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** to join our ambitious team.

Role responsibilities:

- Acting as EU-QPPV/deputy EU-QPPV/ Local QPPV with the responsibilities to maintain Pharmacovigilance system and responsibilities taken by Biomapas on behalf of the contractual Biomapas partner for assigned project(s);
- Active involvement in PV Medical Writing activities: Addendum to Clinical Overview preparation, Periodic Safety Master File development and regular review;
- Ensuring weekly monitoring and/or monthly quality control of local and international literature review, national and international PV regulation;
- Ensuring continuous safety profile monitoring, detection of new signals and evaluation, actively working in EudraVigilance on behalf of the customer, as applicable;
- Collection and processing of safety information from solicited and unsolicited sources;
- Collection and processing of any medical enquiry/inquiry/answer received via phone/e-mail/fax or by other means from any source for assigned project(s);
- Ensuring compliance with processes for proper collection, duplicate check, processing, accurate translation, quality control (at least second self-control), data entry into PV database, documentation, reporting and follow-up of all safety reports for all Biomapas contractual partners products within agreed timelines following Biomapas or contractual partners procedures;
- Preparation and submission of Periodic Safety Update Reports, Risk Management Plans; oversight of risk minimization implementation and effectiveness evaluation;
- Ensuring successful communication with Competent Authorities and Biomapas and/or Biomapas contractual partners in reasonably timely manner;
- Ensuring that reconciliation process is in place and performed regularly with Biomapas contractual partners and stakeholders;
- Delivering PV trainings to Biomapas and Biomapas contractual partners personnel, when required;
- 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/international processes;
- Continuously developing his/her professional and personal skills and participating in PV relevant trainings delivered by Biomapas and/or Biomapas contractual partners;
- Following the principles of data integrity, confidentiality and personal data protection, as applicable;
- Informing Biomapas key personnel in advance about his/her absence and assuring that back-up procedure is in place, as applicable;
- Supporting in proactive awareness and tracking of quality of services within in-house delivered Pharmacovigilance services.

Role requirements:

- Preferable education of Science in health-related field;
- At least 3 years PV experience;
- Excellent knowledge of English language, both oral and written;
- The ability to work independently and as a part of a team;

- Focused on quality and productivity;
- Customer-oriented.

In Biomapas you will find supportive work environment with guarantee for professional and personal development, as well as competitive salary and 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.