JOB PROFILE

Job title:	Director of Quality
Reporting to:	General Manager
Department:	Quality Team
Nº of Direct reports:	3
Location:	Pencoed
Job Details	
Job Purpose:	ReNeuron currently outsources all GMP and GLP activities. The Quality Director is a key player in the journey for ReNeuron as the clinical pipeline and manufacturing strategy progress through later stage clinical trials to commercial. A pragmatic, fit-for-purpose, QMS that encompasses GMP, GLP, GCP and medical devices with a high level of compliance, attention to detail and teamwork are key elements for success. The successful candidate will be a very skilled and experienced, quality assurance professional who has a pragmatic, fit-for-purpose approach and empowering leadership style consistent with the culture in this fast-paced SME. This role requires breadth of vision and ability to co-ordinate across a broad front, working with the GCP function to develop and embed the Quality vision within ReNeuron.
Main areas of responsibility:	Leading the quality team (QMS, GMP and GLP QA Operations and QC) and working through extended project teams and contractor organisations, the successful candidate will deliver the path through clinical trial to commercialisation with: ***Leadership of Quality for GMP, GLP and Medical Devices*** • Leadership of quality function, internally and externally, working closely with the leadership of the GCP team • Managing, motivating, coaching and support of the quality team members. • Maintaining resourcing plans and budgets ***Leadership of Quality Management System*** • Ensure ReNeuron has a fit for purpose, compliant QMS, with meaningful performance measures with narrative to ensure the QMS

	is measured, continually improved and complied with across the organisation. • Ensure that all systems have excellent risk management consideration. • Ensure the QMS is kept up to date and serves across all GXP and medical device requirements of the organisation • Be responsible for the GMP and medical device compliance as per EU Commission Directives 2003/94/EC, 2001/20/EC, FDA Regulations 21 CFR Parts 210 and 211 and Medical Devices Directive ISO13485 and other relevant regulations as they apply to devices and ATMPs. ***Leadership of Quality Control*** • Lead the QC team and provide strategic and operational input into justification for selection of all analytical methods and acceptance criteria in development, including characterisation, in process, for information and specification methods. • Lead the QC team to ensure all assays and procedures are fit for purpose and compliant for the stage of development. • Ensure QC operations and procedures are optimised to ensure best performance from CTOs in terms of quality, time and cost. ***Expert input into Development Programmes*** • Developing and implementing the GMP, GLP and devices Quality Assurance and Quality Control Strategies in line with the Projects and Corporate Strategy • Providing Quality oversight of all GMP, GLP and devices outsourced activities • Maintaining and improving departmental operational performance to meet the requirements of regulatory authorities, company SOPs, and external and internal customers with respect to quality, time and cost. • Developing and implementing the quality and inspection readiness plans that supports the manufacturing processes and analytics that leads to successful BLA submissions and launch in future.

Person Specification		
Qualification/ Experience required	**Essential**	**Desirable**
	• Significant experience in and understanding of the leadership of GMP QA and QC functions and QA GLP and medical devices in small to medium size biotech operations which were progressing to MAA/BLA. Impressive demonstrable track record gained within a similar position at a similar level.	• A QP qualified under the permanent provisions would be preferred. • Experience of taking a product to BLA/MAA

	• A track record of change management (vision and communication) but prepared to be hands-on operating through small teams and external contractors	• Experience and understanding of Leading class II medical devices to 510K and CE
	• A track record of implementing pragmatic, fit-for-purpose systems	
	• Experience of working with CMOs, CROs and CTOs	
	• Experience of Cell Therapy or First in Class therapies or complex biologics.	
	• Scientific degree	
	• Experience in leading an organisation to being PAI (or similar) audit ready	
Skills and Competencies required	• Strong leadership/team management skills and experience. Strategic thinker • Able to understand the complexity of cell therapy and navigate the quality and regulatory requirements successfully, achieving the optimal balance of quality, time and cost. • Credible and confident communicator • Highly patient focussed • Commercially astute • Strong analytical and problem solving ability • First class presentation skills (written and verbal) • Hands on approach with a can do attitude • First class organisational skills • Ability to prioritise, good time management skills • Excellent attention to detail, with the ability to work accurately in a busy and demanding environment. • Self motivated, with the ability to work proactively using own initiative • Committed to learning and development for self and others.	

Author:	Date:
Revised:	Date: