# Position Details

## Research Projects- CSOF3

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| The following information is for applicants |
| Advertised Job Title | cGMP Technician Upstream & Downstream |
| Job Reference | * 75702
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| Tenure | Indefinite (Full-time)  |
| Salary Range | * AU$64,866 to AU$82,556 pa + up to 15.4% superannuation (CSOF3)

or * AU$85,361 to AU$96,573 pa + up to 15.4% superannuation (CSOF4)

***NOTE: The positions are offered across two levels, the appointment level will be determined by the qualifications, skills and relevant experience of the successful candidates.*** |
| Location(s) | Clayton, VIC **NOTE: The appointees may be required to work occasionally at Parkville, or at non-CSIRO sites elsewhere in Melbourne (Parkville or Broadmeadows).**  |
| 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 | 0% |
| Client Focus – External | 100% |
| 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

Research Projects staff in CSIRO 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.

The cGMP Technicians will be involved with CSIRO’s new cGMP pilot scale facility in the production of biologics for clinical trials (Phase I and beyond). Our clients will include Australian and overseas researchers and biotech and biopharmaceutical organisations, supporting the development of new biologics and growing the biotech industry. The cGMP Technicians will work on either upstream processing (media and reagent preparations, cell culture, scaling up to stirred tank bioreactors, filtration), or downstream processing (chromatography, viral reduction, tangential flow filtration), or fill and finish.

The positions are based at Clayton, Melbourne but in the first year the appointees 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:

* Participate in manufacturing activities to meet production schedules, which will require weekend work.
* Perform upstream or downstream processing activities in clean room conditions.
* Adhere to the requirements of the Quality Management System (QMS) and Pharmaceutical Quality System (PQS).
* Accurate and timely completion of quality records.
* Identify and report quality events in a timely manner according to procedure. Participate in investigations related to quality events (OOS, deviations, non-conformance).
* Participate in process reviews, CAPA and risk assessments.
* Review other quality and process documents under the QMS/PQS.
* Contribute to the maintenance of the facility (cleaning and technical sanitisation, environmental monitoring, ordering).
* Assist in the commissioning, validation and re-validation of equipment.
* Contribute to audits by clients or regulatory bodies.
* Under technical direction undertake experiments, laboratory analyses or technology development activities (some non-routine) using a range of techniques, often working on a numerous parallel and competing tasks.
* 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 Code of Conduct, Health, Safety and Environment procedures and policy, Diversity initiatives and Making Safety Personal goals.
* Other duties as directed.

### Duties and Key Result Areas (additional for CSOF4):

* Lead investigations related to quality events (OOS, deviations, non-conformance).
* Draft quality and process documents under the QMS/PQS.
* Oversee the activities of less experienced staff and provide guidance on experimental/ technological techniques and protocols.
* Direct experiments, laboratory analyses or technology development activities (some non-routine) using a range of techniques, often working on a number of parallel and competing tasks.

## **Required Competencies:**

* **Teamwork and Collaboration:** Proactively seeks and considers the ideas and opinions of others from within and outside the team to help form decisions, plans or actions.
* **Influence and Communication:** Puts forward ideas by presenting factual information supported by data, definitions, examples, illustrations or other aids, which will assist in conveying meaning.
* **Resource Management/Leadership:** Provides instruction and assists other staff to complete allocated tasks and activities.
* **Judgement and Problem Solving:** Identifies and considers the implications of a range of available alternatives in order to select the most appropriate response to problems of a familiar or recurring nature.
* **Independence:** Recognise and makes immediate changes to improve performance (faster, better, lower cost, more efficiently, better quality, improved client satisfaction).
* **Adaptability:**Willingness to change ideas or perceptions based on new information, contrary evidence or other people's points of view. Prepared to try out different approaches.

## **Required Competencies (additional for CSOF4):**

* **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.
* **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. Relevant bachelor’s degree or equivalent relevant work experience in Cell Biology, Biotechnology, Biochemistry, Chemical Engineering or Process Engineering.
2. Extensive experience with sterile techniques.
3. A current Australian driver’s licence.
4. Computer literacy and familiarity with MS Office applications.
5. Demonstrated track record of working collaboratively within a team to achieve results.
6. Ability to use judgement to select the best option for improving performance (better yields, higher quality, improved client satisfaction).

## **Desirable:**

1. Previous experience in cGMP manufacture of biologics.
2. Experience working in and maintaining clean rooms.
3. Demonstrated experience in recombinant protein production in mammalian cells at bench scale and industrial bioreactor scale.
4. Previous experience with automated chromatography systems.
5. Experience with viral clearance techniques.
6. Demonstrated experience in fill and finish.
7. Previous experience in formulation studies
8. Experience in working under a QMS

## **Selection Criteria (additional for CSOF4)**

#### Essential

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

1. Demonstrated competence in drafting technical documents, especially those associated with QMS.
2. Evidence of experience in leading and directing projects.
3. Ability to investigate underlying issues of complex problems and develop the most appropriate response by adapting, creating and testing alternative solutions.

## **Desirable:**

1. Demonstrated understanding of TGA, FDA requirements for cGMP manufacture.
2. Experience with single use bioreactor systems (eg Cytiva Wave and Xcellerex).
3. Experience with Äkta Ready or Äkta Pilot chromatography system or Unicorn software.

Special Requirements

Appointment to these roles may be subject to the following conditions:

* The positions are based at Clayton, Melbourne but in the first year the appointees 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.
* The successful candidates 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:**

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