Job Title: Director, Quality Assurance CMC

ARMO is seeking a Director of Quality Assurance to develop, implement, and maintain the company's CMC quality assurance program to ensure regulatory compliance of all internal GMP functions and external GMP vendors (CMOs, CROs). The successful candidate will have experience in biologics manufacturing as well as design and document control pertinent to successful introduction of drug-device combination products such as syringe injection devices.

Responsibilities and Job Functions

- Develop and implement company Quality Systems to ensure compliance with cGXPs and US & EMA regulations, including design control, document control, change control, nonconforming product, manufacturing and production, and CAPA.
- Provide Quality oversight to all cGMP activities, including Drug Substance and Drug product manufacturing, secondary packaging and assembly, and clinical packaging operations
- Manage and support all quality activities related to the manufacturing and release of clinical product including resolution of investigations and quality issues
- Responsible for ensuring that all drug substances and drug products are manufactured in accordance with ARMO's specifications, in compliance with cGMP and consistent with applicable regulatory filings
- Responsible for timely review and release/disposition drug substance, drug product and clinical trial supplies.
- Provide quality oversight, review and approve analytical, manufacturing, stability and validation documents including batch records, protocols, procedures, methods. data and final reports
- Approve and issue specifications, and methods for drug substances and products
- Conduct risk and gap analyses of existing systems and processes
- Oversee qualification, performance tracking, and reviews of contract manufacturers, suppliers and laboratories and manage internal and external audits.
- Manages quality investigations at contract manufacturers to ensure that all critical and major quality issues 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
- Maintain Quality Agreements, and all quality associated documentation files, databases, and logs
- Build the ARMO quality function, with requisite budget and resources to support company's eventual product commercialization

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