

Position Description

Job Title	Laboratory Assistant
Location/ Department	Cell Therapies Pty Ltd Level 9, 305 Grattan Street Melbourne VIC 3000
Reporting To:	Direct: Operations Co-ordinator Indirect: Production Manager
Main Purpose of Position	Supporting developmental work and manufacturing of human cellular therapeutics under the requirements of the code of Good Manufacturing Practice for Human Blood and Tissues (cGMP), by performing activities that support the cGMP compliance of the production facilities and the readiness of production teams.
Key Effectiveness Areas	<ol style="list-style-type: none"> 1. Maintenance and support of the CT Facility including: <ol style="list-style-type: none"> a) Receiving and verifying the suitability of incoming materials and reagents b) Performing environmental monitoring (microbial and particulate) across the facility using a variety of techniques, performing microbiological readings and reporting of results c) Completing other facility monitoring, alarm testing, maintenance and cleaning tasks and supporting documentation d) Calibration and maintenance activities related to process equipment, biological safety cabinets, steam sterilisers, and chaperoning external contractors to do same 2. Supporting successful manufacture of human cell therapeutics according to the written procedures of CT and sponsors/clients <ol style="list-style-type: none"> a) Preparing for production team readiness (assembling kits, moving equipment etc) b) Preparing and packing samples for shipping (Liquid nitrogen handling required) c) Specialist cleaning of production equipment d) Gowning for, working in and cleaning classified cleanrooms e) Occasional shift and weekend work may be required

	<ol style="list-style-type: none"> 3. Support of the Quality Systems of CT including <ol style="list-style-type: none"> a) Quality assurance/quality compliance testing and data entry b) Adhering to standard operating procedures and Good Manufacturing Practice c) Thorough and accurate record keeping and filing of records and reports according to GDP principles 4. Effective and professional communication with other staff of CT and Peter Mac 5. Ongoing training and development in cell therapy
Number of Direct Reports	Nil
Decision Making Authority	Nil
Key Relationships	<p>Internal: Supervised by: Operations Coordinator Liaises with: Production Manager, Project Leaders, QA and QC Teams, Production Teams.</p> <p>External: Vendors, contractors, other Peter Mac departments and VCCC building services</p>
Experience/Qualifications	<ul style="list-style-type: none"> • Qualification (certificate or diploma) in a life sciences or equivalent industry experience. • High level of accuracy, technical capability and attention to detail. • Demonstrated experience in accurate execution of standard procedures and recording of same, ideally in support of a highly complex research facility or production environment. • Experience in an ISO or regulated environment would be advantageous. • Experience in handling liquid nitrogen • Experience in microbiology or cell culture would be advantageous. • Experience in validation and calibration of equipment would be advantageous. • A diligent and quality driven approach • A clear and confident communicator. • Ability to multitask and work autonomously as well as in teams. • Comfortable working within a hospital environment.

Performance Objectives	Key Performance Indicators
Primary concern for patient receiving cellular therapy	<ul style="list-style-type: none"> • Focus on right first time, every time. • Attention to detail and “presence” when conducting GMP activities.
Maintenance and support of the CT Facility	<ul style="list-style-type: none"> • Maintenance, calibration and cleaning activities up to date, on time and accurately recorded. • Minimal quarantine materials • All EM tests completed on terms and action alerts appropriately managed.
Supporting successful manufacture of human cell therapeutics according to the written procedures of CT and manufacturing sponsors/clients	<ul style="list-style-type: none"> • No delays in production starts, no production stoppages due to shortages of materials
Support of the Quality systems of CT	<ul style="list-style-type: none"> • Accurate recording and documentation • Willingness to report/declare errors and non-conformances (own and others). • Timely close out of NCR’s/CAPA’s where tasks are assigned
Effective and professional communication with clients and other staff of CT and Peter Mac	<ul style="list-style-type: none"> • High levels of internal and external client satisfaction; knows how to get things done and where to go to get things done that require Peter Mac/Honeywell support
Ongoing training and development in cell therapy	<ul style="list-style-type: none"> • Active learning and development plan • Gradual certification to conduct/verify procedures such as media preparation; short cell processing steps
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.

<p>Continuous Quality Improvement</p> <p>Infection Control Adheres to the principles of Infection Control in accordance with CT policies and procedures</p> <p>Occupational Health & Safety Takes all reasonable steps to ensure a safe environment</p> <p>Understands emergency procedures and location of emergency equipment</p> <p>Privacy Adheres to the Cell Therapies privacy policy</p>	<ul style="list-style-type: none"> • 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
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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.