JOB PROFILE

Job title:	Regulatory Affairs Project Manager
Reporting to:	VP Regulatory Affairs and Pharmacovigilance
Department:	Regulatory Affairs
Nº of Direct reports:	0
Location:	Frimley/Pencoed
Job Details	
Job Purpose:	To provide regulatory input into regulatory strategy and submissions on a global basis for designated projects. To support pharmacovigilance activities.
Main areas of responsibility:	• To work closely with other functions to provide strategic regulatory input into the development of designated projects. • Act as regulatory affairs representative on development project teams. • Preparation, compilation and submission of CTAs/INDs/MAAs and amendments to regulatory authorities globally. • Review of changes to documents submitted in support of CTAs/INDs and assessment of these changes with respect to the need to submit amendments. • Maintain regulatory electronic and paper filing systems and archives, including regulatory components of the TMF for designated projects. • Maintenance of detailed trackers of submissions and approvals of CTAs/INDs for designated projects. • Prepare and update the Investigator Brochure and DSUR for designated products. • Prepare and submit for regulatory approval ODDs, PIPs etc as necessary for designated products. • Manage external providers in publishing and submission of regulatory filings. • Co-ordinate input into briefing documents for scientific advice meetings with regulatory agencies. • Provide regulatory input into non-conformances and change controls and provide regulatory affairs updates to QA metrics. • Development of and/or input into SOPs relating to regulatory affairs and pharmacovigilance activities within ReNeuron. • Manage pharmacovigilance activities in conjunction with external providers and ReNeuron clinical team. • Ensure regulatory affairs department compliance with relevant GMP/GCP requirements. • Maintain up to date knowledge of regulatory requirements for ATMPs and other areas of interest in relevant territories and disseminate key changes within regulatory affairs and to other departments as necessary. • Act as deputy to the VP Regulatory Affairs and PV in their absence.

Person Specification		
Qualification/ Experience required	**Essential**	**Desirable**
	First Degree in a biological science	Post-graduate qualification/training in regulatory affairs.
	At least 3 years' experience in development regulatory affairs.	Preferably in a small biotech company.
		Experience of managing pharmacovigilance activities during clinical trials
		Understanding of GCP
Skills and Competencies required	• Ability to understand complex scientific issues • Good organisational and planning skills • Ability and willingness to challenge information provided by others to improve quality of regulatory submissions • Good presentation skills • Clear written and verbal communications skills • Knowledge of GxPs • Flexible and pragmatic approach • Strong interest in biological science and specifically cell and/or gene therapy	

• 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: Shaun Stapleton	Date: 18 April 2019
Revised:	Date: