CareerCross by JAC Recruitment

PR/094842 | Regulatory Affairs Executive

Job Information

Recruiter
JAC Recruitment Singapore

Job ID
1523578

Industry
Healthcare, Nursing

Job Type
Permanent Full-time

Location
Singapore

Salary
Negotiable, based on experience

Refreshed
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General Requirements

Minimum Experience Level
Over 3 years

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Business Level

Minimum Education Level
Associate Degree/Diploma

Visa Status
No permission to work in Japan required

Job Description

COMPANY OVERVIEW

Our client, a leading MNC is now looking for a positive, outgoing individual to fill the position of a **Regulatory Affairs Executive** who will be able to handle both technical repairs of endoscopy systems, while handling the technical support for the regional subsidiaries and distributors.

JOB RESPONSIBILITIES

- Full awareness of local Health Products and Medical Device Act and their regulations relevant to the business through regularly checking HSA websites and attending HSA briefings
- Communicate changes and new requirements to management
- Request and submit documents for product registration and amendments applications
- Follow up on submitted applications and reply input requests from the authority
- Meet, discuss and negotiate with HSA regulators on matters pertaining to product registrations
- Have working knowledge of current products sold and keep abreast of new product launches by having regular update meetings with all the selling division managers
- Assist Senior Manager, Regulatory Affairs for matters pertaining to regulatory affairs as and when required
- Communicate with manufacturers, the local regulatory requirements, to facilitate the provision of appropriate documents for submission to HSA for product registration/amendments and compliance to local regulations

- Work with regulatory partners/distributors to obtain successful registration of new products
- Coordinate, facilitate, monitor, and track all regulatory activities in each market
- Regulatory reporting for recalls, FSCAs, Adverse Events and complaint handling
- Ensure conduct of business according to local regulations for medical devices
- Ensure compliance and participate in GDPMDS internal and external audits
- Registers complaint with samples to manufacturer. Follow-up on reply from manufacturer.

JOB REQUIREMENTS

- General Degree (preferred in discipline of Biomedical Science or Biomedical Engineering)
- Preferred 1 year working experience or completion of Internship in the related field
- Familiar with local and regional regulatory affairs requirements (medical devices)
- Good interpersonal relationship, project management and organisation skills
- Good written and verbal communication skills
- Team spirit, Proactive, motivated, self-starter

Apply online or feel free to contact me directly for more information about this opportunity. Due to the high volume of applicants, we regret to inform that only shortlisted candidates will be notified. Thank you for your understanding.

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Company Description