vendors to confirm acceptable review, approval and closure of each deviation.

OOS, OOT Tracking and Trending: Collaborate with QC to support review, manage and track OOS Events, Investigations, OOT and Trending Metrics.

Change Controls: Initiation, review, approval and closure of Change Controls and pre/post-implementation actions with multi-disciplinary functions according to SOP. Review and approve CO change control requests, such as batch record, analytical test method and material specification revisions.

CAPAs: Initiates, reviews, approves and monitors closure of all Bolt and vendor CAPAs and implementation actions are on track with appropriate staff members per SOP.

Batch Record Review and Lot Disposition: Review, organize and archive contract organization batch production records, supplemental data, and lot release documentation, such as Certificate of Analysis, Certificate of Compliance, TSE certificates, etc. In addition, responsible to resolve lot flags, such as open deviations or change controls, complete or collect batch record Manufacturing and QC data review checklists and conduct final lot disposition.

Stability Data: May provide support in data review of stability study data, as applicable.

Product Complaints and Clinical Stock Recovery: Tracks and confirms all product or customer complaints and clinical stock recoveries are on track for completion and follows up with appropriate staff members to confirm closure of each complaint and stock recovery. May assist in obtaining deliverables to close complaints and stock recovery.

Quality Risk Management:

- Facilitate, develop or review quality risk assessments (e.g., FMEA, Fault Tree Analysis, DMAIC, Quality Risk Logs), gap analyses, audit/inspection readiness assessments, as necessary.
- Facilitate or participate in the identification and implementation of continuous improvement initiatives, such as addressing compliance gaps, system, and process improvements.

Compliance Performance Metrics and Management Review

Support identification and design of Sr. Management Compliance metric reports, including maintenance of Quality data utilizing data analysis and trending tools, as applicable.

Regulatory Submissions

Provide authors of regulatory submissions applicable documents or summaries to support drafting the submission including audit information, changes controls, deviations, vendor facility information, process and method changes that may impact the submission. Perform Quality

review, organization and archiving of critical documentation including regulatory submissions, technical protocols/reports, studies, methods, and raw data verification.

Qualifications

- BA, BS, and/or MS in analytical chemistry, biochemistry, biotechnology or chemistry with a minimum of 5-7 years of industry experience preferred.
- Experience with Word, Excel, PowerPoint
- Familiarity and experience with cGMP / GLP / GDP, (e.g., 21CFR, ICH, WHO, ISO, Parts 210, 211 and 11, EU Eudralex Annexes)
- Good technical writing skills and detail oriented
- Excellent communication, organizational and collaboration skills
- Independent with excellent prioritization skills
- Experience with Quality Management Systems highly desirable
- Experience managing Contract Organizations highly desirable
- Root Cause Analysis, Investigator and/or Operational Excellence (e.g., Six Sigma, Kaizen qualification) skills highly desirable
- Some travel may be required, including domestic and international (10-20%)

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.