BIOMAPAS
Clinical Trials & Regulatory Solutions

We keep promises. Always.

Senior Regulatory Affairs Specialist

Biomapas – Clinical Trials & Regulatory Solutions.

Biomapas is a team of experts providing clinical development, marketing authorization and post-marketing support for Biotech, Pharma and Medtech companies. For more than 15 years Biomapas is supporting companies in Europe and CIS region.
At the moment we are looking for experienced, open-minded person to join our team in **Senior Regulatory Affairs Specialist** role.

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.
- 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.