Insuvia is an outsourcing and consultancy services provider for the pharmaceutical industry. We help pharmaceutical & biotech companies make safe and effective healthcare products available worldwide by providing superior quality pharmacovigilance and regulatory affairs services.

Currently, we are looking for a Senior Pharmacovigilance (PV) Specialist to join our team in Lithuania. As part of the Senior PV Specialist role, the person would act as the European Union Qualified Person for Pharmacovigilance (EU-QPPV) for some of our PV clients.

SENIOR PHARMACOVIGILANCE SPECIALIST IN LITHUANIA (INLUDING THE ROLE OF EU-QPPV)

Main Tasks and Responsibilities

- Act as EU-QPPV or Deputy EU-QPPV within assigned projects.
- Contribute to the establishment and maintenance of Pharmacovigilance (PV) System, including all activities which contribute to the detection, assessment, understanding and communication of safety information, as well as risk management activities.
- Develop and maintain the Pharmacovigilance System Master File (PSMF) ensuring that the PSMF is an accurate and up-to-date reflection of that safety system.
- Promote, maintain, and improve compliance with PV legal requirements and maintain up-to-date knowledge of current PV regulations.
- Act as a single point of contact for the EMA and EU Competent Authorities on a 24-hour basis, and the contact point for inspections.
- Provide oversight over the functioning of the PV system in all relevant aspects. Oversee development and implementation of standard operating procedures (SOPs) and processes as they pertain to the function of the EU QPPV.
- Collect and process safety reports from solicited and unsolicited sources, ensuring compliance with the required timelines and applicalbe procedures.
- Ensure continuous safety profile monitoring, detection and evaluation of new signals and any emerging safety concerns.
- Have an overview on any conditions or obligations adopted as part of the marketing authorisations and other commitments relating to safety or the safe use of the products and other relevant finding raised from studies/programmes conducted by the Company.
- Provide input on regulatory actions in response to emerging safety concerns (e.g. variations, urgent safety restrictions, and communication to patients and healthcare professionals).
- Prepare and submit Periodic Safety Update Reports, Risk Management Plans; manage risk minimization measures implementation and effectiveness evaluation.

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- Review and approve protocols of post-authorisation safety studies conducted in the European Union (EU) or pursuant to a RMP agreed to in the EU.
- Ensure full and prompt response to requests from Competent Authorities for the provision of information necessary for the benefit-risk evaluation of the products.
- Ensure Back-up procedures are appropriately maintained and tested including PV Business Continuity, Disaster Recovery, and Deputy EU QPPV.
- Lead by example to ensure effective and cooperative cross-functional teamwork at the country, regional, and global levels.
- Work within EudraVigilance and ensure timely reporting of safety and product information.
- Ensure the necessary quality, including the correctness and completeness, of PV data submitted to the Competent Authorities in Members States and the European Medicines Agency (EMA).
- Deliver PV trainings when required (to colleagues, customers, partners)
- Participate in inspections and/or audits, including post inspection/audit support, when required.

Experience required skills and competencies

- Degree in Medicine and/or Pharmacy;
- At least 3 years PV experience (previous experience as EU QPPV and/or Deputy EU QPPV would be a significant advantage);
- Solid knowledge of PV system operations and functions;
- Fluent command of English (written and oral);
- Strong attention to details with a quality-focused attitude;
- Advanced knowledge of MS Office (Word, PowerPoint, Excel);
- Excellent organizational, time management, and communication skills;
- Self-motivation, ability to assume responsibility and work autonomously in a professional manner.

What we offer:

- Interesting, dynamic and diverse work in a young and rapidly growing company;
- Broad opportunities for self-expression and professional growth;
- Professional training and development;
- Contributing to challenging tasks and achieving ambitious targets;
- Office in the old town of Kaunas, flexible working hours and partial home-office possibility.

Please send your CV and short intro letter to career@insuvia.com

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