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 **Senior Regulatory Affairs Specialist** to join our global team, position is homebased globally (CIS region).

Role responsibilities:

- Responsible for management of dedicated tasks in the dedicated CIS country (countries) and coordination of the vendors;
- Compile, coordinate and monitor applications for registration, renewals, variations in accordance to the national and CIS 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 and other relevant documents;
- Update and collect information on registration instructions and regulations.

Role requirements:

- Preferable education of Science in health-related field;
- 2-5 years experience in Regulatory Affairs;
- Fluent English, local language (CIS region);
- Good organization and analytical skills;
- Flexibility and ability prioritize the tasks.

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.