

# JOB PROFILE

<b>Job title:</b>	QA Associate	
<b>Reporting to:</b>	Quality Operations Manager	
<b>Department:</b>	Quality Team	
<b>N° of Direct reports:</b>	0	
<b>Location:</b>	Pencoed, South Wales	
<b>Job Details</b>		
<b>Job Purpose:</b>	Performing QA duties to support the outsourced manufacturing and testing of clinical cell banks and drug product.	
<b>Main areas of responsibility:</b>	<ul style="list-style-type: none"> <li>• Provision of QA operational support to the CMC team</li> <li>• Provide QA input into tech transfer activities, including travel to CMOs and testing houses</li> <li>• Liaison with 3<sup>rd</sup> party CMOs and transmittal of controlled documents</li> <li>• Provide QA support for audits and regulatory inspections</li> <li>• Perform internal and external audits</li> <li>• Work effectively within project teams, provide QA input where required – escalating issues to the Quality Operations Manager where appropriate</li> <li>• Review batch records, QC data etc associated with product release and provide, in conjunction with the Quality Operations Manager, disposition packs to the QP and Director of Quality</li> </ul>	
<b>Person Specification</b>		
<b>Qualification/ Experience required</b>	<b>Essential</b>	<b>Desirable</b>
	<ul style="list-style-type: none"> <li>• Minimum of 1 – 2 years' experience in QA</li> </ul>	Experience in a production or testing environment
	<ul style="list-style-type: none"> <li>• Relevant scientific degree (or equivalent)</li> </ul>	
	<ul style="list-style-type: none"> <li>• Able to demonstrate a commitment to quality including good understanding of QA</li> </ul>	
<b>Skills and Competencies required</b>	<ul style="list-style-type: none"> <li>• Computer literate</li> <li>• Knowledge of current GMP guidelines</li> <li>• Able to work as part of a team and individually</li> <li>• Excellent attention to details</li> <li>• Effective planning and organisational skills</li> </ul>	

# ReNeuron

- To carry out any other tasks or duties within post holders capability as requested by the Company to meet business needs.
- The Company reserves the right to vary or amend the tasks and responsibilities of the post holder at anytime according to the needs of the Company's business.
- Information contained therein is not exhaustive but describes key elements of the function.

Author:	Date:
Revised:	Date: