inpharmatis

WE ARE LOOKING FOR A REGULATORY AFFAIRS SPECIALIST (RA) IN LITHUANIA

Inpharmatis offer comprehensive regulatory affairs services to Life Science Industry including Drug Development and Vigilance Services to pharmaceutical, medical device, food supplements, cosmetic and biotech companies. Our area of expertise lies in the European & CIS market.

Please send your CV and application letter to

cv@inpharmatis.com

+371 6721 0500

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REGULATORY AFFAIRS (RA) SPECIALIST

Duties and responsibilities:

- Writing product labels, patient information leaflets and summary of product characteristics;
- Monitoring and setting timelines for registration variations and renewal approvals;
- Pre-lodgement assessment of documents for new applications with respective regulatory authorities;
- Keeping abreast of international legislation, guidelines and customer practices;
- Preparing proposals, developing reports and documentation, reporting within electronic systems, monitoring and lodging all necessary reports for PharmacoVigilance;
- Reviewing practices and providing advice on changes to systems (SOPs);
- Collaboration with other colleagues in Clinical, Quality, Auditing and Regulatory Affairs Departments;
- Working with specialist computer software and resources (e.g. eCTD software, Eudravigilance, etc.).

Skills:

- Minimum of BPharm, MPharm preferred;
- Proven experience in Regulatory Affairs;
- Good computer literacy, speed and accuracy essential (MS Office);
- Excellent verbal and written Lithuanian, English skills, Russian (as advantage);
- Proven ability to tight deadlines.

What we offer:

- Competitive salary.
- Fast-growing organisation.
- A dynamic and inspiring working environment.

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