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

Job Description : Clinical Manufacturing Manager
Type : Full-time
Location : Indianapolis - remote
Date : Immediate

About Us

Telix Pharmaceuticals Limited (Telix) is an Australian public Company (ASX: TLX) headquartered in Melbourne with operations in Europe, the United States and Japan. Telix's mission is to be the leading, global radiopharmaceutical company in the field of "theranostic" medicine and the Company is currently developing an extensive early through to commercial stage pipeline of products in prostate, kidney and brain cancer.

About the Role

As a key member of the Global Operations and Manufacturing team, the Clinical Manufacturing Manager will support the CMC team in establishing, maintaining and managing Telix's manufacturing programs in various locations. Reporting to a US-based Director, this role will also work closely with key team members located globally, requiring some flexibility in hours. Key responsibilities include:

- Managing and conducting the development and review of technical documentation to support the development and optimization of cGMP manufacturing operations for radiopharmaceutical preparations with CMC and quality teams
- Managing approvals and reviewing technical documents, protocols and reports from CMOs
- Managing the daily activities with CMO vendors involved in the routine manufacture, analysis and release of drug for clinical studies
- Managing the technical transfer of manufacturing processes and analytical methods
- Ensuring the global harmonization of manufacturing processes for programs alongside the CMC team
- Managing the review of production and quality control records and the review and approval of SOPs, Change Controls, Material Specifications, CAPAs and other GMP related documents from CMOs
- Managing the preparation and/or review work orders, agreements and contracts for contract manufacturers, laboratories, vendors, and suppliers
- Managing the daily global logistics of raw materials, drug substance and drug product in clinical trials.

About You

You hold a Bachelors degree in Engineering, Chemistry or a related field and/or have progressive, equivalent practical experience in cGMP Manufacturing, Contract Manufacturing or Quality. You also have experience in drug development with key expertise in CMC (cGMP, biologics or small molecule manufacture, bioconjugation, radiolabelling or analytical methods) and clinical studies. Direct experience in Sterile Injectable Filling and Lyophilization of Drug Product/Substances manufacturing supporting both clinical and commercial products is a must and, experience working with International Contract Manufacturing Organizations is highly advantageous. You are also open to travelling (domestically and internationally) up to 30% of the time (though the role is Indianapolis-based and can be hybrid).

Why work at Telix?

We are a dynamic, fast-growing biopharmaceutical company working towards a shared mission: to help patients with cancer live longer, better quality lives. This is an exciting time for Telix and we are looking for like-minded, passionate professionals to join us on the journey.

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