Associate Director, Quality Control

ARMO is seeking an Associate Director, Quality Control who will be responsible for method transfer, validation and overseeing Quality Control activities at CMO and CRO's. The successful candidate will have documented success in process and product analysis supporting biologics manufacturing development from Phase 1 thru commercialization.

Responsibilities and Job Functions

- Responsible for ensuring that all drug substances and drug products are manufactured and analyzed in accordance with ARMO's specifications, in compliance with cGMP and consistent with applicable regulatory filings
- Provide technical expertise for product and process analysis necessary to meet technical and regulatory requirements including development of physical, chemical and biological methods for characterization of biologic products both internally and externally.
- Provide technical expertise necessary for development, review and approval of analytical methods, stability protocols, validation studies and method transfer.
- Responsible for timely review QC test data for release and stability data for drug substance, drug product and clinical trial supplies
- Develop data-based justification for, in-process, drug substance and drug product specifications, and methods for intermediates, drug substances and drug products release testing
- Conduct risk and gap analyses of existing method and processes
- Supports quality investigations at contract manufacturers to ensure that all critical and major quality issues associated with QC analysis are thoroughly investigated with appropriate corrective actions
- Responsible for management of ARMO's stability program including trend analysis

Knowledge, Experience and Skills

- Degree in biochemistry/analytical chemistry or related discipline
- 8-10-year demonstrated expertise in bio-pharmaceutical industry with 5 years minimum QC management experience.
- CRO based analytical development and CMO based QC management experience.
- Expert knowledge of FDA and ICH quality regulations with respect to drug development; combination devices, nonclinical and CMC

How to Apply

If you are interested in applying, please submit your resume with Associate Director, Quality Control 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.