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 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 **Regulator Affairs Project Manager** to join our ambitious and growing Regulatory Affairs team (position in Kaunas or Vilnius offices, with remote work possibility).

Key role responsibilities include but not limited to:

- Manage assigned Regulatory Affairs projects, their timelines, budget and resources (both internal and external).
- Manage and facilitate all marketing authorization/registration related activities in the applicable countries.
- Provide input for Regulatory Affairs department strategic plans.
- Be fully responsible for obtaining and providing consistent, value-added, and timely information on project planning, review and project management for minimizing impact/risks on project objectives and deliverables.
- Analyse and improve local regulatory processes, SOPs, other activity related documents as well as ways of working.
- Maintain contact with regulatory authorities', client/sponsor representative.
- Provide the Regulatory team with regulatory input in order to obtain timely regulatory approvals for the products.
- Implement and develop Regulatory Affairs high-level project management for multiple medium to large projects.
- Direct, supervise and manage the scope of work, objectives, timelines, quality of deliverables, and all other project management activities.
- Direct, supervise and manage project plans development for all regulatory phases of the project lifecycle.
- Maintain lines of communication with Client in order to meet project deliverables and milestones.
- Manage and oversight Local Regulatory Officers and Regulatory Affairs Specialist to ensure appropriate communication channels are maintained and reporting schedules adhered to.

Key role requirements:

- Education in Science/Health discipline.
- Experience in Regulatory Affairs and/or project management (Pharma sector) over 5 years.
- Experience in team management.
- Professional use of English and Russian languages.
- Attention to details, careful planning to achieve accurate and timely results.
- Work according to procedures, rules, regulations.
- Recognise recurring issues and analyse their causes in order to reach a solution.
- Strategic thinking and innovative approach.
- Good knowledge of MS Word, Excel, PowerPoint, Outlook etc.

For more detailed information please do not hesitate to contact by telephone +370 698 15736.

Please apply to **personalas@biomapas.eu**

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