

## Schedule 2 Position Description

Job Title	Document Administrator
Location/ Department	Cell Therapies Pty Ltd Level 9, 305 Grattan Street Melbourne VIC 3000
Reporting To:	Direct: Director of Quality
Main Purpose of Position	Reporting to Director of Quality, the Document Administrator is to ensure documents are managed as per the Quality Management System and ensure GMP compliance for the clinical and commercial manufacturing and distribution of cellular and tissue therapy products.
Number of Direct Reports	Nil
Experience/Qualifications	Essential <ul style="list-style-type: none"> <li>• Advanced Microsoft Word skills experience</li> <li>• Ability to follow procedures and defined work-flows</li> <li>• Demonstrable ability to work and communicate cooperatively with multiple teams and competing demands</li> <li>• Excellent attention to detail and organisation skills</li> <li>• Responsible attitude and work ethic</li> <li>• Ability to multitask and work autonomously as well as in teams</li> </ul>
Experience/Qualifications	Desirable <ul style="list-style-type: none"> <li>• Specific experience in document control in a cGMP compliant service</li> </ul>

Performance Objectives	Key Performance Indicators
Able to support the production of high quality therapeutics within acceptable turn-around times	<ul style="list-style-type: none"> <li>• Achieve a deep understanding of GMP.</li> <li>• Procedures are performed exactly as specified by SOP</li> <li>• All manufacturing needs are provided in a timeframe to ensure no delay to the production schedule</li> <li>• Demonstrable examples of identifying, trouble-shooting and resolving issues.</li> <li>• Liaise with various departments, including Quality Assurance, Quality Control, Manufacturing and Validation and other departments to address document-related queries and facilitate smooth operations.</li> <li>• Sets and meets annual performance objectives</li> <li>• Supports continual improvement of the quality system</li> <li>• Developing, drafting, updating and authoring SOPs</li> </ul>

<p>Quality assurance</p>	<ul style="list-style-type: none"> <li>• Adheres to quality systems and procedures</li> <li>• Promptly reports procedural breakdowns and incidents by means of the non-conformance reporting system.</li> <li>• Uses specialised knowledge and depth of experience to continually improve documentation system process</li> <li>• Participates in educational activities including attendance at internal and external training courses</li> <li>• Maintains and develops own specialised skills</li> <li>• Embraces skill extension, innovation and change</li> <li>• Ensures quality systems remain compliant with relevant licensing and certification requirements</li> <li>• Participation in the maintenance of cGMP compliant quality systems as audited by the Therapeutics Goods Administration</li> <li>• Ensuring Quality needs as required by Manufacturing and QC are met</li> </ul>
<p>Manage document control for human cellular therapeutics to ensure compliance with cGMP, PIC/S, and clinical requirements</p>	<ul style="list-style-type: none"> <li>• All batch records are issued and controlled on time to meet manufacturing timelines;</li> <li>• Documents are formatted as per SOPs prior to approval into the electronic quality management system.</li> <li>• New or up versioned documents are controlled as per GMP procedures within the electronic management system in accordance with relevant SOPs;</li> <li>• Manage the archive of documents, both physical and electronic, ensuring proper storage and retrieval</li> <li>• Issue critical documents and labels for process and final product materials to production, QC, and other relevant departments.</li> <li>• Maintain and update electronic quality management system, ensuring that all documents are readily accessible and up-to-date.</li> </ul>
<p>Works as part of a team</p>	<ul style="list-style-type: none"> <li>• Communicates and cooperates with co-workers to ensure work is completed within appropriate timeframes in a harmonious manner.</li> <li>• Support to other members of the QA team as required</li> <li>• Effective and professional communication with other CT staff and external laboratories.</li> </ul>
<p>Health, Safety and Environment Obligations</p>	<ul style="list-style-type: none"> <li>• Take reasonable care for their own health, safety &amp; wellbeing as well as others.</li> <li>• Comply with any reasonable CTPL instruction, including the use of safety equipment and PPE.</li> <li>• Ensure their personal fitness for work.</li> <li>• Notify and report to their supervisor / Line Manager as early as practical any hazard, hazardous process, incident or injury.</li> <li>• Participate in incident investigations and/or risk assessments when requested.</li> <li>• Provide a supportive environment for injured employees returning to work.</li> </ul>

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|  | <ul style="list-style-type: none"><li>• Support the OH&amp;S coordinators initiatives and promote a safe and healthy workplace</li></ul> |
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