# Position Details

## Research Projects- CSOF6

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| The following information is for applicants | |
| Advertised Job Title | Analytical Lead, Regulated Biomanufacturing |
| Job Reference | 99357 |
| Tenure | Specified term up to 3 years, Full time |
| Salary Range | AU$131k - AU$153k per annum (pro-rata for part-time) plus up to 15.4% superannuation |
| Location(s) | 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 |
| Position reports to the | Team Leader Quality Control |
| Client Focus – Internal | 20% |
| Client Focus – External | 80% |
| Number of Direct Reports | 0 |
| Enquire about this job | Patrick James, patrick.james@csiro.au |
| 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 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 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. At senior levels, Research Projects staff may be involved in providing consulting services, science and technology management and/or industry liaison.

The purpose of this position is to provide leadership in the field of Analytical Development for GMP testing of novel vaccines and biotherapeutics for use in preclinical and human clinical studies. The position reports to the Team Leader, Quality Operations in CSIRO Regulated Biomanufacturing 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.

### Duties and Key Result Areas

* Provide advanced scientific leadership in all aspects pertaining to testing of biological products including physiochemical, biological, protein chemistry, and compendial techniques. Apply specialist expertise to solve complex problems within the discipline across a diverse range of projects.
* Ensure that client needs are met and play a leading role in the effective transfer of new technology to industry. Serve as the point of accountability for project teams with scope that includes development, qualification, verification, and transfer of new methods into the CSIRO Biologics Quality Control laboratory. This includes hands-on leadership of experimental development programs and writing of protocols and reports for qualification and transfer of new test protocols.
* Lead assigned strategic initiatives. Extend existing scientific knowledge of experimental design to facilitate the development of new perspectives in the field. For example, implementation of new technologies that streamline analytical development, improve throughput, or enhance the quality of services provided to CSIRO customers.
* Play a key advisory role in decisions concerning the scientific direction of the discipline within the program. Evaluate new analytical technologies to determine feasibility/fit/value delivered to CSIRO Analytical development projects. This includes data consolidation, analysis, and reporting to support continuous improvement initiatives.
* In partnership with project team members and subject matter experts, use expert knowledge of biological testing requirements to generate specifications for GMP manufacture in accord with Preclinical, Phase I (phase-dependent) and Phase II project requirements.
* Act as a trusted advisor and demonstrate creativity to determine and anticipate client project needs. Engage with clients as an expert on matters related to Analytical Science in the CSIRO regulated Biomanufacturing program. Act as a trusted advisor, utilising knowledge of client’s business and understanding of their underlying needs.
* Participate in project scoping and planning activities that shape the future direction of the function. Anticipate industry needs and market direction through client liaison/networking and identify and adapt quickly to changes.
* Assume ownership of 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 compliance and audit-readiness in assigned Analytical laboratory functions.
* Constructively mentor and coach junior scientists and early-career colleagues in partnership with other leads
* 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

## **Selection Criteria**

#### Essential

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

1. A relevant degree or experience in fields of Chemistry, Biochemistry, or related.
2. Comprehensive industry experience in the development of complex analytical methods for characterisation and quantification of recombinant proteins and antigens for regulated markets.
3. Expert knowledge of the design and management of Quality Control frameworks for testing of new biotherapies including verification, qualification and subsequent transfer into GMP operations.
4. Technical expertise and hands-on experience with state-of-the-art LCMS and other instrumentation used in the characterisation of proteins and biologics.
5. Experience in leading staff on projects, including setting up effective and efficient teams.
6. Extensive experience influencing third parties through communication to gain support for potentially contentious proposals.

## **Desirable**

1. 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.
2. Managing a collective of staff, including overseeing career development.
3. Demonstrated ability to represent the organisation in external scientific or technological forums and examples of establishing and leading such forums or panel discussions.

## **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 team 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, goals and priorities.

Special Requirements

Appointment to this role may be subject to conditions including the provision of a national police check as well as other security/medical/character clearance 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 [Manufacturing](https://www.csiro.au/en/work-with-us/industries/manufacturing) for more information.

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

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