# Position Details

## Research Projects- CSOF4

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| The following information is for applicants | |
| Advertised Job Title | Quality Control Scientist |
| Job Reference | 75981 |
| Tenure | Indefinite  Full-time |
| Salary Range | AU$85,361 to AU$96,573 pa (pro-rata for part-time) + up to 15.4% superannuation |
| Location(s) | CSIRO 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 | The job title for the line manager of this position |
| Client Focus – Internal | 10% |
| Client Focus – External | 90% |
| Number of Direct Reports | 0 |
| Enquire about this job | Contact Dr Olan Dolezal via email at olan.dolezal@csiro.au or phone +61 3 9662 7229 |
| 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. |

### Role Overview

Research Projects staff in CSIRO 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.

The purpose of this position is to provide support in the field of Quality Control (QC) testing to for GMP manufacture of vaccine and biotherapeutic candidates for use in preclinical and early human clinical (Phase 1) studies. The position reports to the Director of GMP in CSIRO Biomedical Manufacturing and brings knowledge of Analytical test methodologies to support the development of new human biologic products. The successful candidate will be a team player with highly developed written and verbal communication skills.

The positions are based at Clayton, Melbourne but in the first year the appointees may be required to work at Parkville, or at non-CSIRO sites elsewhere in Melbourne to gain experience in additional aspects to the cGMP manufacture of biologics.

### Duties and Key Result Areas:

* Provide support in all aspects of Quality Control for testing of biological products including physiochemical, biological, microbiological, and compendial techniques.
* Work on programs that enable qualification, validation, and transfer of new methods into the GMP testing laboratory. This includes writing sections of analytical validation protocols and reports for transfer of both drug substance and drug testing methods.
* Support the implementation and maintenance of a LIMS for sample tracking and data recording within a GMP environment.
* Assume ownership of testing equipment and maintain the same equipment in a GMP-ready state. Work in partnership with the supervisory staff to maintain the testing laboratory in a state of cGMP compliance and audit-readiness.
* Engage with internal partners as an expert in selected analytical methods as they pertain to the analysis and testing of new vaccines and recombinant proteins.
* 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, often regionally dispersed research team, and business unit 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:** 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.

## **Selection Criteria**

#### Essential

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

1. A relevant degree in fields of Analytical Chemistry, Biochemistry, Microbiology or related field.
2. Industrial experience (2-5 years) in the development of analytical methods for characterisation and quantification of recombinant proteins and antigens for regulated markets.

## **Desirable:**

1. Advanced degree in Analytical Chemistry, Microbiology, or Biochemistry.
2. Working knowledge of the requirements for assay qualification, validation, and transfer within a GMP framework.
3. Direct experience and working knowledge of the GMP frameworks for manufacture of vaccines and biotherapeutics with global regulators such as the Therapeutic Goods Administration, US Food and Drug Administration, or European Medicines Authority.
4. Experience in sample tracking through a Laboratory Information System (LIMS)

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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