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

Job Description: Quality Assurance Manager, Americas
Type: Full Time
Location: Indianapolis preferred
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 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 Roles

This role will lead the Quality Assurance team for the Americas' region for Telix and contribute to the achievement of the Group's strategic quality goals by supporting the effective delivery of approved manufacturing, clinical and regulatory program plans for the Group's lead asset/s. The role will actively participate in and support the quality needs of the programs across the organisation's country jurisdictions and provide support to other TLX programs and other team members as required. The role will hold responsibility to:

- Prepare, review and approve documents within Telix Quality Management System (QMS)
- Maintain Quality Management Systems
- Participate in the preparation of the quality sections for regulatory submissions
- Participate in the management of internal quality audits on all Telix systems within the QMS, prepare reports and recommend solutions and close out activities under the guidance of the Director of Quality
- Engage and effectively manage CMOs
- Collaborate with production / manufacturing teams to monitor all work according to requirements under Telix quality system
- Review and evaluate all standard operating procedures, batch records and quality control results to ensure compliance with Telix quality and regulatory requirements

About You

You hold a Bachelor's degree in Sciences or Engineering and have strong experience in quality from pharmaceutical/biotechnology industry. Knowledge of applicable regulations within Australia, Japan, EU and the USA

- Management of projects and /or people
- Direct experience leading or contributing to FDA Pre-Approval Inspection
- Experience with sterility assurance principles
- Experience with quality risk management
- Radiopharamceutical industry experience preferred

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. There is

opportunity for individual growth and development and, an exciting pipeline of work.   This is a genuine opportunity to be part of an organisation which is entering its next phase of maturity.

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