POSITION DESCRIPTION

Job Description : Quality Manager
Type : Full-time
Location : East Coast – Indianapolis preferably
Date : Immediate

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited ("Telix", the "Company") is a 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 prostate, kidney and brain (GBM) cancer.

Description

To 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 through the creation, review and approval of key documents. Coordinate and assist in the active management and implementation of the Telix program/s as directed, including aspects of quality requirements. Actively participating in and supporting the quality needs of the programs across the organisation's country jurisdictions. Provide support to other TLX programs and other team members as required.

The role will be based in the USA and reports to the Global Director of Quality (based in Australia) but is expected to have extensive interaction with key staff in the USA and other international locations.

Key Accountabilities:

1. Prepare, review and approve documents within Telix Quality Management System (QMS).
2. Maintain quality requirements, quality system registers and training on Telix eQMS. Participate in writing and implementing Deviations, Investigations, CAPA and Change Control reports.
3. Participate in the preparation of the manufacturing and quality sections for regulatory submissions.
4. 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.
5. Participate in the management of supplier quality audits and agreements.
6. Engage and effectively manage CMOs (vendors involved in manufacture, analysis and release of drug) and other external suppliers to ensure delivery on time and complies with GMP/GCP/GLP requirements as directed, including 21CFR211 and 21CFR212.
7. 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. Release the clinical trial and/or commercial products as needed.

8. Provide support to cross-functional team.
9. Lead agency Pre-Approval Inspection readiness efforts for product launch at key CMOs.
10. Provide sterility assurance oversight at key CMOs for drug and biologic finished doseage form products.
11. Implement appropriate quality risk management principles to ensure a level of compliance commensurate with stage of product lifecycle
12. Personal development – maintain standard knowledge and make recommendations for professional development and training.

Education and Experience:

- BA/BSc
- 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

Personal Attributes:

- Commitment to the vision and mission of Telix
- Ability to work under pressure
- Ability to prioritise competive priorities/ objectives
- Ability and willingness to work collaboratively with global team members across multiple timezones
- Good understanding of the principles of GMP, GCP and GLP
- Understanding of basic medical terminology, understanding of Quality Management Systems within the pharmaceutical industry
- Ability to work independently and communicate effectively with internal and external stakeholders.
- Developed problem solving skills

Contact

For further details and information pertaining to compensation for the role, as well as expressions of interest, please contact Telix People and Culture at employment@telixpharma.com