



Manager/Sr. Manager, Biosample Operations

SUMMARY

Bolt Biotherapeutics, a dynamic biotechnology company located in Redwood City, CA. is recruiting for a Manager/Sr. Manager, Biosample Operations, to manage the lifecycle of all clinical specimens in Bolt's clinical development portfolio. The ideal candidate will possess demonstrated success at ensuring clinical samples are collected, processed, and stored with the highest degree of quality.

Responsibilities:

- Accountable for planning, organizing and overseeing the collection and shipping of samples from investigator sites or Central Labs and their subsequent delivery to assay laboratories to ensure clinical protocol compliance, timely delivery and optimal quality
- Maintain oversight of all study sample operational activities and regularly report on status, including sample collection and reconciling against consent
- Manage relationships with laboratory vendors, including forecasting and tracking of study costs associated with sample management
- Review protocol and Informed consent form to ensure feasibility of biological sampling and alignment with ICH/GCP and sample testing plans
- Review laboratory manuals and laboratory specification materials to ensure accuracy and consistency with the study protocol and clinical needs
- Participate in CRF development to ensure laboratory sample information is collected for sample tracking and reconciliation purposes
- Lead the identification, contracting and ongoing management of central labs and biostorage repositories, including conducting RFP exercise for new vendors and managing scopes of work for ongoing vendors
- With input from Clinical and Translational stakeholders, develop study-specific sample management plans to document cross-functional agreements on the lifecycle and reconciliation plan for each sample type
- Facilitate sample shipments and query resolution among vendors to ensure timely data delivery
- Oversees biomarker analysis timelines, budget, risk and quality
- Support sample analysis data transfer, data reconciliation, and data review
- Maintain professional knowledge of current GCP, biobanking, and sample management best practices and ethical guidelines and apply knowledge appropriately

Requirements:

- Bachelor's, or equivalent, degree in a scientific discipline.
- Master's or Doctorate level degree in a scientific discipline preferred, but not essential



- Demonstrated understanding of pharmaceutical regulatory requirements, both US and abroad
- Demonstrated knowledge of ICH and GCP
- Effective team player and ability to collaborate with cross functional clinical study teams
- Ability to manage lab vendors and oversee sample management activities across multiple clinical trials
- Demonstrated ability to work independently to manage complex projects with multiple priorities in a fast paced, team-based environment
- Excellent written and interpersonal communication skills necessary to interface with vendors and team members
- Direct experience in managing sample operations of various sample types
- Experience with vendor and CRO management
- Proficient with sample data reporting, managing metrics and understanding the overall quality and stability of study samples
- Proven critical reasoning skills including the identification and resolution of complex problems
- Able to travel 10%-20%

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 Employer.

APPLY:

Send a cover letter and resume to hr@boltbio.com