



creating
possible

Position Description

Position Title:	Quality Manager
Salary Range:	MCRI Professional & Administrative Salaries – Level 7-8
Reporting Manager:	Cord Blood Bank Director
Direct Reports:	1
Home Group:	Blood Development

Who are we?

The Murdoch Children's Research Institute (MCRI) is home to significant scientific discoveries. We believe there is an answer, a cure or a better treatment for every childhood condition — and we're determined to find it.

We are a diverse team of world-leading researchers, doctors, engineers, and hardworking professionals in operational and scientific services from all corners of the world with one shared goal — to transform child health worldwide.

Our strength lies in our partnership and co-location with The Royal Children's Hospital and the University of Melbourne — the Melbourne Children's Campus. This partnership model amplifies opportunities to quickly translate research into clinical care.

MCRI includes a wholly owned subsidiary, the Victorian Clinical Genetics Services (VCGS), a private not-for-profit organisation. VCGS is a specialist childhood, prenatal and adult genetics service. VCGS provides an integrated genetic consultation, counselling, testing and diagnostic support service to children, adults, families and prospective parents.

Together, we share a powerful vision:

Our purpose:

We want all children to have the opportunity to live a healthy and fulfilled life.

Our 2025-2030 Strategy:

Towards Precision Child Health

We exist for a **purpose**, to give all children an opportunity to live a healthy and fulfilled life.

We **value** individuals with the determination to solve complex problems, who thrive on collaboration, and who embody honesty, respect, and accountability.

Our **goals** centre around an inclusive environment in which our people can undertake bold research that can be scaled for impact through strategic partnerships.

We **operate** in a collaborative environment, tackling problems in teams, across disciplines and across boundaries.

Our research generates evidence underpinning changes that **impact** the lives of children in our hospitals, in our communities, and across the globe

What is it like to work for us?

We are dedicated to ensuring a positive working environment that values all backgrounds and experiences. We cultivate an inclusive culture that is underpinned by equal opportunity for all and a culture based on respect, consideration, and dignity. We invest in developing our People and fostering an environment where learning and development is central to our staff reaching their full potential.

The Institute is also committed to the safety of children and young people and takes a zero-tolerance approach to all forms of child abuse, exploitation, and harm. The Institute prioritises child safety in our decision-making at all levels of the Institute and supports our employees to understand and enact their safeguarding responsibilities.

About BMDI Cord Blood Bank

The BMDI Cord Blood Bank (CBB) is a joint initiative of MCRI, The Royal Children's Hospital and the Fight Cancer Foundation (formerly Bone Marrow Donor Institute). It is a member of the AusCord network, linking three public cord blood banks and the Australian Bone Marrow Donor Registry. Its core activity is the collection, production and release of high quality cord blood units for patients unable to find a suitable bone marrow donor who need transplant tissue. The CBB is located at The Royal Children's Hospital, Melbourne, and includes the cord blood processing laboratory, cryo-storage facilities and main administrative and quality system control offices, with collection centres also located at The Royal Women's Hospital and Frances Perry House.

Position Overview

The role of the Quality Manager is to maintain the quality management system of the BMDI Cord Blood Bank and ensure that it complies with the requirements for licensing of the Cord Blood Bank and Collection Centres by the Therapeutic Goods Administration (TGA) and the Federation for the Accreditation of Cellular Therapy (FACT).

The BMDI Cord Blood Bank Quality Manager also collaborates with the Quality Managers of other AusCord Cord Blood Banks to promote conformity and efficiency of the quality management system across the Australian Cord Blood Bank network.

Key Accountabilities

General

- Maintain the Quality Management System (QMS) of the BMDI Cord Blood Bank (CBB) to ensure compliance with TGA licensing requirements and FACT–NetCord accreditation standards.
- Ensure the Cord Blood Bank and associated collection centres operate in compliance with GMP and FACT–NetCord standards.
- Oversee quality documentation and processes to ensure alignment with regulatory requirements and quality management principles.
- Collaborate with Quality Managers across the AusCord network to promote consistency, efficiency, and the sharing of best practices.
- Participate in quarterly AusCord CBB meetings, management meetings, and staff meetings.

