

# JOB PROFILE

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<b>Job title:</b>	Medical Director
<b>Reporting to:</b>	Chief Medical Officer
<b>Department:</b>	Clinical
<b>N° of Direct reports:</b>	N/A
<b>Location:</b>	Boston area
<b>Job Details</b>	
<b>Job Purpose:</b>	The Medical Director (MD) will support all areas of clinical development within ReNeuron, bringing their clinical development and medical experience and expertise to help the organisation meet its goals of completing well designed studies on time and to generate high quality data.
<b>Main areas of responsibility:</b>	<p>Drive the clinical development of REN products through helping form the company consensus on what patient groups to target; how to measure our products safety/efficacy and the design of the development programme</p> <p>Develop external relationships with medical thought-leaders relevant to REN disease areas and our products; make the most of these relationships in feeding the medical community view into study and programme strategy</p> <p>Input into development and writing of clinical study protocols</p> <p>Work with the clinical study manager and the CRO on operational aspects of individual studies e.g. patient flow; recruitment; database and CRF design</p> <p>If appropriate act as Medical Monitor for certain studies (e.g. smaller, UK based), and provide medical advice to the CRO</p> <p>Act as Sponsor Medical Reviewer for product safety e.g. attendance and input into safety review meetings; DSMB meetings; periodic safety document review; individual adverse event review</p> <p>Review and comment on study data: interim data for coding and deviation confirmation; final data for assessment of safety and efficacy signals</p> <p>Build and maintain excellent working relationships, and exchange of ideas and information with key REN development functions: Regulatory; CMC and product supply; Quality; Project Management</p> <p>Keep up to date with medical knowledge and current medical practice and emerging technologies; through reading and attendance at select medical conferences</p> <p>Present the external face of REN and promote our science and development activities, through authoring or reviewing medical publications, presenting at medical or industry meetings</p>

	Be aware of, contribute to and work within the Company's policies and procedures that relate to this role; especially GCP, Quality, Health and Safety; financial probity	
<b>Person Specification</b>		
<b>Qualification/ Experience required</b>	<b>Essential</b>	<b>Desirable</b>
	A medical qualification (MD, MB BS, MB ChB)	UK GMC registration
	Experience of working within the pharmaceutical or biotech industry within clinical development for at least 3 years, representing the Sponsor	3-5 years' experience as Sponsor
		Phase 1-3 experience
		Orphan disease, rare disease, complex medical products experience
	Ability to travel within the UK and internationally. Up to 25% international travel in support of this role.	Experience in either ophthalmic or nervous system research
<b>Skills and Competencies required</b>	<ul style="list-style-type: none"> <li>Assimilate data from multiple sources and develop strategic view on REN product development</li> <li>Work in a collaborative fashion; recognising the importance of information and advice from multiple internal sources</li> <li>Know when to escalate an issue, and when to take personal responsibility and make decisions</li> <li>Work consistently and accurately, with patient safety and data quality always in mind</li> <li>Bring a creative dimension to study design and problem solving</li> <li>Be able to work independently; be self-motivated to complete tasks and projects to meet agreed goals</li> <li>Be able to communicate complex issues clearly; both verbally and in writing</li> <li>Manage multiple competing priorities; both through personal time management and stakeholder communication</li> </ul>	

<ul style="list-style-type: none"> <li>To carry out any other tasks or duties within post holders capability as requested by the Company to meet business needs.</li> </ul>
<ul style="list-style-type: none"> <li>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.</li> <li>Information contained therein is not exhaustive but describes key elements of the function.</li> </ul>

Author:	Date: 27 July 2017
Revised:	Date: