# Position Details

## Research Scientist/Engineer- CSOF5

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| The following information is for applicants |
| Advertised Job Title | CGMP Production Co-ordinator |
| Job Reference | * 75890
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| Tenure | Indefinite Full-time  |
| Salary Range | * AU$100,710\_ to AU$108,985 pa (pro-rata for part-time) + up to 15.4% superannuation
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| 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 | GMP 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 GMP manufacture of vaccine and biotherapeutic candidates for use in preclinical and early human clinical (Phase 1) studies. The position reports to the GMP Team Leader in CSIRO Biomedical Manufacturing and brings advanced knowledge of manufacturing technology 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 position 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 guidance, support, and leadership in all aspects of GMP manufacturing to enable activities in both the CSIRO GMP facility and the CSIRO NCRIS GMP (APVMA/ISO) facility together with a supporting Quality Control laboratory.
* Create, maintain, and communicate a master schedule for manufacturing activities within both CSIRO GMP facilities.
* Work in partnership with Upstream and Downstream leads and Facility Manager to lead the construction of Bills of Materials (BOMs) and establish batch documentation for manufacture of new vaccines and therapeutic proteins including regular weekend work.
* Work in partnership with QC manager and QA manager to construct in process sampling plan and help to schedule QC testing.
* Provide expert facilitation of technology transfer of new manufacturing protocols into GMP operations. Lead teams through risk assessment activities using industry-relevant tools such as Failure Mode Effects Analysis (FMEA) to ensure first-pass success in establishment of new manufacturing systems.
* Generate and analyse GMP process manufacturing parameters to identify opportunities for continuous improvement in operations. Initiate, lead, and sponsor continuous improvement programs that have impact to streamline operations in the facility and improve manufacturing efficiencies.
* Engage with clients as an authority on all matters related to GMP manufacture of vaccines and biotherapeutic candidates for early preclinical and clinical studies.
* Provide leadership in the development of new project proposals. Leverage advanced knowledge of manufacturing science to participate in project scoping, planning, and budgeting activities that shape the future direction of GMP manufacturing operations within CSIRO.
* 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:** Uses knowledge of other party's priorities and adapts presentations or discussions to appeal to the interests and level of the audience. Anticipates and prepares for others reactions.
* **Resource Management/Leadership:** Allocates activities, directs tasks and manages resources to meet objectives. Provides coaching and on the job training, recognises and supports staff achievements and fosters open communication in the team.
* **Judgement and Problem Solving:** Investigates underlying issues of complex and ill-defined problems and develops appropriate response by adapting/creating and testing alternative solutions.
* **Independence:** Plans, sets and works to meet challenging standards and goals for self and/or others. Recognises where endeavours will make the most impact or difference, decides on desired outcome and sets realistic goals to reach this target.
* **Adaptability:**Copes with ambiguity or situations that lack clarity. Adapts readily to changing circumstances and new responsibilities (which may include activities outside own preferences) in the interests of achieving team objectives. Recognises the need for and undertakes personal development as a result of changes.

## **Selection Criteria**

#### Essential

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

1. A degree in Biotechnology, Biochemical Engineering, or related field.
2. Comprehensive industrial experience in the development and manufacture of biotherapeutic proteins and vaccines for regulated markets.
3. Extensive experience working under the framework for Good Manufacturing Practices (GMP) gained through industrial experience.

## **Desirable:**

1. An advanced degree in Biotechnology, Chemical Engineering, or other relevant field.
2. Experience in project planning and management in the industry for development and GMP manufacture of vaccines and biotherapeutics.
3. Demonstrated track record in the application of risk management tools and principles (eg: ICH Q8, Q9, and Q10 and FMEA) to support transfer of new manufacturing processes into GMP operations.
4. Experience in using Microsoft Project, or similar planning software, for managing projects.
5. Direct experience and working knowledge of the GMP frameworks for manufacture of human vaccines and biotherapeutics with global regulators such as the Therapeutic Goods Administration, US Food and Drug Administration, or European Medicines Authority.
6. Experience in leading staff.

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.
* The position 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.

## **About CSIRO:**

We solve the greatest challenges through innovative science and technology. To find out more visit us [online](http://www.csiro.au/)!

Find out more about CSIRO [Manufacturing](https://www.csiro.au/en/Research/MF)