

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 a **Regulatory Affairs Specialist** to join our global Regulatory Affairs team and support our team activity in **Romania**.

Role responsibilities:

- Manage and facilitate all registration related activities mainly for RO and the other EU countries;
- 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 Romanian or English language;
- Update and collect information on registration instructions and regulations.

Role requirements:

- Education in Science/Health discipline;
- At least 2-3 years experience in Regulatory Affairs in international environment;
- Experience with medical devices and marketing material review is advantage;
- Excellent knowledge of English (Russian would be considered as big advantage);
- Decision making skills;
- Careful planning to achieve accurate and timely results;
- Recognize recurring issues and analyze their causes in order to reach a solution.

The position is home-based with some flexibility to visit clients and company Headquarters.

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

Thank you for your attention.

Be kindly informed that only selected candidates will be contacted.