# Position Details

## Research Projects- CSOF6

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| The following information is for applicants | |
| Advertised Job Title | Clinical Trials Quality Manager |
| Job Reference | 87262 |
| Tenure | Indefinite, Full time |
| Salary Range | AU$117,917 - AU$138,176 pa + up to 15.4% superannuation |
| Location(s) | Adelaide SA (preferable), Sydney NSW, Canberra ACT, Clayton/Geelong 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 | Deputy Research Director – Human Health Programme |
| Client Focus – Internal | 50% |
| Client Focus – External | 50% |
| Number of Direct Reports | 0 |
| Enquire about this job | Contact Dr Benassi-Evans via email at Bianca.Benassi@csiro.au or phone +61 8 8303 8982 |
| 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).

### 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.

CSIRO deliver innovation to Australia's food, health, medical and wellness industries, resulting in significant health and economic benefits for Australians. We're working to prevent illnesses, develop a better understanding of diseases, and improve detection, treatment, and recovery in a range of medical conditions to help people live healthier lives.

The CSIRO Clinical Trials Unit (CTU) is an important capability within the Human Health Program that aims to improve health, wellbeing, and resilience against chronic, infectious and vector-bone diseases for Australians. The CTU works with CSIRO scientists and industry partners to bring health products and technologies to market that are safe and effective resulting in health and economic benefits for Australia. The CTU has been operating since 1989 and has a strong reputation for delivering high-quality clinical trials, traditionally in nutrition and health studies and are now expanding to a broader range of health and wellness market sectors. The CTU operates out of two vibrant health and medical precincts located at the South Australian Health & Medical Research Institute (SAHMRI) in the Adelaide BioMedCity and a sister clinic within the Westmead Health and Medical Research Precinct, Western Sydney.

Reporting to the Human Health Deputy Program Director, the Clinical Trial Quality Manager will work closely with the CTU to develop, implement and manage a comprehensive Quality Management Strategy (QMS) for the CTU, aligned to the National Clinical Trial Governance Framework under the Australian Health Service Safety and Quality Accreditation Scheme (AHSSQA).

CSIRO is committed to providing learning and development opportunities to accelerate professional development and build skills to enable CSIRO to tackle the greatest challenges.

### Duties and Key Result Areas

* Implement and manage a clinical quality management system for Phase II to IV clinical trials.
* Establish a training curriculum related to GCP systems/processes, including development of training materials, delivering, and documenting training compliance.
* Drive system and process improvement initiatives and develop and maintain appropriate tools and standard operating procedures to further enhance quality management activities.
* Plan, manage, perform and report regular quality reviews for clinical trials and document internal systems and processes, in order to ensure compliance with regulatory requirements, ethics committees and CSIRO policies and procedures.
* Lead and/or participate in the planning, conduct, follow-up and resolution of issues identified from Regulatory GCP inspections and sponsor audits.
* Manage relevant vendor selection and performance.
* Maintain current industry knowledge of applicable regulations, guidelines, and standards.
* 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 Values, Code of Conduct, Health, Safety and Environment procedures and policy, Diversity initiatives and Zero Harm goals.
* Other duties as directed.
* Travel to CSIRO Clinical Trial sites in Adelaide and Sydney will be required.

## **Selection Criteria**

#### Essential

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

1. Bachelor’s degree or equivalent work experience in a discipline relevant to clinical trials and some working exposure to clinical trial quality management.
2. Working knowledge of national and international regulations, guidelines and best practice related to the conduct of Phase II, III and IV clinical trials.
3. Strong computer literacy with knowledge of clinical trials software and MS Office suite.
4. An in-depth understanding of the clinical trials processes.

## **Desirable**

1. Previous experience of working in R&D, Pharmaceutical or Commercial Research Organisation (CRO) environments.
2. Previous experience in training of clinical trial staff

## **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

* The successful candidate will be asked to obtain and provide evidence of a National Police Clearance or equivalent. Please note that individuals with criminal records are not automatically deemed ineligible. Each application will be considered on its merits.
* Depending on the location you reside at; travel to Clinical trial sites in Adelaide and Sydney will be required.

## **About CSIRO**

We solve the greatest challenges through innovative science and technology. Visit [CSIRO Online](http://www.csiro.au/) and [CSIRO Health and Biosecurity](https://www.csiro.au/en/about/people/business-units/health-and-biosecurity) 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