# Position Details

## Research Scientist/Engineer- CSOF6

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| The following information is for applicants |
| Advertised Job Title | Research Scientist – Quality Control Manager |
| Job Reference | 75942 |
| Tenure | Indefinite Full-time  |
| Salary Range | AU$115,605 to AU$135,467 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 | Protein Production Team Leader, CSIRO Biomedical Manufacturing |
| Client Focus – Internal | 10% |
| Client Focus – External | 90% |
| Number of Direct Reports | 0 |
| Enquire about this job | Contact Dr John Power via email at john.power@csiro.au or phone +61 3 9545 2472 |
| 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. |

### Role Overview

The role of Research Scientist Staff in CSIRO is to conduct innovative research leading to scientific achievements that are aligned with CSIRO’s strategies. You may be engaged in scientific activity ranging from fundamental research to the investigation of specific industry or community problems. You will have the opportunity to build and maintain networks, play a lead role in securing project funds, provide scientific leadership and pursue new ideas and approaches that create new concepts.

The purpose of this position is to provide leadership in the field of Quality Control (QC) testing to support GMP manufacture of vaccine and biotherapeutic candidates for use in preclinical and early human clinical (Phase I and Phase II) studies. The position reports to the Protein Production Team Leader in CSIRO Biomedical Manufacturing and brings advanced 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 role is based at Clayton, Melbourne but in the first year the appointee 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 leadership in all aspects of Quality Control for testing of biological products including physiochemical, biological, microbiological, and compendial techniques.
* Serve as the point of accountability for qualification, validation, and transfer of new methods into the GMP testing laboratory. This includes writing of analytical validation protocols and reports for transfer of both drug substance and drug testing methods.
* Implement and maintain a LIMS for sample tracking and data recording within a GMP environment. Data consolidation, analysis, and reporting to support continuous improvement initiatives.
* Assume ownership of testing equipment and maintain the same equipment in a GMP-ready state. Work in partnership with the CSIRO QA Lead to maintain the testing laboratory in a state of cGMP and maintain a state of compliance and audit-readiness in all Analytical laboratory functions.
* In partnership with team members and subject matter experts, use expert knowledge of biological testing requirements to generate specifications for GMP manufacture in accord with Preclinical and Phase I and Phase II project requirements.
* Engage with clients as an authority on all matters related to the Quality Control in the CSIRO GMP program. Act as a trusted advisor, utilising knowledge of client’s business and understanding of their underlying needs. Contribute to the planning of QC components in new project proposals.
* Participate in project scoping and planning activities that shape the future direction of the Quality Control function. Anticipate industry and/or community needs and market direction through client liaison/networking and identify and adapt quickly to changes.
* 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:** Identifies critical stakeholders and influences them via an influential third party, for example through an established network, to gain support for sometimes contentious proposals/ideas.
* **Resource Management/Leadership:** Sets up and maintains effective and efficient work teams and manages performance and resources, to achieve objectives. Chooses appropriate management strategies and communication styles to maintain high levels of motivation and productivity. Gives feedback for development purposes and provides support and direction for improvement.
* **Judgement and Problem Solving:** Anticipates and manages problems in ambiguous situations. Develops and selects an appropriate course of action and provides for contingencies. Evaluates, interprets and integrates complex bodies of information and draws logical conclusions, synthesises proposals and defends options with reasoned arguments.
* **Independence:** Assesses the risk and opportunity of identified strategies, options and actions. Overcomes problems and setbacks in achieving goals. Invariably includes consideration of value-added future impact on bottom line when determining the optimal and efficient use of resources.
* **Adaptability:**Demonstrates flexibility in thinking and adapts to, and manages, the increasing rate of organisational change by adjusting strategies, goal and priorities.

## **Selection Criteria**

#### Essential

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

1. A relevant degree in fields of Chemistry, Biochemistry, or related field.
2. Demonstrated industrial experience in the development of analytical methods for characterisation and quantification of recombinant proteins and antigens for regulated markets.
3. Experience is writing Standard Operating Procedures
4. Knowledge of the design and management of Quality Control frameworks for testing of new biotherapies including validation and transfer into GMP operations.

## **Desirable:**

1. Advanced degree in Analytical Chemistry or Biochemistry.
2. Direct experience and working knowledge of the GMP frameworks for manufacture and testing of vaccines and biotherapeutics with global regulators such as the Therapeutic Goods Administration, US Food and Drug Administration, or European Medicines Authority.

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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