

JOB PROFILE

Job title	QC Associate
Reporting to	Head of Analytics
Department	Quality Team
N° of Direct reports	0
Location	Pencoed, south Wales
Job Details	
Job Purpose	Coordinating tech transfer of assays from ReN to GMP contract testing houses (CTOs) and between CTOs. Providing ongoing QC oversight and support to CTOs. Representing ReN QC in project meetings.
Main areas of responsibility	<ul style="list-style-type: none"> • Review all QC paperwork for assays ensuring compliance with the method. • Working with CTOs to ensure timely initiation of testing and any laboratory investigations/OOSs . • When necessary work at third parties in support of technology transfer activities and direct third party work • Collate, analyse, conclude and present data and author/review/approve technical reports • Ensure that experimental work is recorded in appropriately controlled laboratory books or protocols in accordance with the requirements of GxP • Perform analytical techniques in a non-GMP environment in readiness for establishing and tech transferring methods into contract laboratories. • Acquire and maintain a broad knowledge of the science behind analytical methods and cell culturing for stem cell therapy. • Work with the Head of Analytics to provide required technical support to GMP QC activities.

	<ul style="list-style-type: none"> • Author GMP documentation as appropriate. • Review GLP technical documentation from Contract testing laboratories as appropriate. • Own technical aspects of GMP investigations relating to QC testing methods. • Contribute to Quality processes/initiatives at a local and Company level where required. To follow and assist in the implementation of GMP standards which contribute to the Company and site objectives • Coordination of stability studies and generation of associated protocols and reports • Develop and tech transfer test article preparations for assays • Generate tech transfer protocols and reports
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Person Specification

Qualification / Experience required	Essential	Desirable
	<ul style="list-style-type: none"> • 3-6 years working in an analytical lab or similar scientific role. 	<ul style="list-style-type: none"> • Experience working with third parties
	<ul style="list-style-type: none"> • A good understanding of Cell based assays with experience in a comprehensive range of assay platforms. 	
	<ul style="list-style-type: none"> • A knowledge and understanding of working to GMP 	
	<ul style="list-style-type: none"> • Aseptic cell culturing and cell counting (manual and automated) 	
Skills and Competencies required	<ul style="list-style-type: none"> • A motivated individual committed to being an integral team player in the QC. • Good communication skills, both verbally and written, comfortable to meet with all ReNeuron staff. • Knowledgeable and capable of presenting ideas and sharing information appropriately. 	

	<ul style="list-style-type: none">• Be able to analyse and interpret data generated using standard computer programmes.• Individual roles may be predominantly lab-based or predominantly focused on supporting GMP QC activities, or balanced between the two; depending upon the current business need.• Some UK and international travel to meetings, conferences, and third parties (e.g., CMOs, CTOs, and collaborators) is expected.
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<ul style="list-style-type: none">• To carry out any other tasks or duties within post holders capability as requested by the Company to meet business needs.
<ul style="list-style-type: none">• 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: