

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 pro-active person with creative approach to join our team as a **Regulatory Affairs Specialist**.

Role responsibilities:

- Manage and facilitate all registration related activities;
- Compile, coordinate and monitor applications for registration, renewals, variations in accordance to the national and EU legislation, standard operating procedures;
- Make regulatory monitoring of the current duties related with particular product;
- 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;
- Translate/update the specific product dossier documents, i.e. Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), labelling etc. into Lithuanian or English language;
- Update and collect information on registration instructions and regulations.

Role requirements:

- University degree in Medicine, Pharmacy, Life Sciences;
- Fluency in English ;
- At least 2 years experience of Regulatory Affairs;
- Good knowledge of MS Word, Excel, PowerPoint, Outlook, etc.
- Attention to detail, time-management and problem-solving skills;
- Proactive, flexible, customer oriented;
- Detail oriented and have analytical skills.

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.