POSITION DESCRIPTION

TLX-JD029
Job Description : Sr. Biologics/Antibody Manager
Type : Full-time
Location : USA
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 leading the development of a range of Telix's antibody products globally – including delivering project management, CMC/manufacturing, clinical and regulator engagement as part of a multi-disciplinary team. The role reports to the President of Telix USA and Director of Operations (based in Australia) but is expected to have extensive interaction with key staff in Australia and other international locations. Telix's US headquarters are in Indianapolis but suitable candidates may be based anywhere in the continental United States.

Key Objectives: To contribute to the achievement of the company's strategic goals by managing all technical bioprocess activities for a late-phase biological candidate program in support of Telix's development and commercial aims.

Key Accountabilities:

1. Planning, coordination and active management of all biologics manufacturing activities conducted by external vendors for a late-phase program such as analytical method qualifications, antibody production, bioconjugate manufacture and fill/finish activities.

2. Biologics manufacturing strategy development including phase-appropriate vendor selection in line with technical, regulatory & quality requirements to suit clinical and commercial needs.

3. Effective management of outsourced manufacturing activities and tracking of expenditure to ensure delivery on time and budget.

4. Contributing to regular project meetings and providing verbal or written feedback to inform the team or management of progress.

5. Providing technical support to other TLX projects (or sourcing appropriate advice) to support radiochemistry process development and regulatory filings.

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Australia

Education and Experience:

- At least 10 years of relevant Biologic drug production experience with at least 2 years in commercial drug development.
- Post-graduate qualifications strongly 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.
- Formal regulatory/quality training is not required, but useful.

Competencies:

- Proven ability to effectively manage technical biologics manufacture projects conducted by external vendors.
- Project management skills including contracting, budget tracking/control and timeline management.
- Ability to multitask and coordinate parallel activities in a busy drug development program.
- Aptitude to learn, understand and contribute to technical subjects or to source further expert advice as necessary.
- Effective communication and reporting with excellent written/presentation skills
- Forward-thinking, proactive and creative. Natural problem-solver & team player.

Scientific & Pharmaceutical Knowledge Areas:

- A solid science background, with qualifications in biochemistry/ pharmacology/ chemistry preferred.
- Direct experience in biologics manufacturing processes including cell line development, upstream & downstream development, viral clearance studies, biologics-relevant assay qualification, bioconjugation and fill/finish.
- Knowledge of a range of scientific techniques from relevant subject areas such as biochemistry, pharmacology, proteomics, immunology.
- Understanding of regulatory requirements for biologics including preparation of documentation describing manufacture activities for regulatory filings and clinical study submissions.

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.