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** (Medical/Clinical Safety) to join our ambitious and growing team.

Role responsibilities:

- Processing Serious Adverse Event (SAE): safety database entry, tracking, narrative writing, requesting follow-up from site, quality checks/review and reporting to client (s) or agencies for assigned projects;
- Acting as main point of contact for assigned customers;
- Providing regular updates to assigned customers, in writing and/or (on-line) meetings;
- Ensuring successful communication with Competent Authorities and Biomapas and/or Biomapas contractual partners in reasonably timely manner;
- Ensuring continuous safety profile monitoring, detection of new signals and evaluation, as applicable;
- Active involvement in Pharmacovigilance Medical Writing activities from medical/scientific perspective: PSUR, DSUR, Risk Management Plans, Addendum to Clinical Overview;
- 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;
- Assuring that appropriate back-up procedures are 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 2 years PV experience;
- Excellent knowledge of English language, both oral and written;
- Experience with case processing in safety databases (e.g. ARGUS, ArisG, Veeva);
- The ability to work independently and as a part of a team;
- Focused on quality and productivity;
- 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.