Telix Pharmaceuticals Limited
ACN 616 620 369
Suite 401, 55 Flemington Road
North Melbourne
Victoria, 3051
Australia

Job Description : Director of Regulatory Affairs - APAC
Type : Full-time
Location : APAC Region (preferably Melbourne)
Date : Immediate

About Us

Telix Pharmaceuticals Limited (Telix) is an Australian public Company (ASX: TLX) headquartered in Melbourne with operations in Europe, the United States and Japan. Telix's mission is to be the leading, global radiopharmaceutical company in the field of "theranostic" medicine and the Company is currently developing an extensive early through to commercial stage pipeline of products in prostate, kidney and brain cancer.

About the Role

Reporting to the VP - Global Regulatory Affairs, the primary responsibility of the *Director of Regulatory Affairs - APAC* role will be to set regulatory strategy for the APAC Region and to ensure regulatory operations objectives are aligned to and achieved in accordance with Telix's corporate objectives. This role will hold responsibility for the management of the strategic and operational goals in the Region by providing regulatory expertise, risk assessment and mitigation necessary to advance Telix drug candidates. Key accountabilities will include:

- Developing regulatory strategies to enable the APAC Region's Regulatory Authorities' review and approval of drug submissions
- Collaborating with Global Regulatory Operations in preparation of submissions and interactions with the Australian TGA and other APAC Regulatory Authorities
- Planning, writing and reviewing Regulatory Authority document submissions
- Supporting relationships with regulatory and legislative agencies
- Provideing regulatory assessment in change management
- Representing Regulatory Affairs on project teams as a subject matter expert
- Participating in regulatory agency interactions and contributing to written correspondence
- Leading interactions with Telix's APAC partners (licensees, distributors) on regulatory matters.

About You

You have a Bachelors degree in science, chemistry, pharmaceutical sciences or another related degree. Postgraduate qualifications will be considered favourably. You also have progressive experience in the pharmaceutical industry and are confident and adept in writing agency applications (i.e. CTA, IND, NDA, BLA, DMF) to TGA, Medsafe, and ideally one or more of NMPA, KFDA, PMDA, DCI. You hold comprehensive knowledge of the drug development process, pharmaceutical technology, drug manufacturing processes, GMP and related issues.

You are passionate and comfortable working in a cross-cultural, matrixed environment and, have the ability to work independently and manage multiple projects. You enjoy strategizing, planning, and executing projects within cross-functional teams.

Do you speak language(s) other than English? Bonus! Please highlight your language skills in your application.

Why work at Telix?

We are a dynamic, fast-growing biopharmaceutical company working towards a shared mission: to help patients with cancer live longer, better quality lives. This is an exciting time for Telix and we are looking for like-minded, passionate professionals to join us on the journey.

Agency support is not required for this role and no submissions will be considered.