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

Job Description: Director – Global Regulatory CMC
Type: Full Time
Location: US – East Coast Preferred
Date: Immediate

About Us

Telix Pharmaceuticals Limited ("Telix", the "Company") is an Australian public Company (ASX:TLX) headquartered in Melbourne with operations in Europe, the USA 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 position on the Regulatory team. Reporting to the *Global Head of Regulatory Affairs*, the primary responsibility of this role will be to ensure regulatory operations objectives are met and aligned with corporate objectives. The successful candidate will oversee the management of regulatory chemistry manufacturing controls strategy and execution. The role may evolve as the business continues to grow however core responsibilities will include:

- Providing CMC strategy and risk assessment preparation of CMC regulatory submissions
- Participating in regulatory agency interactions and contributing to written correspondence
- Understanding and interpreting Federal, State and Local regulations and supplemental guidance documents relevant to CMC regulatory submissions
- Collaborating with colleagues to plan and execute timely regulatory submissions
- Providing regulatory assessment in change management
- Representing Regulatory CMC on regulatory affairs and project teams as a SME
- Monitoring global health authority regulations, guidelines, and specifications including FDA, EMA, Health Canada and TGA to maintain regulatory submission compliance
- Serve as the sponsor point of contact to the health authority for CMC related queries.

About You

You hold a Bachelor of Science in chemistry, pharmaceutical science or another related field. If you have an advanced degree (PhD, Chemistry or Pharm D) – even better! You will also have experience in writing CMC sections for agency applications (i.e. IND, NDA, BLA, DMF) and demonstrated, progressive experience in the pharmaceutical industry. You possess comprehensive knowledge of drug development process, pharmaceutical technology, drug manufacturing processes, GMP and related issues.

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.