Position Description

Job Title	Quality Assurance Manager
Location/ Department	Cell Therapies Pty Ltd Level 9, 305 Grattan Street Melbourne VIC 3000
Reporting To:	Direct: Director of Quality
Main Purpose of Position	Reporting to the Director of Quality, the Quality Assurance Manager is responsible for driving, establishing, and maintaining overall Quality Operations to ensure GMP compliance for the manufacturing and distribution under license of cellular and tissue therapy products. The position requires risk-based decision-making capability, leadership competency, and an ability to contribute to a collegiate and positive team environment.
Direct Reports	Senior QA Associate – 1 QA Associates – 3 Document Administrator - 1
Key Relationships	Internal: Supervised by: Director of Quality Liaises with: Senior Operations Manager, QA Clinical Manager, AS&T Manager, Production Manager, Project Managers, Facility Manager, Validation Manager, IS Manager, Manager, Supply Chain Manager External: Liaises with: Clients, Peter Mac
Skills and Experience	Essential • Tertiary qualifications in Life Sciences. • Minimum 3 years previous experience in senior roles in QA or Manufacturing. • Advanced knowledge of GMP as applied to Clinical and Commercial phase products. • Demonstrated decision making ability in relation to high-value, high risk products. • Highly effective communicator. • Demonstrated ability to influence at all levels of the business. • A diligent and quality-driven approach. • Ability to multitask and work autonomously as well as in teams.

Skills and Experience	Desirable • Excellent communication and presentation skills. • Previous QA or manufacturing experience in GMP biologics manufacturing, cell therapy manufacturing / Quality experience highly regarded. • Previous experience in leading a team of direct reports. • In-depth, operational understanding of a GMP manufacturing facility and the interlinking between functional groups. • Demonstrated ability in developing and managing scientific and technical staff. • Previous experience working within a CDMO environment and associated client interactions highly desirable.

Key Accountabilities	Demonstrated by/ Key Performance Indicators
Annual Objectives	As set by the Annual Performance plan.
QA Operations	• Ensuring day to day requirements for manufacturing support are met. • Providing QA input on technical manufacturing issues
Quality Management System	• Oversight and approval for QA programs including Deviation, CAPA, Change Control, Suppliers, and Internal Audits. • Oversight of the batch review process. • Batch Release of commercial and clinical trial products. • Collation and assessment of Quality metrics
Management	• Management of communication with external clients, ensuring escalation and turnaround timelines are met. • Managing a team of QA Specialists including responsibility for development plans
Works as part of a team	• Communicates and cooperates with co-workers to ensure work is completed within appropriate timeframes in a harmonious manner.

<u>Health, Safety and Environment obligations</u>	• 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.