

A more equitable world through better health.



POSITION DETAILS

TITLE	Quality Systems Manager
CLASSIFICATION	Level 9 - 10: \$131,964 - \$141,390 + super + salary packaging (negotiable depending on experience)
LOCATION	85 Commercial Road, Melbourne 3004
REPORTS TO	Director, Burnet Diagnostics Initiative
DIRECT REPORTS	2 x Quality Assurance Specialists
LAST UPDATED	October 23

POSITION SNAPSHOT

The Quality System Manager directs the development, implementation, and administration of Burnet Institutes quality management systems, including the Diagnostics Initiative's (BDI) under ISO9001. This position is the primary contact for all external bodies on quality related matters and will recommend to the organisation specific activities and resources required to support the Burnet Institute's activities and ensure it conducts its scientific activities to the highest quality standards.

KEY RESPONSIBILITY AREAS

1. QUALITY SYSTEMS	<ul style="list-style-type: none">• Develop and implement quality assurance and regulatory strategies for the BDI to ensure compliance with international Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) and ISO9001 certification. It will also involve review of ISO13485 and implementation of practices to comply with this standard if added in the future.• Direct and oversee the implementation of quality systems in other relevant Burnet teams as required.• Define, establish and ensure compliance with all internal standard operating procedures consistent with international quality standards for design, development and manufacturing; assist functional group supervisors and staff in the development of standard operating procedures.• Approve all functional group standard operating procedures and monitor the development, approval, periodic review, revision, version control and historical archival of all standard operating procedures.• Direct the internal auditing function to ensure that the operations of all functional groups are compliant; oversee external auditing; manage and establish priorities for the quality assurance staff responsible for audits.• Serve as an internal resource to address and resolve any questions or issues of a regulatory nature; consult with organisation regarding matters of regulatory strategies and matters of legal risk.• Direct and implement training programs consistent with organisational needs in accord with current international ISO regulations and/or principles of quality management systems.• Stay abreast of evolving regulatory trends that are relevant and ensure that appropriate action is initiated.• Represent the Burnet teams and its affiliates' interactions with external organisations including Customers and Contract manufacturers, the TGA or other regulatory bodies; serve as a primary contact during all audits and approve responses to audit reports.• Integrate quality system requirements with current OHS requirements.• Liaise with Facilities team to implement quality system into laboratory practices.
2. DATA MANAGEMENT	<ul style="list-style-type: none">• Ensure that all relevant data and documentation are kept up to date and accessible in relevant servers and in online project management tool.• Serve as an external approver to review and sign off on online laboratory notebooks and ensure all data is being logged and captured correctly.
3. TRAVEL	<ul style="list-style-type: none">• Travel to attend relevant project specific conferences to keep abreast of developments in the field.
4. REPORTING	<ul style="list-style-type: none">• Provide verbal and written reports to senior management in meetings and via project management software including resource review.• To contribute to reporting on government and commercial funding provided including milestone reports, as required.

	<ul style="list-style-type: none"> Prepare reports for internal and external auditing as required.
5. PEOPLE LEADERSHIP	<ul style="list-style-type: none"> Ensure participation of all staff in the People Development Framework (PDF) to enhance performance and identify training, professional development and career coaching needs. Ensure compliance within the group in relation to all required compliance training including online and face to face training. Manage HR issues with the support and guidance of HR as needed. Manage leave within the group to ensure leave balances are kept within institute policy guidelines. Coach and support staff and students.
6. TRAINING	Responsible for completing all required training in line with the position / role.

KEY SELECTION CRITERIA

QUALIFICATIONS / EXPERIENCE / KNOWLEDGE / ATTRIBUTES		
1.	Bachelor's degree in life science or engineering	Essential
2.	Minimum 5 years of experience working in a senior quality role	Essential
3.	Significant managerial experience in a quality, laboratory, or medical device manufacturing position at a company that has a formal quality system (e.g., ISO 9001, ISO 13485 or GMP)	Essential
4.	Significant experience in vaccines and/or diagnostics and/or therapeutic product development from preclinical to clinical stages and knowledge of quality and/or regulatory requirements	Essential
5.	Laboratory quality management, audit and accreditation expertise (NATA training in GLP)	Essential
6.	Demonstrated experience managing, supporting, and developing staff	Essential
7.	Practical experience in project management tools and systems	Essential
8.	Excellent relationship management and communication skills	Essential
9.	Demonstrated capacity to work independently, exercising strong judgment, decision making and problem-solving skills	Essential
10.	Awareness of occupational health and safety and risk management issues in a range of settings	Preferable

About Burnet Institute

Vision

A more equitable world through better health.

Purpose

Create and translate knowledge into better health so no-one is left behind.

Values

Respect, Equality, Inclusiveness, Diversity.

Who we are

Burnet Institute is an Australian-based medical research and public health institute and international non-government organisation that is working towards a more equitable world through better health.

What we do

We are committed to creating and translating knowledge into better health so no-one is left behind. We do this through engaging with and understanding the needs of a broad range of communities and stakeholders to develop laboratory-based and social research programs, policies and products that deliver better health outcomes.

Where we work



Priority countries:

Australia | Papua New Guinea | Myanmar

We also support and contribute to research and public health programs in other Asian, Pacific and African countries.

Australian Institute for Infectious Disease (AIID)

Bringing together Burnet Institute, The University of Melbourne, and the Doherty Institute with funding from the Victorian Government, the AIID is a visionary initiative designed to protect Australia and the region against infectious disease and future pandemics. As part of this exciting collaboration, a newly established state-of-the-art facility will be the new home of Burnet.



OCCUPATIONAL HEALTH AND SAFETY

The Burnet has a commitment to providing a safe and healthy workplace in accordance with the Occupational Health and Safety Act 2004. All staff are obliged to take all reasonable care to ensure that their actions do not place themselves or others at risk.

OTHER REQUIREMENTS

The Burnet Institute is a child safe organisation. The incumbent of this position will be required to undergo a Police Check and possibly a Working with Children Check as a condition of employment. The types of contact with children can be viewed [here](#). This position involves the following contact with children (any individual aged under 18 years):

CONTACT TYPE

No Contact With Children

ENQUIRIES

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