# JOB PROFILE

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| **Job title:** | Director of CMC |
| **Reporting to:** | General Manager |
| **Department:** | CMC Team |
| **Nº of Direct reports:** | 6 |
| **Location:** | Pencoed |
| **Job Details** | |
| **Job Purpose:** | The job holder is responsible for all aspects of CMC for ReNeuron's pipeline, and for maintaining supply of Drug Product to meet ReNeuron's clinical trials.<br>This role is also for accountability for the inputs into CMC regulatory submissions and interactions with regulatory agencies.<br><br>This is a senior position and a deputy to the General Manager for site leadership and health and safety, and a member of the overall company management team. |
| **Main areas of responsibility:** | Deliver across the full range of CMC development and manufacturing work for ReNs programmes to ensure supply of product to clinical studies and inputs to regulatory submissions up to the point of achieving successful applications to market ReNeuron products in key territories.<br><br>**Process development and Laboratory Management**<br><br>• Lead the CMC laboratory operations to ensure efficient and safe practices are implemented at all times<br><br>• Own the high level roadmap for the process development path leading to marketing authorization. Lead an appropriate scientific/technical team to carry out this work and identify suitable CMOs for defined work packages as needed.<br>• Ensure that the production process can meet Phase III and market supply demands and that the COGs is optimized.<br>• Work with team to identify critical quality attributes and identify and track all critical process parameters. Ensure the team has the technical skills and training to diagnose and rectify process development issues and manufacturing events and can respond quickly and effectively to maintain material supply<br>• Develop optimized, robust processes with in-process controls and defined parameters and limits<br>• Lead the team to develop, optimize and validate the biological function/potency assays to move them from the R&D team to the in-house QC team. |

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| | • Take overall accountability for ensuring all data/reports generated by the team are to appropriate quality and regulatory standard for compilation into CMC submission and meet submission deadlines.<br>• Create and own a risk register across CMC activities and propose mitigation plans<br>• Provide data and text as needed to support generation of CMC sections of regulatory submissions. Attending regulatory agency meetings as required.<br><br>**Manufacturing of clinical supplies through CMOs**<br><br>• Take responsibility for ensuring all primary tissue sourcing and control via outsourced partners meets HTA regulations<br>• Be accountable for the selection of suitably technically qualified CMOs for cost effective manufacture of clinical material.<br>• Manage the day to day interaction with the CMOs to ensure material is delivered on time and in budget and is manufactured in accordance with GMP and achieves specifications. Personally manage the high level relationship with the CMO to ensure on-going high service levels to ReN<br>• Ensure the team has the appropriate skills to produce and review GMP paperwork covering process development and validation and creation of SOPs, batch records etc<br>• Manage the budget for CRO/CMO work and other CMC activities<br>• Ensure all work is planned with clearly written protocols and that all reports are written in a timely manner. Ensure that all documentation from CMOs is reviewed and stored as appropriate within the QMS<br>• Manage the supply and distribution through the Supply Chain Manager, ensure all processes for logistics are in place and that the information re handling of products at site are clear.<br><br>**Health and Safety**<br>• Key member of Health and Safety committee which is responsible for H+S leadership across the site<br>• Mentorship of team and other site staff with respect to working safely and continuous improvement |

| **Person Specification** | | |
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| **Qualification/ Experience required** | **Essential** | **Desirable** |
| | • Proven experience in cell processing, well respected in the bioprocessing community | |
| | • Track record of managing a biological process development package to Phase III/commercial. Proven experience of QBD | |

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| | • Experience of writing CMC packages for regulatory submissions, preferably for license | |
| | • A thorough knowledge of distribution of short shelf life products to market and clinical sites | |
| | • Experience of working in a GMP support environment-natural GMP mind set-highly organised | |
| | • Direct experience of face to face interactions with regulatory authorities on CMC matters. | |
| | • Proven experience of process validation for a biologics process | |
| | • IOSH Managing Safely | NEBOSH General Certificate |
| **Skills and Competencies required** | • Able to communicate precisely but succinctly to the Exec team to present decisions, risks etc<br>• A driven team leader, motivating, enthusiastic<br>• Able to work both at the overview level but with a keen attention to detail | |

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| • 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.<br>• Information contained therein is not exhaustive but describes key elements of the function. |

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| Author: | Date: |
| Revised: | Date: |