## Job Description

Leucid

| Job title | CMC Specialist |
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| Reports to | Associate Director CMC |
| Department | Manufacturing Operations |
| Location | London and Manufacturing Sites as required (Within London) |
| Date last updated | 07 JUL 2022 |

**Job Purpose (main purpose & function)**

The position on offer allows the applicant an opportunity to become involved in cutting edge translational research at the interface between science and clinical medicine and reflects bench to bedside concept. The applicant will be involved in the manufacture of cutting edge CAR-T cell products used to treat a multitude of solid tumours.

The post holder will use their experience and specialist knowledge in Good Manufacturing Practice (GMP), immune cell culture, immune cell purification or other methods to take responsibility for developing and delivering the manufacturing/quality control processes for novel cutting-edge clinical trial studies.

Also, a significant attribute of this job would be to perform process development /Quality control allowing for seamless clinical trials authorisation by generating data for regulatory document submission along with building product knowledge.

**Core accountabilities / responsibilities:**

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

Responsible for delivering a highly specialist technical service by leading in the manufacturing or QC of immune cell therapy products for the clinical needs of participants on current and future clinical trials.

Responsible for maintaining an up-to-date knowledgebase of Immunological products used in Adoptive Cellular Therapies.

Capable of working independently and as part of a team.

Required to work with other team members the Manufacturing team to develop multicolour phenotyping, and cell-based Quality control assays.

Required to work with collaborators by taking pre-clinical ideas and technology transferring to the manufacturing centre and ensuring phase appropriate GMP compliance.

Lead Validation and qualification procedures for processes and equipment's used for manufacture/quality control of immune cell products.

Provide specialist knowledge of the latest developments within cell and gene therapy manufacturing science and technology.

Provide specialist knowledge of Immunology of human cells and suggesting continuous process improvement ideas.

Take responsibility for developing and implementing independently controlled documents: Investigational Medicinal Product Dossiers, Product Specification Files, Batch Manufacturing Records and Standard Operating Procedures (SOPs) for Production activities in the manufacturing centre.

Hands-on experience operating in an aseptic GMP Unit manufacturing ATMPs will provide you with the skills to meet these developing needs.

Be proficient in advanced scientific data analysis. Knowledge of specialist scientific software e.g., R, Flow Jo, Graphpad Prism is desirable.

**Line Management responsibilities:**

- None

**Budgetary responsibilities:**

- None

**Experience & knowledge:**

**Either:**

Degree in Biological Sciences with some experience of ATIMP manufacturing or development in an academic or industrial setting.

**Or:**

2+ years' experience in the manufacture /development of ATIMPs or stem cell products

Hands on experience of functionally closed system cell culture of primary human cells (e.g., Closed system Bioreactors for cell culture)

Experience of cell culture

**Desirables**

Experience of isolation of primary human cells

Experience of developing and qualifying ATIMP's from pre-clinical ideas up to cGMP manufacturing

Experience of equipment /process validation

Experience of process scale up and Out

Experience in process development, developing CQA/CPPs for ATIMPs

Extensive experience of batch manufacture of ATIMPs and Specials

| **Person Specification:** |
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| A strong can do and positive attitude.<br><br>Able to work flexibly during the working week and or weekend as required.<br><br>Good Interpersonal skills along with pragmatic view of timelines and deadlines and understanding the need for flexibility.<br><br>High level of work organisation, self-motivated and autonomous with strong professional integrity<br><br>Proactive<br><br>Ability to learn new concepts and scientific ideas |

| **About Leucid Bio Ltd** |
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| 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. |

**APPROVAL SIGNATURES (print name and signature)**

Manager: Date:

CEO: Date:

Human Resources: Date: