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

Job Description: Global Regulatory Affairs - Intelligence and Label Lead
Type: Full Time
Location: Indianapolis (Hybrid)
Date: Immediate

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited ("Telix", the "Company") is an Australian public Company (ASX:TLX) headquartered in Melbourne with operations in Europe, the US and Japan. Our mission is to be a leading, global biopharmaceutical Company in the field of "theranostic" radiopharmaceuticals and the Company is currently developing a mid-late stage pipeline of products in oncology and rare diseases.

About the Role

This is a newly created opportunity within Telix. Reporting to the *VP, Global Regulatory Affairs*, the Global Regulatory Affairs Intelligence and Label Lead will develop and manage regulatory intelligence platforms and label compliance globally in alignment with Corporate and Group strategic goals. The role will hold responsibility for providing clear direction, regulatory guidance and regulatory expertise across the business related to labelling and regulatory intelligence and will serve as a key point of contact to advance Telix drug candidates.

The role may evolve as the business continues to grow however core responsibilities will include:

- Monitoring internal and external changes, trends, developments and other dynamics relevant to the regulatory environment that may influence the strategy and proposing action plans.
- Developing and leading key initiatives to support efficient global label development for worldwide submissions and approvals.
- Managing, reviewing & coordinating approval of all jurisdiction labels, ensuring labelling compliance.
- As SME, supporting responses from Global Health Authorities and related inspection activities.
- Leading regulatory label functions and interacting with cross-functional SMEs to manage pre and post approval for global Health authority submissions.
- Leading regulatory project management to manage activities in preparation of submissions.
- As an SME, keeping well-informed of key global guidance documents, regulations, or directives and monitoring, analysing and sharing relevant information on regulatory matters.

About You

You hold a Bachelors' degree (or higher) in a relevant discipline and have progressive and demonstrable experience in pharmaceutical drug development, label management operations, project management, and quality/regulatory lead (ideally with US FDA, TGA and EU filings). If you have experience with a biologics or radiopharmaceutical company, please highlight this on your application as it will be highly regarded.

You also have a global mindset and have experience working in a cross-functional team, ideally global. You are action-orientated and work well in a dynamic environment. Above all, you are passionate about your work and committed to Telix's mission.

Why work at Telix?

We are a dynamic, fast-growing biopharmaceutical company where employees have a shared purpose: to help people with cancer and rare diseases 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.