



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

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**Job Description: Global Regulatory Affairs – Operations Manager**

**Type: Full Time**

**Location: USA**

**Date: Immediate**

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**About Telix Pharmaceuticals Limited**

Telix is an Australian public company (ASX: TLX) headquartered in Melbourne with international operations in Europe, the US and Japan. Our mission is to be a leading, global biopharmaceutical company that delivers on the promise of precision medicine through targeted radiation, and we are currently developing a portfolio of clinical-stage products that address significant unmet medical need in oncology and rare diseases.

**About The Role**

Telix Pharmaceuticals has created a new opportunity to continue to support Company and Group strategic goals. Reporting to the *Director, Global Regulatory Affairs - Operations*, the Regulatory Operations Manager will manage coordination of regulatory submission documents with internal stakeholders as well as external partners and vendors. This individual will hold responsibility for providing clear instructions, regulatory guidance and regulatory expertise across the business related to Investigational and Marketing applications.

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

- Collaborating with teams on regulatory requirements for compliant submissions
- Tracking and executing submission plans
- Managing the maintenance and business administration of global regulatory information management systems
- Participating on cross-functional teams to execute computer system validation of Regulatory Information Management Systems and EDMS
- Managing and executing the electronic publishing of regulatory submission documents (INDs, DMFs, Marketing applications, in eCTD and NeES, etc.)

**About You**

You hold a Bachelor's degree (or higher) in a relevant discipline and have progressive and demonstrable pharmaceutical drug development experience as it relates to Regulatory Operations. You have keen attention to detail, strong project management skills, and high-level of comfortability communicating with internal and external partners. You have proven knowledge of eCTD publishing and document management systems. You understand the collaboration of a global company and have flexibility to work outside of normal business hours as needed.

**Why Work at Telix?**

We are a dynamic, fast-growing biopharmaceutical company based in Melbourne, Australia that is continuing to grow our presence in the US. In addition to competitive salaries, we offer our employees an annual bonus structure, health and wellness benefits, and the opportunity to build (and hold) equity in the company. You will also be surrounded by an engaged and supportive team of colleagues who all have a shared purpose: to help people with cancer and rare diseases live longer, better quality lives.

Application deadline is Friday 6 May 2022.

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