

Position Description

Job Title	Manufacturing Scientist
Location/ Department	Cell Therapies Pty Ltd Level 9, 305 Grattan Street Melbourne VIC 3000
Reporting To:	Direct: Manufacturing Manager Indirect: Manufacturing Scientist – Team Leader
Main Purpose of Position	Aseptic cleanroom manufacturing of human cellular therapeutics that meet the requirements of the code of Good Manufacturing Practice for Human Blood and Tissues (cGMP), Safety Testing and the clinical needs of patients.
Job Level	Junior Professional – Level 3
Number of Direct Reports	Nil
Key Relationships	<u>Internal:</u> Supervised by: Manufacturing Manager Liaises with: Quality Systems personnel, all other CT staff, and other hospital staff. <u>External:</u> Liaises with external suppliers and collaborating institutions
Experience/Qualifications	Essential <ul style="list-style-type: none"> • BAppSc or BSc in life sciences or other relevant discipline, or other tertiary qualification plus equivalent industry experience • Recognised training and demonstrated competence relevant to the position (such as knowledge of and proficiency in cell culture techniques, aseptic media preparation, cryopreservation of cells and tissues, and associated analytical methods) • Preparation of documentation (procedures, batch records, forms) in accordance with cGMP and with TGA/FDA regulatory guidelines • Capable of identifying GMP and procedural deviations and proactively raising issues to facilitate system improvements • Professional approach to patient care, service confidentiality and the provision of CT contracted services • Demonstrable ability to work and communicate cooperatively in a multidisciplinary team • Demonstrable technical capability and high attention to detail • A diligent and quality-driven approach • Ability to multitask and work autonomously as well as in teams

Experience/Qualifications	<p>Desirable</p> <ul style="list-style-type: none"> • Minimum 2-3 years experience with the manipulation of human cells, tissues, plasma and/or blood components (Experience within clean rooms is highly desirable) • Specific experience in delivering a cGMP (Human Blood & Tissue) compliant service • Small and large scale aseptic cell culture handling, biopharmaceutical manufacturing and biotechnological equipment use • Proficiency in the use of information systems (MS Word, Excel, Outlook, BMS/EMS, LIMS). • Understanding of Medical Microbiology • Demonstrated research and analytical skills including the use of a variety of data sources to provide advice and recommendations to senior staff •
---------------------------	--

Performance Objectives	Key Performance Indicators
1. Able to support the production of high quality therapeutics with acceptable turn-around times	<ul style="list-style-type: none"> • Procedures are performed exactly as specified by documented SOPs, Batch Records and Quality Assurance requirements. • Processes are recorded and documented according to cGMP requirements and are presented for authorisation. • Therapeutics are manufactured to cGMP requirements and stipulated time frames to meet clinical need. • Successful aseptic manufacture of human cell therapeutics according to GMP requirements and the written procedures of Cell Therapies (CT) and manufacturing sponsors • Compliance with the OGTR guidelines for the containment of genetically modified organisms
2. Equipment is calibrated and maintained according to laboratory policy & procedures	<ul style="list-style-type: none"> • Equipment Standard Operating Procedures are adhered to and equipment suitability for use is adhered to in accordance with cGMP standards and protocols • All documentation is completed including batch records, procedures and quality assurance documentation according to CT, sponsor and cGMP standards and protocols. • Maintenance and support of the cleanroom and laboratory activities of the CT Manufacturing Facility
3. Quality of manufacturing performance and reporting complies with CT policies.	<ul style="list-style-type: none"> • Manufacturing, testing and documentation consistent with CT and cGMP standards and protocols. • Completing clinical batch record improvements and other facility documentation according to GMP and Quality Assurance requirements

	<ul style="list-style-type: none"> • Reviewing, updating and authoring SOPs and other documentation
4. Clinically significant results and NCRs are reported to Manufacturing Manager and Quality teams or delegates according to CT protocol	<ul style="list-style-type: none"> • Non Conformances (NCR) and out-of-specification results are communicated expediently to the Quality and Production nominees as per CT procedures. • Non-conformance documents are investigated and completed as required.
5. Maintains and develops a centre of excellence for cell therapy	<ul style="list-style-type: none"> • Courteous and efficient communication with CT and Peter Mac clients, customers and patients. • Ability to prioritise workflow based on clinical and cGMP needs. • Complaints and Non-conformances are investigated and completed.
6. Quality assurance	<ul style="list-style-type: none"> • Adheres to quality systems and procedures of CT. • Adheres to CT requirements as specified by the CT Quality and Manufacturing managers and their delegates. • Supports validations of new processes and equipment. • Promptly reports procedural breakdowns and incidents by means of the CT non-conformance reporting system. • Uses specialised knowledge and depth of experience to continually improve manufacturing practices after validation. • Participates in educational activities including attendance at internal and external training courses, clinical and scientific meetings. • Maintains and develops own specialised skills. • Embraces skill extension, innovation and change. • Documentation of manufacturing protocols and test methods according to cGMP. • Participation in the maintenance of cGMP compliant quality systems as audited by the Therapeutics Goods Administration
7. Works as part of a team	<ul style="list-style-type: none"> • Communicates and cooperates with co-workers to ensure work is completed within appropriate timeframes in a harmonious manner.
Health, Safety and Environment obligations	<ul style="list-style-type: none"> • Take reasonable care for their own health, safety & wellbeing as well as others. • Comply with any reasonable CTPL instruction, including the use of safety equipment and PPE.

	<ul style="list-style-type: none">• Ensure their personal fitness for work.• Notify and report to their supervisor / Line Manager as early as practical any hazard, hazardous process, incident or injury.• Participate in incident investigations and/or risk assessments when requested.• Provide a supportive environment for injured employees returning to work.
--	--