# Position Details

## Research Scientist/Engineer- CSOF6

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| The following information is for applicants | |
| Advertised Job Title | Regulated Operations Engineer |
| Job Reference | 101310 |
| Tenure | Indefinite; Full time |
| Salary Range | AU$131,113.00 - AU$153,639.00 per annum (pro-rata for part-time)  plus, up to 15.4% superannuation |
| Location(s) | Melbourne (Clayton), VIC |
| Relocation Assistance | Will be provided to the successful candidate if required |
| Applications are open to | Australian/New Zealand Citizens and Australian Permanent Residents currently residing in Australia |
| Position reports to the | Regulated Operations Lead, regulated Biomanufacturing |
| Client Focus – Internal | 80% |
| Client Focus – External | 20% |
| Number of Direct Reports | 0 |
| Enquire about this job | Contact Jay Pillai via email at jay.pillai@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 Scientist/Engineer staff is to conduct innovative research leading to scientific achievements that are aligned with CSIRO’s strategies. The Research Scientist/Engineer may be engaged in scientific activity ranging from fundamental research to the investigation of specific industry or community problems. The Research Scientist/Engineer 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 Regulated Operations Engineer will provide technical validation and engineering support to the Regulated Operations team within CSIRO’s Biomedical Manufacturing project, part of the National Vaccine and Therapeutics Laboratories. This program includes a GMP-compliant manufacturing facility and associated Quality Control (QC) laboratories.

The role is critical for ensuring the compliant, efficient, and reliable operation of the facility, which produces clinical trial materials for Phase 1 and Phase 2 studies. Key responsibilities include contributing to facility operations, equipment qualification, process validation, and continuous improvement initiatives. The incumbent will ensure alignment with applicable regulatory requirements and internal quality standards.

The position requires collaboration with engineers, scientists, and project leaders across CSIRO to provide technical advice and support during project development and implementation phases.

### Duties and Key Result Areas

* **Facility & Equipment Support**
  + Support troubleshooting and resolution of facility, plant and equipment issues impacting production.
  + Coordinate with external vendors and internal stakeholder for timely repairs and preventive maintenance.
  + Establish project specifications by studying facility design, customer requirements, performance standards and completing technical studies.
  + Directly support regulatory audits by presenting operations related information to auditors. Maintain facility documentation in a state of inspection readiness.
* **Validation & Qualification**
  + Author and execute commissioning or validation protocols (IQ/OQ/PQ) for equipment, utilities, and systems as required.
  + Execute requalification activities and maintain validation lifecycle documentation in compliance with GMP and regulatory expectations.
* **Facility Support Projects**
  + Assist in the design, installation, and commissioning of new equipment and facility upgrades.
  + Participate in project planning, risk assessments, and change control processes ensuring solutions meet GMP, safety, and operational requirements.
  + Show initiative to seek new approaches to meet facility needs and improve the services provided.
* **Compliance & Documentation**
  + Ensure all operational activities comply with GMP, EHS, and internal SOPs. Author any documentation as required to support operational compliance.
  + Maintain accurate and timely documentation including deviations, CAPAs, and change controls.
  + Support internal and external audits and inspections.
* **Cross-functional Collaboration**
  + Work closely with Manufacturing, Quality Assurance, Quality Control, and Operations teams.
  + Provide technical support in facility boundaries during tech transfers and scale-up activities.
  + Provide day-to-day supervision and coaching to support technical staff.
  + Establish a network of specialist vendors to provide engineering and technical support. Play a role in negotiations with these vendors to provide support under a quality framework.
* Maintain a safe and clean working environment ensuring adherence to procedures, rules and regulations. This includes providing a safe working environment for CSIRO staff and external technicians working in the facility.
* Under general direction, use professional expertise, knowledge of other disciplines and research experience and achievement to formulate, develop and complete an approved research program.
* Develop and apply knowledge of other scientific disciplines to optimise operational or validation processes adhering to applicable regulations.
* Develop challenging but realistic operational or validation project plans and negotiate resource requirements with team leads or other project stakeholders
* Take responsibility for smaller operational/validation projects or elements of larger projects within and/or across Research Units.
* Work closely with staff and contractors to ensure equipment qualification, validation, and maintenance are conducted in accordance with agreed protocols and are completed within the agreed timeframes and budget.
* Act as a trusted advisor, utilising knowledge of the clients’ business and understanding of their underlying needs.
* Anticipate industry and/or community needs and market direction through client liaison and networking.
* Identify and adapt quickly to changes in client needs and market directions.
* Undertake feasibility studies in operational boundaries, demonstrate a considerable degree of originality, creativity and innovation in solving problems and introduce new directions and approaches.
* Advise policy makers, inform and transfer knowledge to non-scientific audiences as required.
* 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.
* Adhere to the spirit and practice of CSIRO’s Values, Code of Conduct, Health, Safety and Environment procedures and policy and diversity initiatives.
* Other duties as directed.

## **Selection Criteria**

#### Essential

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

1. Bachelor’s degree in engineering (Mechanical, Chemical, Biomedical, or related) or equivalent relevant work experience.
2. Demonstrated experience (minimum 5 years) with operation, validation and/or management of GMP-regulated pharmaceutical manufacturing facilities, plants and equipment.
3. Experience with facility systems (HVAC, clean utilities, EMS etc) and equipment qualification.
4. Demonstrated ability to undertake original, creative and innovative research by generating and pursuing novel ideas and solutions to scientific research problems.
5. Experience in providing technical support to the design, development, and implementation of new projects.
6. Strong understanding of GMP, validation principles, and regulatory expectations (TGA, FDA etc).

## **Desirable**

1. Experience in early-phase clinical trial manufacturing environments.
2. Demonstrated experience in a regulated environment with experience of GMP standards, including electronic quality systems (e.g., TrackWise, Veeva, ACE).
3. Experience with implementation and management of facility or equipment operational procedures.
4. Experience in regulatory audits and presenting operational related information to auditors.
5. Knowledge of risk management tools (FMEA, HAZOP).
6. Strong problem-solving and analytical skills.
7. Experience in Computer Systems Validation (CSV), including validation of manufacturing and quality-related software systems would be advantageous.

## **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.

Special Requirements

Appointment to this role is subject to provision of a pre-employment background check and may be subject to other security/medical/character clearance requirements.

* The successful candidate will undertake a pre-employment background check.
* 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/) for more information.

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

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