# Position Details

## Research Management- CSOF7

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| The following information is for applicants |
| Advertised Job Title | Senior Quality Manager – Digital Health |
| Job Reference | 85355 |
| Tenure | Term - 3 years , Full-time  |
| Salary Range | AU$141,949 - AU$157,055 per annum plus up to 15.4% superannuation |
| Location(s) | Brisbane QLD, Sydney NSW, Melbourne VIC |
| Relocation Assistance | N/A |
| Applications are open to | Australian/New Zealand Citizens and Australian Permanent Residents, and candidates already in Australia with full work rights for the term of the contract |
| Position reports to the | Research Director  |
| Client Focus – Internal | 70% |
| Client Focus – External | 30% |
| Number of Direct Reports | 0 |
| Enquire about this job | David Hansen david.hansen@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 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 Australian e-Health Research Centre (AEHRC) is CSIRO’s national digital health research program. We’re championing the digital delivery of healthcare enabled by ​world-leading digital research and innovation​, industry partnerships, community connections​, and national trust. We’re a dedicated and committed team, passionate about transforming the health of Australians. You’ll find some of our health and biomedical informatics research:

### Delivered through virtual care to monitor health remotely;

### Informing evidence-based digital health solutions; or

### Transforming the efficiency of hospital and health systems – nationally and internationally.

### With over 100 scientists and engineers across Brisbane, Sydney, Melbourne, Canberra and Perth, the AEHRC is Australia’s largest digital health research program.

### The unparalleled demands of COVID-19 have been a catalyst for increased focus on digitisation and innovation in health. CSIRO, via the AEHRC, is leading a national agenda focused on innovation to foster continued transformation and sustainable healthcare delivery practices. We're hiring a number of talented researchers, engineers, leaders and project staff to contribute to this significant objective.

The **Quality Manager** will join the Australian e-Health Research Centre (AEHRC). The successful candidate will work across the Centre to implement and maintain a Quality Management System (QMS) including compliance with the applicable regulations and guidelines, ISO 13485, 21 CFR 820, ISO 62304, ISO 14971. This is a hands-on quality role and the Quality Manager will guide and collaborate with staff across a range of areas in the implementation and adoption of various ISO standards.

The Quality Manager is designated as the Management Representative for the QMS and has the responsibility and authority that includes:

* Ensuring that processes needed for the QMS are established, documented, implemented, and maintained;
* Reporting to management on the performance of the QMS and any need for improvement; and
* Ensuring the promotion of awareness of regulatory and customer requirements throughout the AEHRC and more broadly the Health & Biosecurity Business Unit and CSIRO.

The Quality Manager is also responsible for conducting management review meetings, regulatory reporting, post-market surveillance, coordinating production recalls and corrections, and reporting regularly to the Business Unit on all aspects of the QMS.

The role is also responsible for assisting specific projects and advising on all QMS related requirements. The Quality Manager will play a key role in developing a validation framework for undertaking validation activities across the AEHRC.

### Duties and Key Result Areas

The primary roles and responsibilities of the Quality Manager are:

* Ensure the QMS is suitable and effective.
* Provide strategic oversight and direction for the QMS and regulatory compliance.
* Implement and maintain the QMS and ensure compliance with all applicable regulatory requirements.
* Provide input and direction in the product development and production processes, including project planning, specification development, risk analyses, verification and validation activities, design reviews, design transfer activities, etc. for all projects.
* Facilitate training and promote general awareness of the QMS and regulatory requirements. Oversee the training program to ensure all training is conducted as required.
* Establishing and reviewing the quality goals and objectives.
* Ensuring the quality policy is understood, implemented, and maintained at all levels of the organisation.
* Oversee the documentation control system and ensure compliance to ISO13485 and 21 CFR 820.
* Oversee the corrective and preventative actions (CAPA), engineering change control, complaint handling, post-market surveillance (PMS) and engineering change order programs.
* Where applicable, communicate with regulatory authorities, e.g., FDA, TGA, EU Competent Authorities, etc.
* Facilitate and chair management review meetings to review the suitability and effectiveness of the QMS.
* Liaise with external regulatory organisations for ongoing maintenance of the QMS, product approvals and the preparation of new product regulatory submissions.
* Conduct internal and supplier QMS audits as per schedule or arrange for other qualified auditors to perform audits as required.
* Drive continuous improvement programs.
* Manage any other employees in the quality department. Provide leadership and direction.
* As part of the AEHRC Leadership Team contribute to the strategic planning and assist in the preparation of the AEHRC QMS Annual Report for Senior Management which assesses the effectiveness of all elements of the quality system in meeting the objectives of the Centre and the requirements of ISO Standards.
* Build and maintain strong, positive partnering relationships with customers, Business Unit partners and staff and QMS corporate citizen champions through developing a thorough understanding of their respective QMS needs and tailoring solutions.
* 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 team 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.

## **Selection Criteria**

#### Essential

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

1. Demonstrated experience with a minimum of 5 years in in a regulatory and quality role, in the medical device industry.
2. Experience and knowledge in medical device regulations and quality management standards such as 21 CFR 820, ISO 13485, ISO 14971 and their application.
3. Demonstrated experience in taking multiple products to market including regulatory approval.
4. Proven experience in managing quality teams and influencing business decisions to align to quality standards.
5. Demonstrable experience as a specialist advisor and contributor to teams and networks of scientific and industry colleagues, with a proven ability to lead and foster a culture of knowledge transfer, open communication, coaching and collaboration.

**Desirable**

1. Certificate in Lead Auditing desirable.
2. A relevant Degree in Science or something similar.
3. Experience in the use of various software systems that support the Quality Management process, such as Confluence.

## **Required Competencies**

* **Teamwork and Collaboration:** Creates and fosters an environment in which there is a high level of cooperation within and between teams. Facilitates positive team relationships to build interactions across Business Units and the organisation.
* **Influence and Communication:** Uses complex influencing strategies, for example, assembling strategic coalitions, building behind the scenes support and the tactical use of information to gain support.
* **Resource Management/Leadership:** Provides leadership that fosters an environment that encourages new ideas and provides support for the development of emerging skills. Creates trust by displaying consistency, understanding, integrity and patience. Plans, seeks, allocates and monitors resources to achieve outcomes.
* **Judgement and Problem Solving:** Resolves major conceptual scientific, technical, commercial or management problems, which have a significant impact upon the field of research, professional function, the Business Unit or the Organisation. Situations faced have little or no precedent and require original concepts and approaches.
* **Independence:** Commits significant resources in the face of uncertainty and takes calculated risks to improve performance and achieve challenging goals. Uses personal energy to drive change strategies. Formulates and implements contingency plans to minimise the impact of potential risks. Accepts personal responsibility for the outcomes of decisions/risks taken.
* **Adaptability:**Is flexible in response to external change or when faced with external constraints. Identifies and promotes the opportunities arising as a result of change.

Special Requirements

Appointment to this role may be subject to conditions including provision of a national police check as well as other security/medical/character clearance requirements.

## **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