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

Job Description: Specialist, Global Regulatory Affairs
Type: Full Time
Location: Indianapolis
Date: Immediate

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 vision is to be a leading, global biopharmaceutical company in the field of "theranostic" radiopharmaceuticals and we are currently developing a portfolio of clinical-stage products that address significant unmet medical needs in oncology and rare diseases.

Description

We are currently looking for a *Global Regulatory Affairs Specialist* to execute and manage assigned Regulatory tasks across the development pathway and to support operations and submissions. This is a dynamic role: the successful candidate will work closely with internal and external stakeholders to contribute to executing project specific regulatory submissions' plans aligned with Corporate and Group strategic goals.

Key accountabilities will include:

- Supporting regulatory process and operations planning to manage global regulatory process. Evaluating options to expedite document review and approval of drug submissions in conjunction with Global Regulatory Program leads within Global Regulatory Affairs.

- Leading project specific regulatory operations meetings, interacting with cross-functional SMEs to manage pre and post approval Health authority submissions and coordinating internal and external resources in preparation of interaction with the FDA and other health authorities in support of development programs and products.

- Managing regulatory activities in preparation of submissions and translating regulatory requirements into actionable plans and documents.

- Supporting regulatory operations SMEs, planning, writing, reviewing, and publishing Health Authority document submissions (e.g., internal presentations, INDs, NDA, DMF or Briefing Documents).

To be considered for the role, candidates require a minimum of a Bachelor of Science degree in biology and experience in a laboratory setting with either, drug development, operations, project management or quality/regulatory lead, preferably with biologics or radiopharmaceutical background. You must also demonstrate a desire to learn and interest in the drug development process.

This is an exciting time for Telix. Come join us on our mission to help patients with cancer live longer, better quality lives!

No agency submissions will be considered for this role.