

Regulatory Consultant – Medical Devices and Borderline Products

Yordas Group: www.yordasgroup.com www.yordasgroup.com/hive

Yordas Group is a leading international provider of scientific, environmental, human health, global regulatory and sustainability services. Delivering innovative solutions for business, industry and government, Yordas services various key sectors, including: Consumer Goods, Advanced Manufacturing, Chemicals Manufacture and Processing, and Oil, Gas and Mining. The Group has regional representation in Europe, the Americas and Asia Pacific and partners worldwide. Yordas has established a solid and internationally recognised reputation as a provider of training, advice and services to ensure compliance across the globe.

Job Title Regulatory Consultant – Medical Devices and Borderline Products

Location McMaster Innovation Park, Hamilton, Ontario, Canada

Salary Dependent on experience, full-time permanent position

Date Posted January 22, 2019

Closing Date March 1, 2019*

Contact recruitment@yordasgroup.com

About the Role

Yordas Group is expanding and demand for our services is ever-growing. We are on the lookout for a hardworking and professional regulatory consultant in the area of Medical Devices, Medicinal Products and Borderline Products.

The successful candidate will work as part of the Regulatory team of the business, and in collaboration with project managers and consultancy staff. Depending on experience and interests, you will support companies with registrations of delivery devices/API combination in North America. The successful candidate will undertake client-driven activities as directed by the business and must be able to effectively and efficiently communicate with colleagues, clients, international partners and the authorities.

Role and Responsibilities

Duties and responsibilities include:

- Acting as account manager for the North American market, specifically Canada, the USA and Mexico
- Providing regulatory guidance and developing compliance strategies for industry and our partners according to North American legislation
- Supporting the development of regulatory strategies and deliveries of client products and coordinating with regulatory authorities
- Providing gap analysis based on regulatory requirements and presenting options to mitigate risk
- Assisting clients to trade internationally by facilitating the delivery of registrations and regulatory notifications through Yordas Group's in-country offices and partners

- Taking a key role in the delivery of services including the preparation, implementation and coordination of regulatory projects with support from the scientific and regulatory teams
- Communicating clearly and effectively with colleagues, clients, the authorities and Partners across multiple time zones
- Project managing and supporting the development and delivery of new business opportunities in North America by working closely with the business development team
- Supporting and furthering the development and delivery of Yordas training solutions in the field of North American medical device and borderline product regulations

Profile and Qualifications

Required

- A scientific background and university degree (MSc or PhD in Environmental or Medical Sciences, Chemistry, Biology, or equivalent)
- Knowledge of the relevant medical device legislation for North America (FDA PMA in USA and TPD in Canada)
- Experience in identifying and determining regulatory obligations in relation to medicinal products and borderlines and borderline medical products and accessories, such as: cosmetics, personal protective equipment, biocides, etc.
- An active interest in pursuing a career in consultancy
- An ability to learn, assimilate and effectively communicate information to support colleagues, discuss with partners and advise clients of regulatory requirements
- Be able to work effectively with colleagues in other global offices
- Excellent interpersonal skills, service-oriented personality and attitude
- Strong organisational and presentation skills
- Ability and willingness to travel to train and consult with colleagues in other global offices and attend and present at (inter)national conferences
- Excellent language skills in English

Desirable

- Some knowledge of other regulatory legislation, such as European MDD / MDR / IVDR etc.
- Prior experience of managing projects and supporting teams to achieve their objectives is an advantage
- Language skills in French and/or Spanish would be an asset

Benefits

- Competitive salary and benefits package
- Generous paid vacation package
- Personal and professional development
- Contributory company pension scheme
- Opportunities to travel
- Working as part of our friendly team, locally and internationally
- Based at McMaster University, Hamilton

We are an equal opportunity employer and welcome applications from all suitably qualified persons regardless of their race, sex, disability, religion/belief, sexual orientation or age.

Apply with a cover letter and resume to: recruitment@yordasgroup.com

***Note: it may be possible to interview for early applicants during week commencing 4 February 2019 when senior UK management are in Canada.**