Duties

- Act as the Quality Nominee for the BMDI CBB TGA licence.
- Manage and contribute to the annual review and submission of the Technical Master File to the TGA.
- Lead TGA and FACT–NetCord audits and coordinate audit activities.
- Prepare and submit audit responses to the TGA and FACT–NetCord.
- Serve as the primary liaison between the CBB and the TGA.
- Manage document preparation, review, approval, and control, including AusCord documentation.
- Oversee change control processes and implementation activities.
- Manage internal and supplier audit programs.
- Coordinate corrective and preventive action (CAPA) processes.
- Oversee equipment maintenance, calibration, and qualification activities.
- Manage product recall procedures and readiness.
- Coordinate temperature mapping of critical storage equipment and facilities.
- Manage the implementation, review, and renewal of agreements and contracts.
- Maintain the approved critical supplier list.
- Prepare and present Quality Management System reports for Management Review Meetings.
- Prepare quarterly reports on Cord Blood Bank activities for Commonwealth reporting requirements.
- Prepare the annual Quality Management Report.
- Participate in validation and qualification studies as required.
- Contribute to laboratory, management, and national Cord Blood Bank meetings.
- Facilitate GMP training at the annual CBB Staff Education Day.

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- Support the management of agreements and contractual arrangements.
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Selection Criteria

Essential

- Degree qualification in Applied Science, Health Sciences, or a related discipline.
- Relevant expertise gained through a combination of experience, training, and/or professional accreditation.
- Demonstrated advanced facilitation and stakeholder engagement skills.
- Advanced proficiency in the Microsoft Office Suite.
- Proven ability to lead, mentor, and support staff to achieve project and operational outcomes.
- Excellent interpersonal, written, and verbal communication skills, with experience engaging a broad range of stakeholders.
- Demonstrated ability to exercise sound judgement, initiative, and influence.
- Strong knowledge of Quality Management Systems, Good Manufacturing Practice (GMP), and TGA regulatory requirements relating to blood and blood products.
- Demonstrated ability to interpret and apply relevant legislation, regulations, and standards to maintain and continuously improve quality systems.
- Strong organisational, analytical, and reporting skills, including experience preparing submissions and reports for regulatory bodies.
- Demonstrated ability to work collaboratively and communicate effectively with multidisciplinary professional groups.

Desirable

- Experience working within a GMP-compliant quality environment.
 - Knowledge of, or experience with, FACT-NetCord Standards for Cord Blood Banking.
 - Formal qualifications or training in Quality Management Systems.
 - Demonstrated management and leadership experience.
 - Experience using electronic Quality Management Systems (eQMS), such as Q-Pulse.
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Conditions of Employment

- Keeping children safe is our highest priority. We maintain rigorous safeguarding standards and employ comprehensive screening processes to ensure the safety of the children we work with. This includes mandatory screening processes for all successful candidates, including:
 - Valid Working with Children Check (or equivalent)
 - Satisfactory criminal record check
 - The right to reside and work in Australia and you meeting any applicable visa conditions
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Health, Safety & Wellbeing

- We are committed to providing and maintaining a working environment which protects the health, safety and wellbeing of our people, partners and the community
 - Employees conducting duties on behalf of MCRI are expected to meet the environment, health and wellbeing requirements and responsibilities specifically required for the role
 - We are committed to supporting children in their right to be safe and adhere to the responsibilities we have to ensure their protection and safety as per the Child Safety Policy
 - The Institute is committed to the safety of children and young people, and takes a zero-tolerance approach to all forms of child abuse, exploitation and harm. The Institute prioritises child safety in our decision-making at all levels of the Institute and supports our employees to understand and enact their safeguarding responsibilities
 - We are committed to a diverse, inclusive workplace where all staff are supported to reach their full potential, regardless of gender, career status, age, disability, cultural background, religion or sexual orientation
 - Specified positions may be subject to medical review to ensure that the inherent requirements of the role can be undertaken safely
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