

Company: Pfizer

Job Title: Associate Director, Medical Monitor, Vaccines (MD or DO Required) Pharma experience not required.

Job Location: Possibly Remote - Company locations include Pearl River, NY & Collegeville, PA (NOTE: Other North America sites would be considered for the right person. Role is currently remote. Contact: Global Source & Search Consultants, Inc. (Retained Executive Search Company)

Website: www.gblsearch.com

Email resume submission to: info@gblsearch.com

ROLE SUMMARY The clinician medical monitor may contribute towards providing medical and scientific expertise and oversight for Clinical Trials. The clinician medical monitor may be required to design a development strategy for multiple protocols designed to obtain worldwide approval for a compound or group of compounds.

ROLE RESPONSIBILITIES Accountable for safety across the study: o Provide study team with medical advice for all medical issues during risk assessment and mitigation planning to enable quality, compliance and patient safety at the trial, site and patient level. Additional Protocol design and strategy information available. Contact us for full details. o Contributes towards the medical input during protocol development and updates to the clinical development plan.

- Work closely with other medical monitors to ensure that documents (protocol, Informed Consent Document [ICD], etc.) meet regulatory requirements and company policy and has been reviewed by IRB/IECs.
- Provides medical input into country feasibility. Support study team. With supervision of medical monitor (director/Sr director) provides clinical input to protocol/study team for monitoring guidelines, statistics analysis plans, ICDs, clinical review forms, data edit checks, data quality planning, as needed.
- Contributes to contract research organization / vendor selection to ensure study is conducted consistent with protocol requirements, clinical plan expectations, and study timelines; this includes ensuring medical/technical requirements for data integrity are applied. o Works with study team to ensure high quality of data e.g. appropriate patient population, adequacy of clinical assessments as study is ongoing.
- Contributes to medical review and interpretation of efficacy and safety data from clinical trials; this includes delivery of top-line report in collaboration with study statistician, and delivery of clinical study report in collaboration with medical writer and accountable for overall quality and timeliness of analysis and reporting.
- Provides protocol specific training to study team, investigators, clinical research associate, and others.
- Interacts with healthcare professionals at sites during the conduct of the study to enable quality, compliance and patient safety at the trial, site, and patient level.
- Interacts with DMCs and steering committees as required.
- Notifies appropriate study team personnel of the need to inform investigators of any changes in research activity and any significant new adverse events.
- Monitor investigator compliance with protocol and regulatory requirements.
- Support study team in issues resolution, study closeout, audit responses, inspection readiness, etc. Supports the program team:

- Under supervision (director/Sr director) authors clinical sections of regulatory documents (Investigator Brochure, Annual Reports, Investigational New Drug sections, clinical study report).
- May co-author abstracts, posters, presentations, and publications.
- May contribute budget execution of protocols. Interact with regulatory authorities, key opinion leaders, and principal investigators.
- May support Clinical Regulatory Authority interactions accountable for providing responses.
- Liaise with Key Opinion Leaders and Principal Investigators in countries to build a Key Opinion Leaders /Principal Investigators network for new trials.

BASIC QUALIFICATIONS

- Licensed by a health authority to prescribe medicines (independent of supervision) for at least one year (post "intern/houseman" year) and has utilized the license to prescribe medicines in a patient care setting for an aggregate duration of at least one year.
- Possesses the ability to critically evaluate medical/scientific information.
- Excellent written and oral communication.
- Understands the design, development, and execution of clinical programs and studies.
- Capacity to adapt to a fast pace and changing environment

PREFERRED QUALIFICATIONS

- Medical degree (M.D./D.O. or equivalent)
- Documented work experience/knowledge of statistics
- Training and experience in infectious diseases and/or infection control in the hospital setting is preferred.
- Experience with investigational clinical trials is preferred.
- No pharmaceutical industry experience required
- All applicants must have the relevant authorization to live and work in the UK / USA as applicable