# Position Details

## Research Projects- CSOF4

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| The following information is for applicants |
| Advertised Job Title | Quality Assurance Associate |
| Job Reference | 92889 |
| Tenure | Indefinite  |
| Salary Range | AU$89,680 to AU$101,459pa (pro-rata for part-time) + up to 15.4% superannuation |
| Location(s) | Melbourne, Clayton, Victoria |
| Relocation Assistance | Will be provided to the successful candidate if required |
| Applications are open to | Australian/New Zealand Citizens and Australian Permanent Residents Only |
| Position reports to the | Team Leader, Quality Operations |
| Client Focus – Internal | 60% |
| Client Focus – External | 40% |
| Number of Direct Reports | 0 |
| Enquire about this job | Contact Tram Phan at tram.phan@csiro.au or phone 9662 7327 |
| How to apply | Apply online at <https://jobs.csiro.au/> Internal applicants please apply via **Jobs Central**If you experience difficulties when applying, please email careers.online@csiro.au or call 1300 984 220. |

**Acknowledgement of Country**

CSIRO acknowledges the Traditional Owners of the land, sea and waters, of the areas that we live and work on across Australia. We acknowledge their continuing connection to their culture and pay our respects to their Elders past and present. View our [vision towards reconciliation](https://www.csiro.au/en/about/Indigenous-engagement/Reconciliation-Action-Plan).

**Child Safety**

CSIRO is committed to the safety and wellbeing of all children and young people involved in our activities and programs. View our [Child Safe Policy](https://www.csiro.au/en/about/policies/child-safe-policy).

### Role Overview

The role of Research Projects staff in CSIRO is to collaborate collaborates in scientific and technological activities with other research staff usually by assisting with detailed planning, undertaking or assisting with experimental, observational or technology development work, and in carrying out the more practical aspects of the work.

This role provides expert services in the field of Quality Assurance (QA) to support manufacture of vaccine and biotherapeutic biologics for use in preclinical and early human clinical (Phase I and II) studies. The position reports to the Team Leader of Quality Operations in CSIRO Biomedical Manufacturing and brings knowledge of Quality Assurance frameworks for development of new biologic products. The role plays a key function in maintaining the Quality System and supporting the overall Quality approach in manufacture of clinical materials as a step in the pathway towards eventual registration in regulated global markets. The successful candidate will be a team player with highly developed written and verbal communication skills.

### Duties and Key Result Areas

* Provide active support to all aspects of the Quality Management System, including the conceptualisation and implementation of a Quality framework. Intended responsibilities include formulation and drafting of the group Quality Manual, establishment of training programs for staff, and the generation and maintenance of documents that are essential in operations.
* Participate in the design of QA frameworks by adapting existing systems to meet new requirements as commensurate with growth of the group project portfolio. The scope of responsibilities will include programs across multiple laboratories encompassing both manufacturing and testing activities.
* Participate in activities for maintenance of an electronic Quality Management System (eQMS), and implementation of new modules, that supports core activities such as documentation control, establishment and management of controlled changes within operations, and the establishment and tracking of corrective action plans as part of continuous improvement.
* Under general direction of the QA Manager, serve as a point of accountability for inspections conducted by both customers and officers representing national and global regulatory agencies. Provide support to the regulated biomanufacturing function by leading activities in the realm of inspection readiness and management of post-inspection corrective action plans.
* Work in partnership with the leadership team, QA Manager, and other subject matter experts to conduct risk assessments, batch documentation review for release, and evaluate and independently close out deviations encountered in operations.
* Apply sound Quality Risk Management principles and judgement in the investigation of underlying issues of complex nature that contribute to observed deviations and non-conformances encountered in manufacturing and testing operations. Work independently to bring such investigations to satisfactory conclusion with outcome to improve performance of the Quality System.
* Work in a guided manner to engage with clients as an authority on matters related to the QA function in the CSIRO regulated biomanufacturing program. Act as a trusted advisor and compliance champion, utilising knowledge of client’s business and understanding of their underlying needs.
* Communicate openly, effectively and respectfully with all staff, clients and suppliers in the interests of good business practice, collaboration and enhancement of CSIRO’s reputation.
* Work collaboratively as part of a multi-disciplinary manufacturing team to carry out tasks in support of CSIRO’s scientific objectives.
* Adhere to the spirit and practice of CSIRO’s Code of Conduct, Health, Safety and Environment procedures and policy, Diversity initiatives and Making Safety Personal goals.
* Other duties, as directed.

## **Selection Criteria**

#### Essential

*Under CSIRO policy only those who meet all essential criteria can be appointed.*

1. A bachelor’s degree in science or equivalent with relevance to quality management.
2. Comprehensive experience in conducting QA activities to support manufacture of biotechnology products with a minimum of two (2) years’ experience.
3. Good organisation and decision making skills with high level of attention to details.
4. Ability to work independently and as part of a team.
5. Sound knowledge of MS Office applications is required for performance of core duties.
6. Demonstrated experience in the application of Quality Risk Management principles in the investigation of manufacturing deviations with complex underlying causes. Demonstrated ability to make decisions based on risk and provide sound justification.
7. Experience in the application of tools for investigating process deviations (such as fishbone analysis, human error analysis)
8. Sound knowledge and practical experience in the operation of a Quality Management System/Pharmaceutical Quality System i.e. AS/NZS ISO 9001:2015 or equivalent.
9. Sound knowledge and practical experience of QA frameworks for regulated manufacture of human health medicines, such as the Australian TGA, APVMA, US FDA and EMA.
10. First-hand experience in preparing for and/or providing representation in external audits by regulatory bodies.

## **Desirable**

1. Experience in technology transfer
2. Knowledge of manufacturing processes for early phase biotechnology products for human and/or veterinary applications.
3. Working knowledge of eQMS, Materials and Resources Planning (MRP), and Laboratory Information Management Systems (LIMS).

## **Required Competencies**

* **Teamwork and Collaboration:** Cooperates with others to achieve organisational objectives and may share team resources in order to do this. Collaborates with other teams as well as industry colleagues.
* **Influence and Communication:** Uses knowledge of other party's priorities and adapts presentations or discussions to appeal to the interests and level of the audience. Anticipates and prepares for others’ reactions.
* **Resource Management/Leadership:** Allocates activities, directs tasks and manages resources to meet objectives. Provides coaching and on the job training, recognises and supports staff achievements and fosters open communication in the team.
* **Judgement and Problem Solving:** Investigates underlying issues of complex and ill-defined problems and develops appropriate response by adapting/creating and testing alternative solutions.
* **Independence:** Recognise and makes immediate changes to improve performance (faster, better, lower cost, more efficiently, better quality, improved client satisfaction).
* **Adaptability:**Copes with ambiguity or situations that lack clarity. Adapts readily to changing circumstances and new responsibilities (which may include activities outside own preferences) in the interests of achieving team objectives. Recognises the need for and undertakes personal development as a result of changes.

Special Requirements

The successful candidate will be asked to obtain and provide evidence of a National Police Check or equivalent. Please note that people with criminal records are not automatically deemed ineligible. Each application will be considered on its merits.

## **About CSIRO**

We solve the greatest challenges through innovative science and technology. Visit [CSIRO Online](http://www.csiro.au/) and CSIRO [Manufacturing](https://www.csiro.au/en/Research/MF) for more information.

CSIRO is a values-based organisation.  In your application and at interview you will need to demonstrate behaviours aligned to our values of:

* People First
* Further Together
* Making it Real
* Trusted