Quality Assurance Associate or Specialist II/III

Job description

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 managing the GxP QMS, document management, audits, batch record review, change controls, deviations, CAPA, training and reporting of appropriate metrics to Quality Management.

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

Responsibilities

Responsible for the oversight, tracking and follow up of all activities relating to Bolt's Quality Management System including but not limited to:

Quality Systems: Generation and management of SOPs, Forms, Work Instructions, Templates and Quality Management System.

Document Control and Management: Indexes and organizes all GxP and developmental documents. Assigning unique document numbers and managing controlled document distribution.

Audits (GxP audits): Tracks and confirms audit schedule, agenda, reports, response, follow-up and close out letters are completed within the target due dates. Works with Lead Auditor to ensure compliance to due dates in regards to audit schedule, agenda, reports, responses and follow up. Participate in internal and/or external audits as necessary.

Quality Agreement Management (QAA): Tracks and confirms all Quality Agreements are in place and effective. Works with applicable staff to update, amend, and review revisions to QAA.

Batch Records: May provide support in the review, organization, and archival of contract manufacturing batch production records, bill of materials, line clearance forms, and supplemental data.

Stability Data: May provide support in data review, organization, and archival of stability study data.

Deviations: Tracks and confirms all Bolt and vendor deviations are completed in a timely manner. Follows up with appropriate staff members to confirm closure of each deviation. May assist in the review and/or verification of deliverables to close deviations.

Change Controls: Tracks and confirms all commitments defined in the related change controls are on track and follows up with appropriate staff members to confirm closure of each task. May assist in the review of deliverables to close change controls.

CAPAs: Tracks and confirms all Bolt and vendor CAPAs are on track and follows up with appropriate staff members to confirm closure of each CAPA. May assist in the review and/or verification of deliverables to close CAPA records.

OOS, OOT Tracking and Trending: Work with QC and QA to help manage and track OOS Events, Investigations, OOT and Trending Metrics.

Complaints and Clinical Stock Recovery: Tracks and confirms all 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.

Training

Tracks and confirms that all GxP staff is trained on applicable procedures and manages annual training. Works with GxP trainer to schedule training, develop training scope and organization of training.

Metrics and Management Review

Generates Quality metric reports and maintains trend data. Tracks and confirms all commitments and action items from Quality Management Reviews are completed on time. Works with appropriate staff members as needed to close out commitments and action items.

Regulatory Submissions

Provide authors/owners of regulatory submissions applicable documents or summaries to support drafting the submission including changes controls, deviations, and QAA changes that might impact the submission. Perform review, organization and archiving of quality documentation including regulatory submissions, technical protocols/reports and source data verification.

Other tasks as assigned accordingly.

Job Requirements

- 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, Power point
- Familiarity and experience with cGMP / GLP / GDP / GCP, (e.g. CFR, ICH, WHO, ISO, Part 11, EU Annexes)
- Good technical writing skills and detail oriented
- Excellent communication, organizational and collaboration skills
- Independent with excellent prioritization skills
- Experience with IND, IMPD and BLA filings desirable
- Experience managing CMO/CRO's desirable
- Some travel may be required, including domestic and international (10-20%)