- L & L Medical Device Corp was founded in 2019 and we provide global market entry and one –stop regulatory & quality assurance consultation services including regional medical device registration/clearance (US FDA PMA, 510(k), Health Canada MDL, EU MDR, IVDR, China MD/IVD registration, APAC MD registrations & etc.), local type testing support, clinical trials service & QMS consultation etc. We also help medical device start up companies with capital investments, nurturing novel idea or initial business model to grow into a globally distributed medical device enterprises.

- Our current locations are West Vancouver, Canada and Beijing, China.
- We are looking for talented and self-motivated medical device /IVD regulatory affairs professionals, bio pharm scientists to fill the limited new space with innovative technologies and enthusiastic attitude.

Location: Remote
Salary: Hourly rate is preferable and billable.
Contact us: Job application can be sent to **lulu.meddevice@outlook.com**

Job Openings

Acromegaly and Neuroendocrine Tumors expert

Responsibilities

1. Need to have profound knowledge of Acromegaly and Neuroendocrine Tumors.
2. Have experience with price and price premium reassessment (upon new routes of administration) specially on end-of-lifecycle pharmaceuticals.
3. Have specific experience with managing rare/orphan disease products (ideally for acromegaly and/or NETs)
4. Have experience with drugs for acromegaly specifically.
5. Can work PST time.

Qualifications

1. 2+ years of experience in large pharmaceutical companies in the U.S. or Europe. Familiar with new development and technologies in the field of Acromegaly and Neuroendocrine Tumors. Experience in project development preferred.
2. Can work legally in the US, Canada or China.
3. Strong ability in interpersonal communication, organization, and team management.

Regulatory Affairs Specialist

Principal Responsibilities

- Maintain compliance to national and global medical device regulations
- Manage and coordinate pre-market submission, including Health Canada medical device licence application, CE marking registration, FDA 510k submission, etc
- Coordinate post market surveillance and incident reporting to all applicable markets
- Provide regulatory inputs to the management during new product development and design change processes
- Support QA function for internal audit to ensure ISO13485 MDSAP is adhered to at all times
- Manage establishment registration, licence renewal and amendment
- Compile and maintain product Technical Files, DMRs and DHFs.

Educational Qualifications:

- BSc or equivalent
- Minimum Two (2) years Regulatory Affairs working experience within healthcare industry
- Certification in Regulatory Affairs (RAC) an asset

Knowledge & Skills

- In-depth knowledge of medical device global regulatory regulations is a must
- Experience of pre-market submission, including FDA510k, CE marking, and Canadian medical device licence application is a must.
- Knowledge of complaints handling, adverse event reporting and recall management is a must plus 4-5 years' experience working with Medical Devices
- Experience supporting successful regulatory or notified bodies QMS audits is desirable
- Knowledge of ISO 13485 MDSAP quality management systems
- Excellent attention to detail is essential
- Strong communication and interpersonal skills.

Contact

E-mail: lulu.meddevice@outlook.com