

JOB PROFILE

Job title:	Senior Manufacturing Science and Technology (MSAT) Specialist
Reporting to:	Director of CMC
Department:	CMC
N° 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			
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Degree in Biological Science</td> <td style="width: 50%;">Ph.D in a Biological Science</td> </tr> <tr> <td>5 yrs biologics development experience</td> <td>Experience in cell and gene therapy process development</td> </tr> </table>	Degree in Biological Science	Ph.D in a Biological Science	5 yrs biologics development experience
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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