

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 **Local Regulatory Affairs Manager** to support global Regulatory Affairs team in **Poland**.

Role responsibilities:

- Responsible for Poland RA operations and coordination of the vendors/oversight of more junior RA staff for other EU central HUB countries;
- 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 and other relevant documents;
- Update and collect information on registration instructions and regulations.

Role requirements:

- University degree in Medicine, Pharmacy, Life Sciences;
- More than 5 years of Regulatory Affairs and/or project management (Pharma sector) experience;
- Highly experienced in local Regulatory Affairs operations for the medicinal products as well as support for the other functions such as Pharmacovigilance and Quality Assurance, experience with review of local marketing materials;
- RA experience for MD is advantage ;
- Fluency in Polish and English;
- Good knowledge of MS Word, Excel, PowerPoint, Outlook, etc.;
- Attention to detail, time-management and problem-solving skills;
- Proactive, flexible, customer oriented.

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.