Bioconjugation Process Development Lead: Sr. Scientist/Principal Scientist

The Position:

This newly created position will serve as the lead of bioconjugation process development for the CMC team and shall have responsibility for leading bioconjugation process development and technical transfer for manufacturing recombinant proteins. This individual will oversee the bioconjugation 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 Director, Process Development & Manufacturing.

About You

You will be responsible for leading the development of bioconjugation, 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 Requirements include:

- Educational degrees in chemical engineering, bioengineering, biology, biochemistry or related area
- Ph.D. with 10+ years, or MS with 15+ years, BS with 18+ years of direct experience in bioconjugation
- Extensive hands-on experiences in bioconjugation at various industrial scales, operational is required.
- Thorough knowledge of protein bioconjugation process techniques including reaction kinetics, filtration, UF/DF and In-process analysis
- Scale down/up experiences and development using QbD
- Extensive experience in antibody and/or antibody purification 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 (IND, BLA etc) 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 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