



Senior Director, Drug Substance Manufacturing

ARMO is seeking a Senior Director, Drug Substance Manufacturing who will be a primary technical liaison for the manufacturing of ARMO's recombinant protein biologic products at Contract Manufacturing Organizations (CMOs). This position will have primary responsibility for managing CMO activities including process development, improvements, technology transfers, scale up and clinical manufacturing of drug substance.

Responsibilities and Job Functions

- Manage relationship with Drug Substances CMO's, including coordination, communication, and technical oversight, to ensure timely delivery of quality GMP products to support clinical trials
- Serve as primary point of contact to the CMOs to support batch manufacture, deviation investigation, batch review and release
- Collaborate with CMO in developing project plans and schedules and ensure the tasks are executed accordingly to the agreement, cGMP requirements and regulatory commitments
- Leads manufacturing development, technology transfer and scale-up of process improvements as required at the CMOs
- Support Person-in-Plant and provide oversight at ARMO's clinical manufacturing CMO's
- Participates in preparation, review and approval of CMC sections of regulatory filings
- Will provide technical recommendations for evaluating process data, trouble-shooting and root cause analysis as well as providing strategic recommendations leading to improved economics and process robustness
- Support development and subsequent manufacturing drug substance from cell line development through upstream and downstream processing
- Management of CMOs is a critical aspect of the job and will include frequent visits to contractors depending on the intensity of ongoing activities
- The ideal candidate will be a self-motivated with a "can do" attitude and be a proven contributor with ability to interact effectively at all levels

Knowledge, Experience and Skills

- MSc or PhD in Chemical/Biochemical Engineering, Biochemistry, Chemistry or Biology with a minimum of 12 years in the bio/pharmaceutical Manufacturing environment
- Proven success in CMO management with late stage clinical (Phase 3) clinical products
- Technical expertise in development of both microbial and mammalian produced biologic products.
- Proven success in phase 3 scale up, validation and BLA filing
- Demonstrated ability to function in a collaborative/team oriented CMC environment.
- Strong project leadership and resource management skills.
- Require excellent written/oral communication skills

**How to Apply**

If you are interested in applying, please submit your resume with Senior Director, Drug Substance Manufacturing in the subject line to careers@armobio.com

About

Being a member of the ARMO BioSciences team is a unique opportunity to make a difference in the life of patients suffering of grievous diseases. We demonstrate a strong sense of personal ownership in everything we do and as such expect honesty, integrity, passion and scientific excellence from our employees. ARMO BioSciences is an equal opportunity employer. We are committed to building a workforce that respects individual skills and diversity and commitment to teamwork. We hire outstanding people and subscribe to a rigorous, fast-paced work ethic where the science leads the business.