## Job title: Vice President, Clinical Development

ARMO BioSciences is seeking a Vice President of Clinical Development to oversee global development programs from late preclinical to registration Phase 3 randomized studies and completion of post-approval commitments within the immuno-oncology therapeutic area.

## Responsibilities and Job Functions

- Responsible for immuno-oncology clinical development programs from late preclinical to registration and completion of post-approval commitments
- Responsible for development of clinical protocols to support the company's product drug candidates, strategy, data collection and management and final reports development in compliance with appropriate standard operating procedures, regulatory and good clinical practice standards
- Responsible for clinical trial execution including, data analysis and reporting to prepare documentation required for regulatory and legislative drug approvals
- Ensure adherence to regulatory requirements of study conduct and industry standards of Good Clinical Practice
- Provide ongoing medical monitoring for clinical trials, including assessment of eligibility criteria, toxicity management, and drug safety surveillance
- Engage thought leaders, investigators, cooperative groups and other experts in constructive scientific and clinical dialog around study design, study conduct, and interpretation of clinical results
- Manage the preparation and/or review of data listings, summary tables, study results, study reports, and regulatory documents, IND annual reports, IND safety reports, investigator brochures, and clinical development plans
- Coordinate the collection and analysis of clinical data, develop manuscripts for publication in peer-reviewed journals and prepare presentations for scientific conferences as well as for clinical study investigator meetings and expert clinical advisory meetings
- Interact with global regulatory agencies and responsible for authoring and/or reviewing relevant IND/BLA sections and generating responses as well as regulatory designation applications such as Breakthrough Therapy, orphan drug, Fast Track and Priority Review
- Work collaboratively to evaluate business development opportunities
- Assist with identifying opportunities to patent data findings to build the IP for the company
- Ability to travel domestically and internationally to company, scientific, regulatory, investigator, and other meetings

## Knowledge, Experience and Skills

- An MD with Board Certification in Oncology or Hematology, preferably with experience in immunology
- Minimum of 10 years of relevant experience in drug development of small molecules, antibodies, cancer vaccines in pharmaceutical or biotechnology company
- Demonstrated experience leading the successful development of complex drug therapies on time, on budget, and with quality assurance and regulatory compliance

- A proven success record in oncology clinical research studies and trial design as well as the successful submission of IND's. Submission of marketing approval-directed filing(s) (BLA's, NDA's, and MAA's) is preferred
- Thorough knowledge of clinical research concepts, practices, and GCP and ICH Guidelines
- Strong scientific background in oncology and immunology
- Experience in translational medicine, clinical pharmacology, and biostatistics

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