Job Description

Job title	Quality Assurance Manager
Reports to	Departmental Heads
Department	Clinical Operations/Manufacturing/R&D
Location	London
Date last updated	26 OCT 2022

Job Purpose (main purpose & function)
This role will play a key role in establishing, growing, and maintaining the quality systems and processes to support the expansion of operations for GMP production and the Company in general. Additionally, ensuring GMP, GCP, GLP[GxP] and other regulatory requirements relating to clinical trial manufacture are met and maintained for ATIMPs (Advanced Therapy Investigational Medicinal Product).

Core accountabilities / responsibilities:

(Job function, specific duties, level of accountability for business results, areas of decision making)

- QA review and approval of procedures e.g., Master Batch Records, Change, Risk Assessments and any other relevant GMP documentation.
- Manage and Perform batch documentation review activities of manufactured drug products.
- Deviation, investigation and Corrective and Preventative Actions (CAPA) management.
- Review and Approve Out of Specification Investigations.
- Support with Qualification & Validation Activities.
- Support the creation, maintenance, and continuous improvement of the company Quality Management System (QMS).
- Ensure compliance with GxP and regulatory requirements including overlap with manufacturing systems relating to manufacturing and clinical trials.
- Perform internal audits to determine compliance with GMP and identify areas for improvement.
- Perform External Audit/supplier qualification of Vendors and service providers

Line Management responsibilities:
▪ None

Budgetary responsibilities:
▪ None

Experience & knowledge:
▪ Few Years Working in QA in a Biotech/Biologics/ATMP GMP Environment, ideally on MIA(IMP) Licensed Site. ▪ 3+Years of Technical Knowledge of Aseptic Manufacturing Processes, Sterility Assurance and Laboratory Techniques, understanding of UK, EU and US GMP Requirements. ▪ Experience within a GMP Quality Assurance Department. ▪ Understanding of Clinical Trial Directives/Regulations. ▪ Experience in Manufacturing and QC GMP Environments, Qualification and Validation Plans, Activities and Reports & external audits. ▪ Experience of training staff to GMP, GCP and GLP expectations.

Person Specification:
• Bachelor's degree in a relevant discipline (preferred) • A strong can do and positive attitude • Able to work flexibly during the working week and or weekend as required • Good Interpersonal skills along with pragmatic view of timelines and deadlines and understanding the need for flexibility • High level of work organisation, self-motivated and autonomous with strong professional integrity • Able to work with external collaborators and stake holders the company is engaged with • Proactive

- Private Medical Insurance (includes gym discounts)
- Life Assurance at 4x basic salary
- Company Pension Scheme

- 25 days Holiday (on top of usual bank holidays)
- Enhanced Sick Pay and Group Income Protection
- Enhanced Family Friendly Policies (Maternity, Paternity, Adoption, etc.)
- Employee Assistance Programme
- Performance-based Company Bonus Scheme
- Incentive Shares Scheme

About Leucid Bio Ltd

Leucid Bio is a clinical stage biotech advancing CAR T-cell therapies for hard-to-treat cancers. Founded to translate 20 years of pioneering CAR-T research led by Dr John Maher at King's College London (King's), Leucid Bio has developed next generation cell therapies based upon Dr Maher's novel approach, in which the CAR structure has been redesigned to recapitulate the lateral distribution of signalling domains as observed in natural immune receptors. The technology gives properties to the CAR-Ts that enable them to consistently outperform previous generations of CAR-T therapies in pre-clinical studies; enhancing T-cell potency and generating a persistent long-term response with reduced toxicity.