

**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/Specialist** to join our global Regulatory Affairs team and support our team activity in the Czech Republic.

#### **Role responsibilities:**

- Responsible for CZ RA operations and coordination of the vendors/oversight of more junior RA staff for other EU 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 Czech 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. Preferably located in Prague.

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 [hr@biomapas.com](mailto:hr@biomapas.com)

In case you would like to get more information – please do not hesitate to contact **Raimonda Klimienė**, HR and Training manager by **+370 69 815 736**.

**Be kindly informed that only selected candidates will be contacted.**