BIOMAPAS
Clinical, Regulatory & Pharmacovigilance

We keep promises. Always.

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 headquarters in Lithuania and offices in Switzerland, Russia, Georgia, Ukraine, Poland, Kazakhstan and Sweden, Biomapas operations are spread over 5 continents, concentrated in Europe, Russia and former CIS region.

Biomapas is looking for **Pharmacovigilance Specialist** (QPPV Office) to join our ambitious and growing team.

Role responsibilities:

- Supporting full pharmacovigilance activities;
- Supporting the maintenance and development of all other IT systems/tools used by the PV department, as required;
- Ensuring successful communication with local Competent Authorities and Biomapas and/or Biomapas contractual partners in reasonably timely manner;
- Ensuring the survey and monitoring of national pharmacovigilance regulations and notifying Biomapas and/or Biomapas contractual partners about the changes, if any, on agreed basis;
- Contributing to the clients full PV and Quality system or parts of it, including but not limited to the maintenance/creation/documentation/preparation of: PSMFs, SOPs, Periodic Aggregate Safety reports, Database operations, Contractual arrangements, PV compliance data, PV training, PV inspections/audits, (additional) Risk Minimization and PV activities and Regulatory intelligence processes;
- Delivering pharmacovigilance trainings to Biomapas and Biomapas contractual partners' personnel, when required;
- Supervision of local handling, including preparation and submission, of Periodic Safety Update Reports, Risk Management Plans and risk minimization activities;
- Participating in related inspection and/or audits, including post inspection/audit support, when required;
- Informing Biomapas Quality Department without delay about any detected non-compliance of local processes.

Role requirements:

- Preferable education of Science in health-related field;
- At least 2 years PV experience;
- Excellent knowledge of English language, both oral and written;
- Knowledge of PV legislation (EU GVP Modules);
- The Ability to accurately and effectively evaluate, interpret and present drug safety data and processes;
- Focused on quality and productivity;
- The ability to work independently and as a part of a team;
- Customer-oriented.

In Biomapas, you will find a supportive work environment with a guarantee for professional and personal development, as well as a competitive salary, benefits and many more initiatives that will make your daily office life comfortable.

Please apply to cv@biomapas.com
Be kindly informed that only selected candidates will be contacted.