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

Job Description: Director – Global Regulatory Affairs, Operations
Type: Full Time
Location: Indianapolis
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.

Description

Due to rapid growth within Telix Pharmaceuticals, this is a newly created role. Reporting to the *SVP, Global Regulatory Affairs*, the Director – Global Regulatory Affairs will develop and manage regulatory strategy, operations and submissions in alignment with Corporate and Group strategic goals. The individual will hold responsibility for providing clear direction, regulatory guidance and operational regulatory expertise across the business and, to represent Telix at external vendor and Regulatory authority meetings. They will also serve as the key point of contact to advance Telix drug candidates.

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

- Development of regulatory strategy and operations capability to manage global submissions.
- Leading regulatory operations functions and interacting with cross-functional SMEs to manage pre and post approval for Health authority submissions.
- Leading regulatory project management to manage regulatory activities in preparation of submissions and translating regulatory requirements into actionable plans and documents
- Planning, writing, reviewing and publishing Health Authority document 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
- Supporting relationships with regulatory and legislative agencies and globally addressing the scientific aspects of the company's product portfolio.

To be considered, candidates should hold a Bachelors' degree (or higher) in a relevant discipline and have progressive and demonstrable experience in pharmaceutical drug development, operations, project management, and quality/regulatory lead (ideally with US and EU filings). Those with a biologics or radiopharmaceutical background will be highly regarded.

Please include a cover letter with your application.

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