Company: Pfizer
Job Title: Associate Director, Clinical 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:

- 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.
- Ensures development of and adherence to the Safety Surveillance Review Plan (SSRP). Consistent with the SSRP, performs and documents regular review of individual subject safety data, and performs review of cumulative safety data with the safety risk lead.
- As appropriate, the clinician medical monitor may delegate these responsibilities to the study clinician scientist identified in the SSRP.
- The specific components of safety data review are detailed in the appropriate SOPs and the "Safety Data Review Guide – for Clinicians."
- Monitor study safety issues and provide input to serious adverse events (SAEs) reports.
- Provides appropriate medical context in terms of risk factors, medical history and other important medical factors required to put the SAE or AE into appropriate medical context.
- Participates in the Safety Review Team to evaluate medical benefits/risks to support targeted clinical indications.
- Reviews literature as needed to respond to safety questions or those posed by the Safety Review Team, Data Monitoring Committee (DMC) or other individuals or bodies involved with the study.
- Communicates safety information to sites across the study and provides responses to questions on safety.

Protocol design and strategy:

- 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.
- 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

Candidate demonstrates a breadth of diverse leadership experiences and capabilities including: the ability to influence and collaborate with peers, develop and coach others, oversee and guide the work of other colleagues to achieve meaningful outcomes and create business impact.

- 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 an 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). Adult ID, pediatric ID and Obstetrics is preferred.
- 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