Position Description

Job Title	**Production Operator**
Location/ Department	Cell Therapies Pty Ltd Level 9, 305 Grattan Street Melbourne VIC 3000
Reporting To:	Direct: Production Manager Indirect: Lead Production Operators + Cell Therapy Specialists
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.
Key Effectiveness Areas	1. Successful aseptic manufacture of human cell therapeutics according to GMP requirements and the written procedures of Cell Therapies (CT) and manufacturing sponsors 2. Compliance with the OGTR guidelines for the containment of genetically modified organisms 3. Maintenance and support of the cleanroom and laboratory activities of the CT Manufacturing Facility 4. Completing batch records and other facility documentation according to GMP and Quality Assurance requirements 5. Participation in the maintenance of cGMP compliant quality systems as audited by the Therapeutics Goods Administration 6. Participating in manufacturing process improvement activities 7. Reviewing, updating and authoring SOPs and other documentation 8. Effective and professional communication with other CT staff
Number of Direct Reports	Nil
Decision Making Authority	Activities relating to cell therapy manufacture as delegated by Production Manager and Cell Therapy Specialists and as defined in Standard Operating Procedures and Batch documentation for which the individual is trained.

Key Relationships	**Internal:** Supervised by: Production Manager Liaises with: Cell Therapy Specialists, Quality Systems personnel, all other CT staff, and other hospital staff. **External:** Liaises with external clients, suppliers and collaborating institutions
Experience/Qualifications	**Essential** • 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) • Minimum 3 years experience with the manipulation of human cells, tissues, plasma and/or blood components (Experience within clean rooms is highly desirable) • 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

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Experience/Qualifications	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***
Able to support the production of high quality therapeutics with acceptable turn-around times	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.
Equipment is calibrated and maintained according to laboratory policy & procedures	All documentation is completed including batch records, procedures and quality assurance documentation according to CT, sponsor and cGMP standards and protocols.
Quality of manufacturing performance and reporting complies with CT policies.	Manufacturing, testing and documentation consistent with CT and cGMP standards.

Clinically significant results and NCRs are reported to requesting clinicians and external clients according to CT protocol	Non Conformances (NCR) and out-of-specification results are communicated expediently to the Quality and Production nominees as per CT procedures. Senior scientific and medical staff are notified of any significant scientific or technical problems in a timely manner. Non-conformance documents are investigated and completed as required.

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Maintains and develops a centre of excellence for cell therapy and responds to customer needs in an appropriate manner	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.
Quality assurance	Adheres to quality systems and procedures of CT. Adheres to CT requirements as specified by the CT Quality and Production managers and their delegates. Performs validations of all 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. Under the direction of senior staff, participates in laboratory and clinical research where appropriate and applicable. Documentation of manufacturing protocols and test methods according to cGMP.
Works as part of a team	Communicates and cooperates with co-workers to ensure work is completed within appropriate timeframes in a harmonious manner.

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Continuous Quality Improvement ***Infection Control*** Adheres to the principles of Infection Control in accordance with CT policies and procedures ***Occupational Health & Safety*** Takes all reasonable steps to ensure a safe environment Understands emergency procedures and location of emergency equipment ***Privacy*** Adheres to the Cell Therapies privacy policy	• Complies with Infection Control policies and procedures 100% of the time • Completes incident reports 100% of the time and responds appropriately to OH&S incidents • Attends Health & Safety training on emergency procedures annually and is capable of identifying emergency equipment in place • Direct care staff will attend the yearly update on theory of fire, code red and orange responses and use of extinguishers Follows established procedures

Signatures:

Department Head	
Employee	
CEO	

Privacy Statement: Information may be collected and stored for the purpose of recruitment and selection. The information will only be used and disclosed for the primary purpose of its collection. Some exceptions exist. These may be obtained from the Privacy Officer.

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