POSITION DESCRIPTION

Job Description : Vendor Assurance Coordinator
Type : Full-time
Location : Australia – preferably Melbourne
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 quality vendors for manufacturing, clinical and other related activities for the Group's lead asset/s through the creation, review and approval of key documents and schedules. Coordinate and assist in the active management and implementation of the Telix vendor program/s as directed, to ensure that vendors are compliant and Telix is compliant to all appropriate and relevant regulatory requirements and best practice. Ensure that we have a risk-based vendor program reporting KPI on a regular basis and ensure effective corrective and preventive action is taken as necessary.

The role will be based in Australia 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) and eQMS, Master Control, in particular the vendor and audits module of Master Control.

2. Maintain quality requirements and quality system requirements are met for the vendor management and audits modules in MasterControl.

3. Participate in writing, implementing and approving Deviations, Investigations, CAPA and Change Control related to Telix vendors.

4. Maintain the Telix Global audit schedule and ensure that is effectively managed on time and on budget. Ensure that the Telix vendor management program is risk based and this is reflected in the yearly audit schedule. Where external auditors and internal Telix auditors conduct audits ensure these audits meet the agreed audit schedule and internal audit requirements.

5. Participate in the management and completion 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 or delegate.

6. Participate in the management of supplier quality audits (scope, audit plans, audits, audit reports, follow up of audit Nonconformances)./ Ensure other vendor assurance activities and supplier quality agreements are completed in a timely manner.

7. 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/GLP requirements as directed.

8. Collaborate with production / manufacturing teams to monitor vendor 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.

9. Identify required system and process gaps at Telix suppliers and facilitate corrective and preventive actions as required.

10. Personal development – maintain standard knowledge and make recommendations for professional development and training.

Education and Experience:

- BA/BSc
- Experience in quality from a regulated industry
- Knowledge of applicable regulations within Australia, Japan, EU and the USA

Personal Attributes:

- Commitment to the vision and mission of Telix
- Ability to work under pressure
- Ability to prioritise competitive priorities/ objectives
- Ability and willingness to work collaboratively with global team members across multiple timezones
- Basic understanding of the principles of GMP, GCP and GLP
- Understanding of basic medical terminology, understanding of Quality Management Systems within the pharmaceutical industry
- Demonstrated experience in development of SOPs and report writing
- 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