Biomapas is a functional and full outsourcing solution provider to the global life science industry, with key expertise in Clinical Trials, Regulatory Affairs and Pharmacovigilance. With headquarter in Lithuania and offices in Switzerland, Russia, Georgia, Ukraine and Sweden, Biomapas operations are spread over 4 continents, concentrated in Europe, Russia and CIS region.

Biomapas is looking for **Pharmacovigilance Director** to join leading position and strengthen Biomapas Pharmacovigilance activity globally.

Key role responsibilities:

- Leading Global Pharmacovigilance Operations and activities of Pharmacovigilance Department.
- Strategic planning and execution of Pharmacovigilance Department structure and reporting.
- Ensuring relationship management with internal and external stakeholders.
- Ensuring compliance with Global Pharmacovigilance and Regulatory requirements.

Other responsibilities:

- Plan Department budget and accomplish financial goals.
- Participate in the preparation of proposals of Pharmacovigilance services, prepares and coordinates contracts with Clients.
- Set the direction for Pharmacovigilance Operations activities for ensuring compliance with all relevant Global PV Regulations and requirements for the processing of adverse events associated with Intercept sponsored drug products, including investigational and marketed products.
- Establish the direction, standards, and processes for supporting Pharmacovigilance Operations including the strategic planning, implementation, and management of activities.
- Responsible for managing internal and external staff allocated to Operational activities including creating a highly efficient team across insourced and outsourced resources.
- Lead the interaction with relevant internal or external functions in inspections, and audits.
- Oversee and ensure the Pharmacovigilance Operations business requirements are met including establishing and monitoring key quality and compliance metrics.
- Responsible for a compliant and quality execution of all operational activities related to case processing including timely submissions of expedited reports.
- Identify immediately deviations and applicable corrective and preventive actions to maintain compliance at its highest level.
- Contributes to, drafts and implements department SOPs, Guidelines and Work Instructions related to Pharmacovigilance Operations and Department activities.

- Supports signal detection activities, aggregate reports, benefit-risk assessment as required.
- Responsible for PV vendor contracts and the oversight of PV Agreements and Safety Data Exchange Agreements with vendors, partners and others.
- Participates in actions to improve the quality of work, processes and procedures in order to continuously improve the quality of services, make suggestions for improving quality.

Candidate profile:

- Medical Doctor, Pharmacist, other Life science education with minimum five-year experience working in leading position in Pharmacovigilance.
- Highly self-motivated, conscientious, meticulous individual able to work with a minimum of supervision.
- Team player who enjoys establishing and maintaining good working relationships.
- Location and / or experience working in Nordic, Benelux countries and Germany would be considered as advantage.
- Professional use of English and Russian languages.
- In-depth knowledge and skills in use of MS Office and other relevant Software.

For more detailed information please do not hesitate to contact by telephone +370 37 366307.

Please apply to **hr@biomapas.eu**

Thank you for attention! Kindly inform that only selected candidates will be contacted.