Sr. Scientist I/II, Downstream Process Development

The Position:

The success candidate will join Bolt CMC team as downstream process development (DSP) functional lead., shall have responsibility for leading downstream process development and technical transfer for manufacturing recombinant proteins. The individual will oversee the DSP activities at the external CDMO, author CMC regulatory submissions, and in-house operations to support Bolt's development pipeline. The position will report to the Associate Director (Process Development & Manufacturing).

About You

You will be responsible for development of purification and UF/DF processes that are scalable, robust and transferable to GMP manufacturing operation for the production of high-quality protein therapeutics for human clinical use, performing gap and risk analysis, as required. You will author and/or review/approve of manufacturing master batch records, and standard operating procedures, process specifications and in-process testing plans. You will lead, review and/or approve investigations/troubleshooting and closure of OOS/OOT, deviations and excursions, and CAPA with QA. You will need to independently author, review and approve portions of the CMC Regulatory sections (IND, BLA, etc). You will manage activities including project timeline and budget (personnel, equipment, etc) and laboratory.

Job Requirement includes:

- Educational degrees in chemical engineering, bioengineering, biology, biochemistry or related area
- Ph.D. with 6+ years, MS with 10+ years, BS with 15+ years of direct experience in DSP Operations
- Extensive hands-on experiences in purification at various industrial scales, operational is required.
- Thorough knowledge of protein downstream process techniques including chromatography, filtration, centrifugation, and In-process analysis
- Scale down/up experiences and development using QbD
- Extensive experience in antibody and/or antibody conjugate process development
- Experience with cGMP regulation & guidance and working in a GMP environment
- Excellent communication, technical writing, organizational and collaboration skills; good decision-making risk-assessment, and leadership
- Experience with regulatory filings required
- Experience managing CMO/CRO's required
- Experience with management or building of a developmental laboratory desirable
- Proficient with the use of MS Office software and DSP application and DOE software

Who We Are:

Bolt Biotherapeutics, based in the San Francisco Bay Area, is a private 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. Applicants should be legally entitled to work for any employer in the US. Note to Employment Agencies: Please do not forward any agency resumes. The company will not be responsible for any fees related to resumes that are unsolicited.