inpharmatis

WE ARE LOOKING FOR A PHARMACOVIGILANCE (PV) MANAGER IN LATVIA

Inpharmatis offer comprehensive regulatory affairs services to Life Science Industry including Drug Development and Vigilance Services to pharmaceutical, medical device, food supplements, cosmetic and biotech companies. Our area of expertise lies in the European & CIS market.

Please send your CV and application letter by August 20, 2019

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PHARMACOVIGILANCE (PV) MANAGER IN LATVIA

The PV manager is responsible for leading safety risk management activities including; signal evaluation and management, update and maintenance of core safety documents, aggregate report production and general PV support to clinical development and post-marketing surveillance.

Duties and responsibilities:

- Perform Medical review of ICSRs.
- Compile data and review of safety data for signal detection/management activities.
- Oversee the maintenance and production of aggregate safety reports.
- Provide PV input into other regulatory documents or dossiers as required.
- Support the safety evaluation team to ensure all activities are carried out and recorded appropriately.
- Provide mentoring and training to newer PV team members, when required.
- Lead ongoing scheduled and ad-hoc safety signal detection activities as required.
- Manage detected signals through the evaluation process.
- Evaluate safety data for presentation at the Corporate Safety Board.
- Create and maintain aggregate safety reports.
- Other medical writing or risk management activities.
- Respond to safety related queries from internal and external partners including Regulators.
- Execute additional tasks in order to meet departmental project-related or developmental / change objectives.

Skills:

- Ability to lead the evaluation and resolution of safety issues with cross-functional teams.
- Requires good operating knowledge, retrieval of data, from pharmacovigilance databases.
- Proficiency with safety databases and safety coding dictionaries (e.g., MedDRA, WHODRUG).
- Detail-oriented, with good organizational, prioritization, communication, and time management proficiencies.
- Strong leadership and people management experience.
- Excellent communication and collaboration skills with the ability to present to internal/external groups and establish and maintain good working relationships at all levels.

Qualifications and Experience:

- Minimum Life Science Degree.
- Demonstrable experience in safety evaluation and risk management in the clinical development and/or post-marketing setting gained in pharmaceutical industry in the previous 5 to 7 years.
- Excellent communication and IT skills.

What we offer:

- Competitive salary.
- Fast-growing organisation.
- A dynamic and inspiring working environment.

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