JOB PROFILE

Job title:	Technical Specialist I
Reporting to:	Team Leader
Department:	Process Development
Nº of Direct reports:	0
Location:	Pencoed
Job Details	
Job Purpose:	To lead aspects of the development and technical support of processes and methods and assist in the transfer and validation activities associated with new and existing products. The role entails both lab-based activities and/or the on-site provision of technical leadership to third parties e.g., internal/external GMP manufacturing functions, contract testing laboratories, and external collaborators. The lab-based activities require laboratory experience; for example, in stem cell biology, tissue culture, assay development. The job holder is accountable for the planning, co-ordinating and execution of experimental work; to investigate, optimize and improve the production process and/or the development of new analytics and delivery of results, documented to the relevant standards, in a timely fashion. The provision of technical support to GMP manufacturing activities and GLP contract testing laboratories requires a working knowledge of GMP in addition to the technical knowledge of the cell culture manufacturing process or analytical method.
Main areas of responsibility:	• To lead aspects of the provision of non-routine support for processes/methods and the development of new/novel methods to support process, transfer and improvement activities. • Organise work and coordinate co-workers to meet deadlines for CMC Group activities. • Act as an internal interface to ensure the execution of activities as planned, following robust ways of working • Oversee the operation and maintenance organisation of CMC facilities. • Identify, liaise and work with third parties in order to progress CMC Group activities. • Enable the Tech Transfer of processes and/or analytical methods between functional groups either within ReNeuron or externally to/from third parties.

- When necessary work at third parties in support of technology transfer activities and direct third party work
- Plan and perform experimentation in accordance with procedures to support CMC activities
- Collate, analyse, conclude and present data and author/review/approve technical reports
- Develop specifications for new products or as part of the life cycle management of existing products
- Ensure that experimental work is recorded in appropriately controlled laboratory books or protocols in accordance with the requirements of GxP
- Manage consumable inventory levels within the laboratory and ensure that equipment maintenance and calibration is performed in line with approved procedures.
- Preparation of URS for laboratory equipment, preparation and execution of subsequent IQ/OQ of the equipment.
- Prepare, review and approve SOPs for processes/methods, assist in the preparation of Training Packages, and perform training.
- Perform routine manufacturing campaigns in order to support in-house process development and analytical development activities.
- Perform routine Development and/or QC analytical testing to support process development and GMP manufacturing activities.
- Take responsibility for specific lab housekeeping/H&S functions.
- Lead the preparation of experimental data for regulatory submissions and support the Regulatory Department in the preparation and review of regulatory documents
- Acquire and maintain a broad knowledge of the science behind stem cell therapy bioprocessing and/or associated analytical methods.
- Liaise with members of the Project Management function to provide data summaries and project timeline updates.
- Work with the Head of CMC/Process Science Manager/Quality Department to provide required technical support to GMP manufacturing activities.
- Author GMP manufacturing documentation (e.g., batch records) as appropriate.
- Author GLP technical documentation from CTLs as appropriate.
- Own technical aspects of GMP investigations relating to manufacturing and analytical testing methods.
- Undergo annual GMP and GCP training according to Appendix 1 of SOP 02-P-02 and acknowledge/record all GxP training in the electronic QMS.
- 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

Health and Safety

	• You are responsible for familiarizing yourself with the Company H&S policies and procedures ensuring that all rules and regulations are followed within your areas of work to ensure a safe working environment. • You must highlight with your line manager any difficulties or misunderstanding or deficiencies in any SOP's Work plans etc that may give rise to a work place risk. • You must ensure that all hazards, incidents and accidents are reported to your line manager

Person Specification		
Qualification/ Experience required	**Essential**	**Desirable**
	MSc /BSc in Cell Biology, Biochemistry, Neuroscience, Pharmacology or another relevant life science degree.	Prior experience in QbD/DoE approaches to development is advantageous though not essential.
	3-6 years working in regenerative medicine, biologics or similar scientific role.	Yellow belt competence in LSS is preferred
	A good understanding of Stem Cell Biology with experience in a range of tissue culture techniques.	
Skills and Competencies required	• A motivated individual committed to being an integral team player in the further development of ReNeuron's stem cell therapies. • Good communication skills, both verbally and written, comfortable to meet with all ReNeuron staff. • Knowledgeable and capable of presenting ideas and sharing information appropriately. • 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 manufacturing/analytical 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, CTLs, and collaborators) is expected. • 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: