JOB DESCRIPTION

Pharmacovigilance Manager – MEA

Emmaus Medical, Inc. is a biopharmaceutical company, located in Torrance, CA (Los Angeles County), engaged in the discovery, development and commercialization of innovative treatments and therapies primarily for rare and orphan diseases. We are initially focusing our product development and commercialization efforts in Sickle Cell Disease, an inherited genetic disorder. Our mission is to improve the lives of people in need.

POSITION SUMMARY:

As a Pharmacovigilance Manager, your responsibility is to manage the safety profile of new drugs in clinical trials, oversee case-processing activities through all phases of development and perform regulatory reporting and medical monitoring tasks. You will manage the set-up, handover, and oversight of the Pharmacovigilance (PV) Hub's various regional requirements (Middle East and Africa), ensuring high PV standards and following regulatory requirements across designated countries. You will be responsible to ensure there is close alignment with the Director of Medical and Clinical Affairs and respective managerial level positions to comply with governance requirements.

KEY TASKS AND RESPONSIBILITIES:

- Organize, manage and maintain a highly compliant Pharmacovigilance (PV) system for Emmaus Medical.
- Maintain awareness and ensure adherence to established and updated local and global processes and guidelines as well as national and international regulations and guidelines for pharmacovigilance.
- Ensure PV business continuity and after hours availability.
- Lead and coordinate internal and external PV audits and inspections.
- Monitor PV system performance and compliance of partners and distributors.
- Maintain expertise in country as well as worldwide regulations and guidelines and promote increased awareness of the legislative and regulatory environment in the country.
- Accountable for all strategic PV activities for MEA.
- Active contribution to the activities relevant to the pharmacovigilance system to ensure monitoring of the safety profile of Emmaus Medical products and to meet regulatory requirements.
- Act as the responsible contact person in the region, internally and externally, for safety-related aspects and PV.
- Ensure internal regulatory/PV processes and procedures are well documented and support compliant regulatory/PV activities.
- Perform other duties as assigned.

SKILLS AND REQUIREMENTS:

- In depth knowledge of national/regional regulatory legislation and guidelines.
- Knowledge of the pharmacovigilance regulations in Middle East and African countries is required and the European countries is a plus.
- Demonstrated ability to provide quality work using strong organizational, facilitation and interpersonal skills in a cross-functional team locally, within PV and externally.
- Skilled at people management including overseeing and controlling outsourced vendor activities in a compliance/regulated field.
- Capable of troubleshooting and managing multiple projects simultaneously.
- Strong knowledge and understanding of medical terminology and clinical development processes
- Rational approach to issues and their business implications, good problem solving and decision making skills.
- Highly analytical with the ability to give attention to detail.
- Excellent organizational skills and capable of working efficiently.
- Possess an excellent interpersonal, verbal, and written communication skills.

MINIMUM REQUIREMENTS:

- Minimum five years of working experience within the pharmaceutical industry and minimum five years within pharmacovigilance.
- Degree / Advanced degree in medicine or in life sciences or equivalent experience e.g. Physician, Pharmacist, Nurse.
- Excellent communication skills including proficiency in verbal and written English and Arabic languages. French is a plus.
- Experience in other affiliate medical functions (e.g., Medical Affairs, Clinical Operations, Medical Information) or global clinical product development is considered advantageous.
- Proficiency in Microsoft Word and Excel.

COMPLEXITY OF WORK:
Requires good verbal and written communication skills, tact, accuracy, and the ability to prioritize work and work well under extreme pressure. Ability to work independently and interface with various levels of administration and management. Must maintain all levels of confidentiality and have a professional, positive attitude towards the job.

SUPERVISION OF OTHERS:
No.

RESPONSIBILITY FOR CONFIDENTIAL INFORMATION:
The majority of information processed by this person is extremely confidential and requires utmost discretion in handling. This person is required to keep this information confidential and not discuss it with the other staff members in the office.

UNUSUAL JOB REQUIREMENTS:
May be required to perform other duties as appropriate to the needs of Emmaus Medical that are not listed and in addition to this job description.