

Biomapas – Clinical Trials & Regulatory Solutions.

We are 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, Eastern Europe and CIS region, including Russia, Ukraine, Belarus, and Georgia

At the moment Biomapas is looking for pro-active person with creative approach to join our growing team as a Regulatory Affairs specialist. This position requires good communication skills and fit to a person who is confident enough to manage a lot of on-going projects.

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

- Professional use of the English language: excellent verbal and written communication skills;
- Careful planning to achieve accurate and timely results;
- Work precisely according to procedures, rules, regulations and legislations;
- Recognize recurring issues and analyze their causes in order to reach a solution;
- Strategic thinking and innovative approach;
- Attention to detail;
- Maturity, autonomy and decision;
- Organization;
- Relational qualities;
- Easy to write;
- Good knowledge of MS Word, Excel, PowerPoint, Outlook etc.

If you have any questions or would like to find out more about the position, please, contact us by e-mail personalas@biomapas.eu or call directly to Personnel Manager Raimonda Klimiene +370 698 15736.