# Position Details

## Research Scientist/Engineer- CSOF5 or CSOF6

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| The following information is for applicants | |
| Advertised Job Title | Research Scientist – GMP Downstream Processing Lead |
| Job Reference | 75941 |
| Tenure | Indefinite  Full-time |
| Salary Range | AU$100,710 to AU$135,467 pa (pro-rata for part-time) + up to 15.4% superannuation |
| Location(s) | CSIRO, 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 Only |
| Position reports to the | GMP Team Leader, CSIRO Biomedical Manufacturing |
| Client Focus – Internal | 20% |
| Client Focus – External | 80% |
| 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](mailto:careers.online@csiro.au) or call 1300 984 220. |

### Role Overview

CSIRO is looking for a Downstream Processing Lead for our newly built Pilot scale cGMP Biologics Facility. The Facility will support Australian Medical and Biotech research by producing Biologics under a GMP framework. Reporting to the GMP Team Leader, the DSP Lead will work closely with clients and internal research teams to develop the purification process then transfer the process to the GMP facility. They will draft process documentation and lead the GMP Downstream Processing effort.

The role is based at Clayton, Melbourne.

### Duties and Key Result Areas:

* Provide hands-on leadership of Downstream Processing activities in a GMP setting and serve as a point of accountability for transfer and implementation of new manufacturing methods, which will require weekend work.
* Lead by expertise and influence to ensure that new manufacturing protocols are established in accord with the cGMP quality framework and are completed within the agree timeframes and budget.
* Generate and analyse downstream processing data to identify opportunities for continuous improvement in the operation of bioprocessing systems.
* Assume ownership of downstream bioprocess equipment and maintain the same equipment in a GMP-ready state.
* Accurately write and review GMP batch manufacturing records. Communicate research results to clients and the scientific community through oral and written reports which may include the preparation of documents for patent applications.
* Engage with clients as an authority on protocols for industrial scale protein purification. Act as a trusted advisor, utilising knowledge of client’s business and understanding of their underlying needs.
* Participate in project scoping, planning, and budgeting activities that shape the future direction of the Downstream function. Anticipate industry needs and market direction through client liaison/networking and identify and adapt quickly to changes.
* 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, 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 Biochemistry, Biotechnology, Biochemical Engineering, or related field.
2. Comprehensive industrial experience in downstream process development for manufacture of biotherapeutic proteins and vaccines for regulated markets.
3. Theoretical and practical knowledge of unit operations for protein isolation and purification including chromatography (multiple modes), virus inactivation and filtration, normal and tangential flow filtration, and buffer exchange. The scope of experience shall include process development, optimisation, transfer, and troubleshooting.
4. Extensive experience working under the framework for Good Manufacturing Practices (GMP) gained through industrial experience.
5. CSIRO requires National Police Checks to be provided by preferred applicants for all new positions.

## **Desirable:**

1. An advanced degree in Biochemistry, Biotechnology, Chemical Engineering, or other relevant field.
2. Direct experience in design and qualification of unit operations for virus removal and inactivation using orthogonal approaches. Such would include virus inactivation (by chemical or pH treatment) and removal by filtration. Experience in the design and execution of virus spiking studies for process qualification will be highly regarded.
3. 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

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:**

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