

A more equitable world through better health.



POSITION DETAILS

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| TITLE | Senior Quality Assurance Specialist |
| CLASSIFICATION | Professional Level 7: \$105,569- \$114,277 + super + salary packaging |
| TIME FRACTION | 1.0 |
| CONTRACT TYPE | Permanent |
| LOCATION | The Alfred Centre, 99 Commercial Road, Melbourne 3004, Boonwurrung Land |
| REPORTS TO | Quality Manager, Research Translation |
| DIRECT REPORTS | Nil |
| LAST UPDATED | May 25 |

POSITION SNAPSHOT

The Senior Quality Assurance Specialist is a member of the Burnet Diagnostics Initiative (BDI) Quality Team and assists research laboratories to perform industry-ready research and to develop easily transferable in-vitro diagnostic assays and therapeutic products to meet practical health needs. This exciting and interesting role is focused on implementing, maintaining, monitoring, improving and auditing the BDI ISO 9001 certified, or equivalent, quality management system (QMS). This role also includes assisting laboratory staff in the design and development and provision of the BDI products and services, preparation of documentation for laboratory procedures, reagents, and equipment as well as the identification and assessment of Health and Safety risks associated with the work described in the documentation.

KEY RESPONSIBILITY AREAS

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|-----------------------------|--|
| 1. QUALITY ASSURANCE (QA) | <ul style="list-style-type: none">To assist the Quality Manager in developing, implementing, maintaining and improving the QMS, ensuring compliance with ISO 9001 and all other applicable statutory and regulatory standards.To perform administrative and quality-related activities, individually and/or as part of a team, that contribute to the efficient and effective operation of the BDI QMS and laboratories.To coordinate and perform document control activities.To plan and conduct internal quality audits and prepare internal audit checklists and reports.To assist in the recording and investigation of non-conformities, and the identification, implementation and timely close out of corrective and preventive actions.To design and lead continuous improvement initiatives for the ISO 9001 QMS across the laboratory work streams.To raise and assist in managing change requests, including the identification, implementation and timely closeout of actions.To assist with the Management Review process including slide pack preparation and taking minutes.To review laboratory notebooks, product manufacturing and QC records, attend project meetings and review quality project documentation as required.To develop and implement (incl. training of laboratory staff) laboratory QA processes and procedures with and across teams.To lead or assist with embedding laboratory practice described in the laboratory documentation across the covered laboratories.To design, perform, coordinate and/or monitor activities for laboratory equipment maintenance, verification, validation, calibration, servicing, and repair.To assist with the quality control of laboratory products and services.To perform clinical trial/study quality assurance activities as required (e.g. monitoring and quality control).To assist with, and participate in, 3rd party audits and conduct external and clinical study site audits as required. |
| 2. LABORATORY DOCUMENTATION | <ul style="list-style-type: none">To assist laboratory staff in the recording of laboratory work and the preparation of documentation for laboratory procedures, reagents, and equipment in accordance with the requirements of the BDI's QMS.To liaise with research staff and the Facilities and Laboratory Operations team to assist in identifying and assessing Health and Safety risks associated with the work described in the laboratory documentation. |

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| 3. DATA MANAGEMENT | <ul style="list-style-type: none"> To ensure that all relevant data and documentation are kept up to date and accessible on relevant servers and software applications. To ensure data management practices adhere to ISO 9001 standards. |
| 4. REPORTING | <ul style="list-style-type: none"> To provide verbal and written reports to management in meetings and via project/task management software when required. |
| 5. TRAVEL | <ul style="list-style-type: none"> To travel to attend relevant work specific events (e.g. seminars, meetings or courses) to keep abreast of developments in the areas of work. Some travel for external and clinical study site audits may be required. |
| 6. OUT OF HOURS CONTACT | <ul style="list-style-type: none"> To respond to and manage temperature-controlled equipment alarms outside work hours as required. |
| 7. TRAINING | <ul style="list-style-type: none"> Responsible for completing all required training in line with the position/role. |

KEY SELECTION CRITERIA

| QUALIFICATIONS / EXPERIENCE / KNOWLEDGE / ATTRIBUTES | |
|--|------------|
| 1. Bachelor of Science/Biomedical Science degree in a biological or clinical laboratory discipline. | Essential |
| 2. Several years of experience in a quality assurance role. | Essential |
| 3. Experience in working within an ISO 9001 certified environment or other standard/regulations (e.g. ISO 17025, ISO 13485, ISO 15189, GMP). | Essential |
| 4. Experience with internal quality auditing. | Essential |
| 5. Knowledge of techniques and tools for process improvement. | Essential |
| 6. Strong laboratory and technical skills. | Essential |
| 7. Experience with immunoassays, protein production and chemistry, molecular biology, clinical and/or translational research. | Essential |
| 8. Proficiency in the use of electronic laboratory notebooks (ELNs). | Preferable |
| 9. Awareness of laboratory OHS 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)

Burnet Institute is a foundation partner of the AIID, a visionary initiative designed to protect Australia and the wider Asia-Pacific region against major global health issues and pandemics. The state-of-the-art facility is expected to be open in 2028 and will be home to Burnet Institute, Doherty Institute and The University of Melbourne, with funding from the Victorian Government. In joining this exciting initiative, Burnet will remain an independent medical research institute.



BURNET 2030 STRATEGY

The Burnet 2030 Strategy focuses on growing our impact, placing equity at the centre of what we do, and paying close attention to the effects of a rapidly changing climate and environment. Our point of difference is our technical breadth—from laboratory-based discoveries to field research, to commercialisation to development programs; all to progress toward a more equitable world. This is what sets us apart. Our Strategy will also see us invest in our people, building our position as the aspirational workplace within the sector with ethical values and a culture committed to fostering talent for future leadership and rewarding careers.

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

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):

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|---------------------|--------------------------|
| CONTACT TYPE | No Contact With Children |
| LOCATION OF CONTACT | N/A |

ENQUIRIES

For enquiries, please contact careers@burnet.edu.au