



Associate Director, Drug Safety

SUMMARY

Bolt Biotherapeutics, a dynamic biotechnology company located in Redwood City, CA. is recruiting for an Associate Director, Drug Safety. The ideal candidate will work closely with the head of Clinical Operations and Clinical Development team to ensure appropriate and timely execution of pharmacovigilance activities in support of Bolt Biotherapeutics clinical development efforts. The successful candidate will be responsible to ensure the highest quality oversight and reporting of drug safety for Bolt clinical candidates.

Responsibilities:

- Develops and implements (insourced and/or outsourced, as applicable) pharmacovigilance systems fully compliant with the applicable worldwide Health Authority PV regulations.
- Leads in the daily management and execution of Drug Safety and Pharmacovigilance operations.
- Develops and implements specific workflows and reporting/querying functionalities to support Bolt Clinical Development needs.
- Manages vendors and business partners. Provides vendor oversight and management for all outsourced or insourced PV activities, including establishing and monitoring key quality and compliance metrics.
- Monitors compliance with regulations, PV agreements and internal SOPs.
- Represents Drug Safety and Pharmacovigilance on Clinical Development teams, as assigned.
- Participate in clinical trial activities (i.e., protocol & CRF reviews, data management plan reviews, CRO agreements & flows)
- Provides sponsor oversight of SAE processing by outsourced vendors, including the review and monitoring of compliance through various monitoring reports and other oversight activities and ensures the implementation of effective corrective and preventative action plans.
- Review MedDRA and WHO Drug coding as needed
- Review case narratives as needed
- Oversees case triage
- Provides Drug Safety support for external submissions, signal detection and risk management planning activities.
- Oversees or contributes to the preparation of periodic safety reports (e.g., DSUR, PSUR)



- Ensures compliant exchange of safety data between Bolt Biotherapeutics and its partners, as applicable.
- Participates in the quality management system in Drug Safety including ensuring department standards are met, including training requirements, monitoring performance, implementing continuous improvement actions and good documentation practices.
- Works with QA department to maintain a state of high PV inspection-readiness across all regions/countries.
- Identifies and collaborates with contract service providers for case processing, aggregate reporting and quality management activities.
- Performance management of PV systems.
- Participates in regulatory inspections and company audits including MHRA/EMA PV inspections as applicable; prepares responses to audit findings that concern Drug Safety and Pharmacovigilance.

Requirements:

- Bachelor's degree in nursing, pharmacy, or other health care related profession or life sciences preferred.
- Master's or Doctorate level degree in health care related profession preferred, but not essential
- Minimum of 8 years of experience in drug safety/Pharmacovigilance in a pharmaceutical industry setting or the equivalent.
- Experience working with CROs, vendors, and relationship management.
- Global pharmacovigilance operations experience with products in development.
- Safety database, MedDRA coding and data entry experience.
- Excellent knowledge of FDA and EU legislation and ICH Efficacy guidelines.
- Strong analytical and problem-solving skills with superb attention to detail.
- Strong verbal, written technical communication and presentation skills.
- Must work effectively/collaboratively in a fast-paced team environment and with individuals at all levels within an organization.
- Proven ability to work within a cross-functional, matrixed team.

COMPANY BENEFITS

We offer competitive salary, incentive compensation, excellent benefits (Health/Vision/Dental Insurance, 401k, flexible spending account, paid vacation and sick leave), employee stock option plan, opportunity for growth within this dynamic and fast-growing organization.

Bolt is an Equal Opportunity Employee.