

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/Manager (Medical Devices)** to support our Regulatory Affairs department in **Russia**.

Role responsibilities:

- Responsible for Russia and CIS RA operations and coordination of the vendors/oversight of more junior RA staff for other CIS countries for medical devices relating projects primarily and provide RA support for medicinal products when required;
- Manage and facilitate all registration-related activities for medical devices and provide support for medicinal products when required;
- Compile, coordinate and monitor regulatory procedures in accordance with the national and EUEA/CIS legislation, standard operating procedures;
- Preparation of documents: Protocols of technical testing, Program and methodology of technical testing, Protocol of clinical testing, Instruction for Use (IFU) and other local specific documents;
- Make regulatory monitoring of the current duties related to a 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;
- Update and collect information on registration instructions and regulations;
- Creation and periodical update of EAEU/CIS regulatory intelligence for medical devices registrations.

Role requirements:

- University degree in Medicine, Pharmacy, Life Sciences;
- Fluent written and spoken in Russian and English;
- 2-5 years experience in Regulatory Affairs field with medical devices;
- Good knowledge of MS Word, Excel, PowerPoint, Outlook, etc.;
- RA experience with medicinal products is an advantage;
- Ability to work independently and as a part of a team;
- Attention to detail, time-management and problem-solving skills;
- Proactive, flexible, customer oriented.

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.