**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 a **Pharmacovigilance Specialist** to join our ambitious and growing team in **Latvia.**

**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 Pharmacovigilance 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 pharmacovigilance 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 pharmacovigilance 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 pharmacovigilance 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 pharmacovigilance 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 of Pharmacovigilance experience;
- Fluent English language;

- The ability to work independently and as a part of a team;
- Focused on quality and productivity;
- Customer-oriented.

The position is home-based with some flexibility to visit clients and company headquarters.

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**

**Thank you for attention! We kindly inform that only selected candidates will be contacted.**