DRUG SAFETY MANAGER

SUMMARY OF POSITION

The successful candidate will be a highly motivated individual to supervise the local safety assurance activities related to use of the commercial product

The Drug Safety Manager position will have demonstrated experience in safety assurance work or or related experience in supporting the major activities and responsibilities as described below.

MAJOR ACTIVITIES AND RESPONSIBILITIES

- Develop and maintain a local safety assurance system to support safe use of commercial product
- Conduct or supervision of safety assurance activities, including but not limited to, collection of drug safety reports, examination of safety information received, timely reporting to competent authorities and planning, reporting and implementation of safety assurance measures
- Conduct self-inspection and support internal process audits and external vendor audits as necessary
- Contribution to and control of documents related to safety management activities, including, but not limited to, the JRMP and the JPSUR
- Development of local SOPs related to safety assurance activities, review or approval of functional area procedures as needed and implementation of associated training requirements
- Oversight of Early Postmarketing Phase Vigilance including managing of vendor, if applicable
- Providing the Head of International Drug Safety and Pharmacovigilance with information on changes in the local GVP regulationsCommunication with necessary parties in the case of communication from the local competent authorities regarding safety matters for the product
- Reporting of any product safety related issues to the Head of Drug Safety and Pharmacovigilance International and the Marketing Compliance Officer/Supervisor General

The role may also support the International Management Team with additional ad hoc safety assurance related management support

ORGANISATIONAL STRUCTURE

Reporting to the Head of Drug Safety and Pharmacovigilance International in the UK office with local reporting lines to the Marketing Compliance Officer/Supervisor General.

QUALIFICATIONS AND BACKGROUND REQUIREMENTS

Educational / Work Requirement

- A minimum of a Masters degree preferably in pharmacy or life sciences.
- Substantial experience in a Safety Assurance role in a GVP related environment

Professional Work Experience

- A number of years of Life Science industry experience required
- Experience of working independently in a safety assurance or related function
- Experience with setting up and leading an Early Postmarketing Vigilance Study
- Leadership and collaboration skills, including excellent verbal and written communication skills at all levels in Japanese, and adequate verbal and written communication skills in English
- Demonstrated knowledge with the following regulations and guidance;
    - Proven knowledge of Japanese GVP for Drugs
    - Understanding of EU GVP and FDA requirements
- Ability to work independently and to make decisions based on experience.
- Ability to travel domestically and internationally

LOCATION

This position will be based at the Amicus KK office, Tokyo