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

**Job Description : Senior Manager- API**
**Type : Full-time**
**Location : Europe, USA or Australia**
**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

The role involves the management of API manufacture and related activities undertaken at CMOs ensuring that Telix's technical, quality and regulatory requirements are met. A thorough understanding of the vendor, from quotations and contract follow-up and troubleshooting with our CMC partners is a key competence as all API manufacturing is outsourced.

The Senior Manager - API is responsible for providing expert contribution to the Manufacturing capabilities of Telix Pharmaceuticals, to support research and development of current and new radiopharmaceuticals and enhance capabilities in API manufacturing.

The location of the role is not defined however will be reporting to the Global Director of Manufacturing but is expected to have extensive interaction with key staff in the USA Belgium and other international locations.

**Key Objectives:** To contribute to the achievement of the company's strategic goals by managing all technical aspects of API manufacture and related activities for early/late-phase candidate programs in support of Telix's development and commercial aims.

## Key Accountabilities:

1. Management of API manufacture and related activities undertaken at CMOs ensuring that Telix's technical, quality and regulatory requirements are met. This includes:
   - Oversight of API manufacturing process development activities
   - Review of Master/Template batch production records and executed batch records
   - Oversight of manufacture and delivery of Telix's API's
   - Ensuring the timely supply of API for non-clinical and clinical development of Telix's drug candidates
   - Support of process validation activities including review and approval of protocols, evaluation of data and review and approval of reports
   - Outsourcing the testing of API to support associated analytical activities
   - Preparation of formal reports for internal and external use
2. Management of the delivery / processing of material for downstream activities including:
   - API product manufacture, release and stability testing
   - Management of the generation and review of the data package relating to API manufacture necessary for inclusion in IND/CTA and DMF/NDA/BLA/MAA submissions

- Supporting the selection of suppliers including the identification of appropriate technical providers and the generation of initial quality assessments
- tracking of expenditure to ensure delivery on time and within budget.

3. Sourcing of appropriate API vendors and backup vendors
4. Contributing to regular project meetings and providing verbal or written feedback to inform the team or management of progress.
5. Personal development – maintain standard knowledge and make recommendations for professional development and training.

**Education and Experience:**

- At least 5 years of relevant biotechnology/Pharmaceuticals manufacturing experience with at least 2 years in commercial drug development and production.
- Past experience in API sourcing
- Experience radiolabelling or radiochemistry (or equivalent) will be desirable but not necessary
- Post-graduate qualifications preferred (with a minimum of an honours degree in a relevant scientific subject plus demonstrated relevant experience)
- Thorough knowledge of GMP / Commercial Process development & validation
- Hands on experience with quality management systems used in the manufacturing environment including control of raw material and product specifications.
- A proven track record or relevant experience of API development and manufacturing processes.

**Competencies:**

- Experience in the validation of manufacturing API processes
- A background or awareness of analytical methods for APIs testing is desirable
- Strong interpersonal skills with experience of managing external CMO's.
- Strong focus on attention to detail is required to review manufacturing batch records
- Compilation of the CMC sections for inclusion in regulatory submissions
- A thorough understanding of the quality and regulatory requirements commensurate with the manufacture of APIs (and preferable sterile drug products) in a GMP environment.
- The ability to work as part of a team to deliver against aggressive timelines and targets.
- The flexibility to adapt to changing circumstances and manage activities to meet the needs of the business while maintaining a focus on quality
- Ability to travel and manage various time zones

## Contact

For further details and information pertaining to compensation for the role, as well as expressions of interest, please contact Telix human resources at employment@telixpharma.com or visit our careers page at www.telixpharma.com.