Position Description – Quality Manager

Position Title:	Quality Manager – Blood Transplant and Cell Therapy
Reporting To:	[Insert Reporting Position Title]
Location:	[Insert Location]
Classification:	[Insert Classification/Level]
Agreement:	[Insert Agreement/Contract]

Primary Purpose

The Quality Manager is responsible for the development, implementation, and continuous improvement of the Quality Management System for the Blood Transplant and Cell Therapy (BTCT) program.

They will provide oversight, guidance and leadership to applicable institution-wide processes and quality goals related to BTCT donors, recipients, and/or cellular products.

The Quality Manager will facilitate and bridge the understanding between clinical considerations, ethnicity and cultural understanding in the context and complexity of Quality and Safety Frameworks.

The role ensures compliance with relevant jurisdictional regulatory and accreditation standards, including FACT-JACIE, NPAAC, Therapeutic Goods Administration (TGA), Food and Drug Administration (FDA), ISO, and other applicable regulatory standards.

Key Responsibilities

Additional responsibilities may arise within the scope of this role. While the quality manager retains oversight of all key responsibilities, tasks may be delegated to suitably qualified and trained individuals.

Quality Management

1. Establish, develop, implement, and maintain a robust quality management system to support the program and the institution, as applicable, ensuring commitment to patient safety and positive outcomes. This will be achieved through the following.
    a. Establish policies, procedures, guidelines, and work instructions describing all activities of the program, including relevant forms to record processes and capture critical data.

a) Develop and maintain a document management system to identify and control critical documents governing all aspects of the program, ensuring adherence to an established review cycle.

b) Oversee and monitor critical quality improvement processes, including deviations or occurrences, CAPAs, audits, change management, risk assessments, and document control to drive quality goals.

c) Coordinate and assist with investigation of adverse events and non- conformances including root-cause analysis and advise management on the effectiveness of risk management strategies.

d) Actively identify, assess, and manage risk, communicating and escalating to the service director, nursing directors and hospital executive as appropriate.

e) Prepare, review and approve qualification, validation and verification plans for new or existing; processes, facilities and environments, equipment and software to ensure compliance with defined quality criteria.

f) Manage records of equipment installation, operation and process qualification, maintenance and service, and ensuring compliance with prescribed service schedules.

g) Conduct supplier qualification audits, approve suppliers and maintain an approved supplier list.

h) Develop and maintain internal and external audit programs to identify and minimise risk, identify opportunities for improvement and activities are compliant with regulatory requirements.

- Design, schedule and perform internal audits of the quality management system, incorporating all aspects of the program including donor identification and assessment, collection, transport, processing and product assessment, storage and release, infusion and follow-up.

i) Lead preparations and coordinate accreditation and regulatory inspections, ensuring readiness and coordination of responses.

2. Prepare reports, applications and submissions pertaining to Quality activities as required, including an annual report of assessment of the quality management system.

Regulatory Compliance

1. Ensure compliance with applicable regulatory standards, including FACT-JACIE, NPAAC, NSQHS, TGA, OGTR, FDA, ISO and other local/international standards and law including Stem Cell Donors Australia.
2. Act as the primary liaison with regulatory bodies, submitting necessary documentation for approvals and maintaining required accreditation.
3. Direct and manage the overall [FACT or other accrediting body] accreditation process.
    a) Collect required documentation and resources to manage and submit accreditation applications.
    b) Collaborate with key stakeholders within, and external to, the program regarding compliance measures needed to complete accreditation processes.
    c) Manage all communication with accrediting bodies regarding applications and maintenance of accreditation.
    d) Negotiate, manage and lead all accreditation and inspection visits.
    e) Fulfil all data analysis and reporting requirements for accrediting body.
4. Monitor and interpret changes in regulatory requirements through gap analysis and communicate their implications effectively to stakeholders, identifying appropriate action to meet new requirements.
5. Maintain knowledge of advancements in cell therapy, transplantation, and related regulations.

Training and Development

1. Develop and deliver training programs to ensure staff are informed of quality and regulatory requirements.
2. Maintain records and schedule of staff training, competency and continual education to ensure compliance with training requirements.
3. Provide annual GxP training.
4. Participate in continual education relating to cellular therapy and quality management, annually.

Stakeholder Engagement

1. Closely collaborate with the Program Director to coordinate quality activities.
2. The Quality Manager will need to interact across boundaries as regulatory standards specific to Transplant (FACT-JACIE) will connect and impact on services across the system.
    a) Collaborate and consult with multiple areas of the institution including, nursing, medical, data managers and scientists, allied health, patient safety and quality, and ancillary supplemental staff to implement and refine processes for risk minimisation and quality improvement.
3. Coordinate Quality and Audit meetings to review progress and address quality-related concerns, identifying and including all relevant stakeholders to attend.
4. Provide advice and guidance on new or updated regulatory requirements and standards, including the implications and implementation.
5. Support the delivery of safe patient care and the consumers experience including seeking feedback and participating in continuous safety and quality improvement activities.

Continuous Improvement

1. Contribute to and support the BTCT program to identify and implement opportunities for improvement in quality systems and processes.
2. Report and investigate incidents and occurrences, performing root cause analysis to identify opportunities for improvement.
3. Use data-driven insights to enhance safety, efficiency, and effectiveness across the program.
4. Coordinate data collection and manage, analyse, and report to the service director regarding key performance and clinical indicators.
5. Annually evaluate the effectiveness of the quality management plan and accurately report outcomes and indicators, using this report to drive change and improvement.
6. Use a risk-based approach to interpret data and resolve issues in operations and related quality events.

Key Challenges

- Balancing multiple regulatory and accreditation requirements against efficient service delivery.
- Driving quality improvement in a highly specialised and evolving field.
- Coordinating quality efforts and fostering involvement across diverse stakeholders, including clinicians, laboratory staff, other medical services and departments, allied health and external bodies.
- Implementing new or revised standards within limited resources.

Essential Selection Criteria

1. Tertiary qualification in a relevant field (e.g., biomedical science, nursing, or healthcare management) or significant experience in a related domain.
2. Experience in quality management within healthcare.
3. Knowledge of relevant regulatory requirements, including FACT-JACIE, TGA, NPAAC, ISO, OGTR and NSQHS standards.
4. Strong problem-solving, analytical, and decision-making abilities, with experience managing critical quality events.
5. Demonstrated ability to work both independently and collaboratively within a multidisciplinary team.
6. Capacity to negotiate effectively with internal and external stakeholders in the development and implementation of projects and monitor achievement of targets and deadlines.
7. Excellent leadership, communication, interpersonal skills with high level spoken and written English skills. Proven ability to build relationships and motivate others.
8. Proven conceptual, analytical and problem-solving skills including the ability to analyse data and interpret information from different sources.

Desirable Criteria

- Experience in haematopoietic cell transplantation, and cellular therapy processes including apheresis, cell processing, and patient care.
- Familiarity with quality management software (e.g. Q-Pulse).
- Certification in quality or quality processes.
- Post Graduate qualifications in a related field.

Additional Requirements

- Criminal record check and health assessment clearance.
- Commitment to continuous professional development and adherence to organizational values.