# Position Details

## Research Projects- CSOF3

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| The following information is for applicants | |
| Advertised Job Title | Quality Assurance Associate |
| Job Reference | 80210 |
| Tenure | Indefinite  Full-time |
| Salary Range | AU$66,163 to AU$84,207 pa (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, GMP Manufacturing |
| Client Focus – Internal | 60 |
| Client Focus – External | 40 |
| Number of Direct Reports | 0 |
| Enquire about this job | Contact John Power at john.power@csiro.au or phone 0457 120 794 |
| 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](mailto: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 area 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)

### Role Overview

Research Projects staff in CSIRO collaborate 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 GMP manufacture of vaccine and biotherapeutic candidates for use in preclinical and early human clinical (Phase 1) studies. The position reports to the Team Leader of GMP in CSIRO Biomedical Manufacturing and brings knowledge of Quality Assurance frameworks for the development of new human biologic products. The role plays a key function in maintaining the Quality Manual and supporting the overall Quality approach in the 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 Manual including the conceptualisation and implementation of a Quality system to support GMP and related ISO and GMP-like activities. The scope of responsibility includes writing sections of the Quality Manual to include GMP facility design and qualification, the establishment of GMP training programs for staff, and the generation and maintenance of documents that are essential in GMP operations.
* Participate in activities for design, implementation, and maintenance of an electronic Quality Management System (eQMS) that supports core GMP activities such as documentation control, establishment and management of controlled changes within GMP operations, and the establishment and tracking of corrective action plans as part of continuous improvement.
* In partnership with 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 GMP function by leading activities in the realm of inspection readiness and management of post-inspection corrective action plans.
* Participate in the design of new QA frameworks by adapting existing systems to meet new requirements commensurate with the growth of the GMP project portfolio. The scope of responsibilities will include GMP programs across multiple laboratories encompassing both manufacturing and testing activities.
* Work in partnership with the GMP Team Leader, QA Manager, and other subject matter experts to conduct risk assessments, batch review and release, and evaluate planned deviations and nonconformances encountered in GMP operations.
* Work in a guided manner to engage with clients as an authority on matters related to the QA function in the CSIRO GMP program. Act as a trusted advisor and compliance champion, utilising knowledge of clients’ 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.

## **Required Competencies:**

* **Teamwork and Collaboration:** Proactively seeks and considers the ideas and opinions of others from within and outside the team to help form decisions, plans or actions.
* **Influence and Communication:** Puts forward ideas by presenting factual information supported by data, definitions, examples, illustrations or other aids, which will assist in conveying meaning.
* **Resource Management/Leadership:** Provides instruction and assists other staff to complete allocated tasks and activities.
* **Judgement and Problem Solving:** Identifies and considers the implications of a range of available alternatives in order to select the most appropriate response to problems of a familiar or recurring nature.
* **Independence:** Recognise and makes immediate changes to improve performance (faster, better, lower cost, more efficiently, better quality, improved client satisfaction).
* **Adaptability:**Willingness to change ideas or perceptions based on new information, contrary evidence or other people's points of view. Prepared to try out different approaches.

## **Selection Criteria**

#### Essential

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

1. A bachelor’s degree in science or business management with relevance to quality management.
2. Experience in conducting QA activities to support GMP manufacture of biotechnology products.
3. Direct knowledge and practical experience in the principles of quality management as defined by AS/NZS ISO 9001 2015.
4. First-hand experience in preparing for and providing representation in external audits by regulatory bodies.

## **Desirable:**

1. Knowledge of QA frameworks for regulated manufacture of human health medicines, such as the Australian TGA, US FDA and EMA.
2. Knowledge of frameworks for technical transfer of new manufacturing technologies from Development to Manufacture (for example: Failure Mode Effect Analysis)
3. Industry-based training in the validation of equipment and computing systems to support GMP manufacture.

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. To find out more visit us [online](http://www.csiro.au/)!

Find out more about CSIRO [Manufacturing](https://www.csiro.au/en/Research/MF)