

JOB PROFILE

Job title:	Senior Manufacturing Science and Technology (MSAT) Specialist
Reporting to:	Director of CMC
Department:	CMC
Nº of Direct reports:	0
Location:	Pencoed
Job Details	
Job Purpose:	<p>Responsible for transferring processes to manufacturing sites and providing technical and scientific support to processing operations in manufacturing to ensure robustness and efficient of manufacturing processes</p> <p>This role covers both the manufacture of cell banks and drug product of ReNeuron's cell therapies as well as exosome downstream purification operations</p>
Main areas of responsibility:	<p>Partner with Process Development, Analytical Development, Quality, Regulatory, Finance/Legal and CMO to transfer processes to manufacturing.</p> <p>Planning, execution and coordination of activities for</p> <ul style="list-style-type: none"> • Identifying CMOs with the capability to manufacture ReNeuron products • Providing RFPs and obtaining quotations for Tech Transfers • Facility fit/gap assessments of new processes into manufacturing plants • Developing the tech transfer plan with reference to the products CQAs • Preparing the tech transfer report to close out the tech transfer • Provide the necessary information packages to effect a tech transfer to the manufacturing site <p>Input into scale up activities to ensure that the solutions/processes developed are fit for manufacture</p> <p>Provide technical support and troubleshooting of manufacturing processes</p> <p>Determine what should be trended and owns process monitoring and process data analysis, identifying trends and flagging issue to that proactive interventions to ensure process consistency can be made</p> <p>Identify continuous improvements opportunities to the manufacturing processes</p> <p>To prepare and deliver technical training on new process improvements</p> <p>Identify and budget for new capital equipment to support the initial tech transfer or process improvements</p>

Health and Safety	
<p>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.</p>	
<p>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.</p>	
<p>You must ensure that all hazards, incidents and accidents are reported to your line manager</p>	

Person Specification		
Qualification/ Experience required	Essential	Desirable
	Degree in Biological Science	Ph.D in a Biological Science
	5 yrs biologics development experience	Experience in cell and gene therapy process development
Skills and Competencies required	<ul style="list-style-type: none"> • Act as an ambassador for ReNeuron in all interactions with third parties • Be an exemplar for team working and co-operation within ReNeuron and build a strong external network of expertise • Adapt the style of communication (verbal, behavioural, visual aids etc) depending on the target audience and the situation • Strong influencing skills in order to successfully implement change • Desire to understand why and improve processes <p>Biologics/Cell therapy:</p> <ul style="list-style-type: none"> • Process development • Scale up and process engineering • Data interrogation • Process monitoring • Technical troubleshooting • Industry trends 	

<ul style="list-style-type: none"> • To perform any other tasks or duties within post holders capability as requested by the Company to meet business needs. • Some UK and international travel to meetings, conferences, and third parties (e.g., CMOs, and collaborators) is expected.
<ul style="list-style-type: none"> • 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:

ReNeuron