Position Description

Job Title	Quality Control Operations Manager
Location / Department	Cell Therapies Pty Ltd Level 9, 305 Grattan Street Melbourne VIC 3000
Reporting To:	Analytical System & Technology Manager
Main Purpose of Position	The QC Operations Manager is responsible for the daily operations of the quality control team ensuring the successful quality control testing associated with cell therapy products. This position requires a strong understanding of GMP regulation, quality control test method and ability to lead teams in high-compliance environment.
Direct Reports	Quality Control Scientist shift Leaders Quality Control Scientists
Job Level	Level 4 - Works to achieve operational targets with significant impact on departmental results. Works independently under limited supervision.
Key Relationships	**Internal:** • Quality • Production Manager • Facility • Supply Chain **External**: Peter MacCallum Cancer Centre and Centre for Blood Cell Therapies stakeholders and sponsors
Skills and Experience	Essential • BAppSc or BSc in life sciences or equivalent industry experience • 5+ years' experience in GMP environment preferably in quality control associated with cell therapy products • Highly proficient in QC testing platforms as related to cell therapy products including flow cytometry, PCR, potency and safety test • Strong understanding of scientific principle of all procedures, assay validity, requirements, abort and invalid assay and OOS procedures • Excellent problem solving, organisational and communication skills • Proven leadership experience in quality control environment • Demonstrated decision making ability • Strong understanding of equipment qualification and maintenance

	• A strong desire to build a cohesive team through leadership, mentoring, effective delegation, fostering growth and collaboration within the team • Ability to work effectively in a fast paced dynamic environment with priorities ensuring
Skills and Experience	Desirable • Knowledge and experience of PIC/S annexes 1 and 2 • Participated in audits (client, regulatory etc)
Key Accountabilities	**Demonstrated by / Key Performance Indicators**
Operational Management	• Responsible for ensuring teams are appropriately trained and following quality control and GMP procedures • Execute and manage daily quality control activities to ensure the on-time and efficient quality control testing therapy products, maintaining high standards of quality and compliance. • Manages daily coordination of QC lab scheduling and tracking to ensure in process and final product testing is performed to meet the business deadline • Monitor and manage the use of resources to maximise efficiency and minimise downtime • Collaborates with other units within CTPL facilities team to ensure that the GMP meets all operational requirements and remains fit for purpose.
Quality Control Management Activities	• Quality control testing, and documentation consistent with Cell Therapies and GMP standards • Participates in internal audits and audit preparation for both external clients and TGA(Government) • Adheres to quality systems and procedures for Cell Therapies • Leverages specialised knowledge and experience to identify opportunities for improvement and recommend enhancements to quality control activities, driving ongoing optimization and efficiency. • Support investigations and required documentation of quality control non-conformances and out of specification. • Assist in implementing corrective and preventive actions (CAPA) for deviations in the quality control testing, ensuring effective resolution and continuous process improvement. • Play an active role in implementation of new quality control testing procedure or project offering guidance and support to the team throughout

Leadership	• Foster a culture of operational excellence and continuous improvement, encouraging innovation and problem-solving • Participates in educational activities including attendance at internal/external training, clinical and scientific meetings. • Maintains and develops own specialised skills • Embraces skill extension, innovation and change • Fosters a psychologically safe environment and continuously demonstrates Cell Therapies values
Quality Control Scientist activities (when required)	• Procedures are performed exactly as specified by documented SOPs, Batch Records and Quality Assurance requirements. • Processes are recorded and documented according to cGMP requirements and are presented for authorisation. • Uses expertise to find areas for improvement and suggest changes that enhance testing practices, improving efficiency and performance.

Health, Safety and Environment Obligations	• Implement HSE Objectives and Targets within their areas of responsibility and promote a positive health and safety culture. • Ensure that the location of work, work performed, and equipment used within their area of responsibility is safe and without risk to health and safety so far as is reasonably practicable. • Ensure adequate resourcing is provided to implement HSE requirements and ensure a safe system of work. • Take an active lead in the monitoring and review of HSE matters within their area of responsibility to ensure that HSE Policies and Procedures are implemented and look for opportunities to improve those policies and procedures. • Provide information, instruction, training, and supervision to all Workers in their area of responsibility to ensure a safe system of work. • Ensure that all foreseeable hazards and incidents are identified and reported as soon as is reasonably practicable • Where required, ensure that all reported hazards and incidents are investigated in a timely manner and the depth of investigation commensurate to the HSE risk. Ensure that all identified risks associated with hazards or incidents are eliminated or minimised as far as is reasonably practicable. • Participate in the development, implementation and supervision of return to work plans • Assist injured employees to return to their pre-injury duties as soon as practicable after a work related injury in accordance with their return to work plan. • Provide accurate internal and external reporting of HSE performance.