

BalticCRO is an outsourcing and consultancy services provider for the pharmaceutical industry. We are operationally focused on providing clinical research, pharmacovigilance, regulatory affairs, product reimbursement and market access support services. Currently we are looking for a Regulatory Affairs Assistant to join our team.

## REGULATORY AFFAIRS ASSISTANT IN LITHUANIA

### Main Tasks

- Provide necessary support to the regulatory affairs team on administrative matters, coordination and execution of projects, communication with Regulatory Authorities and customers;
- With support from senior regulatory affairs colleagues, prepare, compile and submit regulatory applications, including but not limited to new applications, variations and renewals, MA transfers, and participate subsequent correspondence with the Regulatory Authorities;
- With support from senior regulatory affairs colleagues, prepare and submit notifications and declarations as required (e.g. product placement on the market, out of stock, product recall, price declarations, etc.), and track regulatory reporting schedules;
- Monitor and manage regulatory requirements related to assigned product(s);
- Translate/update specific product dossier documents, i.e. Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), labelling etc. into Lithuanian or English language;
- Review artworks in line with the marketing authorization and local legislation;
- Review promotional materials in line with the marketing authorization and local requirements;
- Update and collect information on registration instructions and regulations;
- Provide other regulatory affairs assistance to customers as requested.

### Experience, required skills and competencies

- Education in Science/Health discipline;
- Excellent knowledge of English language;
- Careful planning to achieve accurate and timely results;
- Attention to detail;
- Experience in pharmaceutical industry would be considered as an advantage;

### Company offers:

- Interesting, dynamic and diverse work in a young and growing company;
- Broad opportunities for self-expression and professional growth;
- Professional training and development;
- Contributing to challenging tasks and achieving ambitious targets;
- Office in the old town of Kaunas, flexible working hours and partial home-office possibility.

Please send your CV and short intro letter by 1<sup>st</sup> of October 2019 to [career@balticCRO.com](mailto:career@balticCRO.com)