

Senior Regulatory Affairs Specialist Vilnius / Kaunas

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.

At the moment we are looking for experienced **Senior Regulatory Affairs Specialist** to join our team. The position is office based with flexible location in Kaunas or Vilnius offices.

Main Tasks

- 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.

Experience, required skills and competencies

- Education in Science/Health discipline.
- At least 2-3 years experience in Regulatory Affairs in international environment.
- 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.

If you have any questions or would like to find out more about this role, we will be glad to discuss with you. Please, contact us by e-mail personalas@biomapas.eu or call directly to HR and Training Manager Raimonda Klimiene +370 698 15736.

Kindly inform that only selected candidates will be contacted.