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 former CIS region.

Biomapas is looking for **Pharmacovigilance specialist** to join our ambitious and growing team in Lithuania.

Key role responsibilities include but not limited to:

1. Acting as Biomapas and/or Biomapas contractual partners, 24/7 local contact person for pharmacovigilance at local level, where legally required;
2. 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;
3. Ensuring successful communication with local Competent Authorities and Biomapas and/or Biomapas contractual partners in reasonably timely manner;
4. Ensuring compliance with processes for proper collection, duplicate check, processing, accurate translation, quality control (at least second self-control), data entry into data base, documentation, reporting and follow-up of all safety reports for all Biomapas contractual partners products within agreed timelines following Biomapas or contractual partners procedures;
5. Collection and processing of safety information at local level received from solicited sources organized by Biomapas and/or Biomapas contractual partner, including Clinical Trials;
6. 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);
7. Ensuring weekly monitoring and/or monthly quality control of local literature review in relation with Biomapas contractual partners products, where applicable;
8. Ensuring that reconciliation process of identified safety information is in place and performed regularly with Biomapas contractual partners and stakeholders;
9. Delivering pharmacovigilance trainings to Biomapas and Biomapas contractual partners personnel, when required;
10. Preparation and submission of Periodic Safety Update Reports, Risk Management Plans and risk minimization activities;
11. Support in Pharmacovigilance Medical Writing activities: Addendum to Clinical Overview, Periodic Safety Master File development/regular review etc.;
12. Support in Clinical Safety activities: development/review of Safety Management Plans, create Case Narratives, perform adverse event full processing in the database, including medical coding and reconciliation with Sponsor;
13. Ensuring continuous safety profile monitoring, detection of new signals and evaluation, as applicable.
14. Participating in related inspection and/or audits, including post inspection/audit support, when required;
15. Informing Biomapas Quality Department without delay about any detected non-compliance of local processes;

16. Continuously developing his/her professional and personal skills and participating in pharmacovigilance relevant trainings delivered by Biomapas and/or Biomapas contractual partners;
17. Following the principles of data integrity, confidentiality and personal data protection, as applicable;
18. Informing Biomapas key personnel in advance about his/her absence and assuring that back-up procedure is in place, as applicable;
19. Ensuring compliance with Biomapas and Biomapas contractual partners procedures;
20. Acting as EU-QPPV/deputy EU-QPPV with the responsibilities to maintain pharmacovigilance system and responsibilities taken by Biomapas on behalf of the contractual Biomapas partner for assigned project(s);
21. Supporting in proactive awareness and tracking of quality of services within in-house delivered pharmacovigilance services.

Key experience, required skills and competencies

- 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.

Please apply to **HR@biomapas.com**

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