# Position Details

## Research Projects- CSOF4

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| The following information is for applicants | |
| Advertised Job Title | Quality Assurance Assistant |
| Job Reference | 80221 |
| Tenure | Indefinite |
| Salary Range | AU$87,068 to AU$98,504 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 biologics for use in preclinical and early human clinical (Phase I and II) studies. The position reports to the Team Leader of GMP in CSIRO Biomedical Manufacturing and brings knowledge of Quality Assurance frameworks for development of new human biologic products. The role plays a key function in maintaining the Quality Manual 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 Manual including the conceptualisation and implementation of a Quality system to support GMP and related ISO and GMP-like activities. Assume responsibility for writing sections of the Quality Manual to include GMP facility design and qualification, establishment of GMP training programs for staff, and the generation and maintenance of documents that are essential in GMP operations.
* Make significant contributions to the Validation program for a newly constructed GMP facility. The QA Associate will apply their expert knowledge of biotechnology manufacturing science in the task of authoring Validation protocols and reports for equipment items, facilities, and newly developed manufacturing protocols. Responsibilities will include the provision of expert QA knowledge in validation of Quality Control test procedures, as conducted under a GMP framework.
* Under general direction of the Team Leader and QA Manager, the QA Associate will accept responsibility for scheduling and completing major sections of the Validation Master Plan. This will involve allocating and directing tasks of other CSIRO colleagues and contractors, where appropriate.
* Apply sound scientific principles and judgement in the investigation of underlying issues of complex nature that contribute to observed deviations and non-conformances encountered in GMP manufacturing and testing operations. Work with limited guidance to bring such investigations to satisfactory conclusion with outcome to improve performance of the Quality System.
* Participate in the design new QA frameworks by adapting existing systems to meet new requirements as commensurate with growth of the GMP project portfolio. The scope of responsibilities will include GMP programs across multiple laboratories encompassing both manufacturing and quality control 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 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 practise, 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 business management with relevance to quality management.
2. Comprehensive experience in conducting QA activities to support GMP manufacture of biotechnology products.
3. Demonstrated experience in drafting Validation protocols and reports and associated quality documents.
4. Demonstrated experience in the application of scientific principles in the investigation of manufacturing deviations with complex underlying causes.
5. Demonstrated knowledge of QA frameworks for regulated manufacture of human health medicines, such as the Australian TGA, US FDA and EMA.
6. First-hand experience in preparing for and providing representation in external audits by regulatory bodies.

**Desirable**

1. Knowledge of frameworks for technical transfer of new manufacturing technologies from Development to Manufacture (for example: Failure Mode Effect Analysis).
2. Experience in the application of tools for investigating process deviations (such as fishbone analysis, human error analysis)
3. Industry-based training in validation of equipment and computing systems to support GMP manufacture.
4. Experience in providing QA support in facility operation, manufacturing, and quality control teams in a biotechnology setting

## **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.

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* 1. People First
  2. Further Together
  3. Making it Real
  4. Trusted

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