JOB PROFILE

Job title:	Technical Scientist I
Reporting to:	Team Leader
Department:	CMC
Nº of Direct reports:	0
Location:	Pencoed
Job Details	
Job Purpose:	To assist in the development, transfer, validation and technical support of processes and methods associated with new and existing products. The role entails both lab-based activities and/or the on-site provision of technical support 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 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 assist in the provision of technical support for processes and methods. • Work with the Process Science Manager to define the requirements of each set of experiments or work package, organising your work to deliver to needed timelines. • Plan and perform experimentation in accordance with procedures to support CMC activities. • Collate, analyse and present data and author technical reports. • Ensure that experimental work is recorded in appropriately controlled laboratory books, protocols in accordance with the requirements of GxP. • Help maintain an efficient working environment, by assisting with all aspects of general lab housekeeping including consumable ordering. • Support 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, provide input into ongoing work and respond to questions from the third party.
- Prepare SOPs for processes/methods, and assist in the preparation of Training Packages.
- 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.
- Assist in the preparation of experimental data for regulatory submissions.
- 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 project timeline updates.
- Work with the Head of CMC/Process Science Manager/Quality Department to provide required technical support to GMP manufacturing activities.
- Review GMP manufacturing documentation (e.g., batch records) as appropriate.
- Review GLP technical documentation from CTLs as appropriate.
- Assist Quality Department with 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.
	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 peers within CMC and Pencoed site • Knowledgeable and capable of presenting ideas and sharing information appropriately. • A willingness to flexibly adjust to the changing needs of an emerging stem cell therapy business. • 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: