

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** to support global Regulatory Affairs team in **Italy**.

Role responsibilities:

- Ensuring RA activities for the medicinal products in IT and provide support for coordination in the other countries in the West HUB;
- 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;
- 2-5 years experience of Regulatory Affairs;
- Experience with review of marketing materials and in Pharmacovigilance is advantage;
- RA experience for MD is advantage;
- Fluency in Italian and English;
- Good knowledge of MS Word, Excel, PowerPoint, Outlook, etc.;
- Attention to detail, time-management and problem-solving skills;
- Proactive, flexible, customer oriented;
- Detail oriented and have analytical skills.

The position is home-based with some flexibility to visit clients and company headquarters.

In Biomapas you will find supportive work environment with guarantee for professional and personal development, as well as competitive salary and benefits and many more initiatives that will make your daily office life comfortable.

Please apply to cv@biomapas.com

Thank you for attention! We kindly inform that only selected candidates will be contacted.