Job Title: Director, Analytical Development and Quality Control

ARMO is seeking a Director of Analytical Development and Quality Control responsible for method development, 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

- Develop and implement strategy and provide management leadership for analytical activities related to the development, manufacturing and release of ARMO products
- 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 and validation studies
- Responsible for timely review QC test data for release of 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
- Review and approve IQ/OQ/PQ and validation protocols, tech transfers and reports, as applicable, for all manufacturing, testing, and packaging activities at all CMO's
- Responsible for management of ARMO's stability program
- Build the ARMO analytical function, with requisite budget and resources to support company's eventual product commercialization

Position Requirements

- PhD in biochemistry/analytical chemistry
- 10-15-year demonstrated expertise in bio-analytical development 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

If you are interested in applying for this position, please submit your resume/CV to careers@armobio.com