JOB PROFILE

Job title:	Manufacturing Manager
Reporting to:	Head of CMC
Department:	CMC
N^{o} of Direct reports:	Approximately 8. Team to be recruited over next two years
Location:	Pencoed
Job Details	
Job Purpose:	Responsible for all facets of establishing a new GMP Aseptic Manufacturing function in a new facility including the recruitment and training of the team, creation of all relevant GMP documentation and establishing the smooth operation of the production process, for the manufacture of GMP clinical batches and full scale production for commercially licensed product.
Main areas of responsibility:	• Lead and represent the manufacturing function in the delivery of the GMP aseptic manufacturing facility, working full-time on the design, build and fit-out project. • Work closely with other functions (Engineering, Quality) to identify and introduce new manufacturing equipment and processes to the facility. • Attend FATs, SATs, IQ/OQ as appropriate during validation of the plant and equipment • Prepare and manage the manufacturing budget. • Plan the production start-up in the new facility and recruit and train new team members in a timely fashion. • Contribute to the development and execution of the technical transfer protocol and process qualification and validation • Participate actively in the preparation for the Manufacturing and Importation Authorisation - be the named person responsible for production on the authorisation. • Establish and manage the production schedule to meet clinical needs and ensure that output is manufactured in accordance to cGMP and Regulatory expectations • Manage all Manufacturing personnel and ensure that the department, premises and equipment are maintained and operated to the required standards and in a safe manner. Ensure full compliance to HS&E across the manufacturing facility. • Participate in, and lead elements of inspections by Regulatory Authorities including MHRA and FDA. Ensure close-out of any deficiencies identified during those inspections that relate to the role-holder's scope of operations. • Champion continuous improvement in the manufacturing facility to enable production to be completed in the most effective manner. • Complete and review risk assessments to ensure no disruption of product to the clinic. • Champion strong relationships with cross functional departments including Quality, Engineering and Regulatory groups • Actively maintain and update knowledge and expertise of current

	developments, standards and operating practices within the ATMP and pharmaceutical industries • Support the design or development of new equipment/processes for existing and future requirements • Responsible for shift and/or out of hours working as required by the manufacturing schedule. • Overseas travel as required to visit, for example, other manufacturing sites or equipment suppliers. • 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 any time according to the needs of the Company's business. • Information contained therein is not exhaustive but describes key elements of the function. • Creation and ownership of the Operational scorecard. • Provide the management and development of the teams through assignment of goals and objectives, resource and performance management. Identify development needs of individuals and create and execute development plans. • Functional Business Acumen – financial awareness; setting priorities, and developing tactical and strategic plans aligned with the bigger picture; collaborate across piers and influence upwards • Derive business cases, manage and execute projects (capital or expense related) that provide quantified incremental or transformational business improvement in Operations in accordance with the project management methodology. • Support forward planning in Operations for the business & capital plan in particular in relation to capacity, automation and any other relevant strategies to support growth in current products or commercialisation of new products • Ensure that operational performance is measured to facilitate data-driven deployment of company resource • Knowledge of Business Continuity Process • Ability to recruit, develop and coach staff; identify and develop high performers; manage performance; and deploy effectively • Lead and own operational CAPA's • Ability to lead and deliver change and ensures that all activities are carried out in compliance with all regulations and laws governing business and quality operations (GMP, ISO, etc.). • Operational champion of relevant SOP's, WKI's, training modules. • Create and own manufacturing batch record system to ensure complete and transparent traceability of product. • Setup and owner of materials ordering, storage and flow for manufacturing from dock to stock • Ensures that all aspects of the operational process have robust risk assessments and appropriate mitigations in place.
Person Specification	
	• Flexible and hard working with proven ability to lead and motivate a team. • Good communication skills; able to interact with and influence individuals across a variety of functions (without a direct reporting relationship).

Qualification/ Experience required	Essential	Desirable
	• Current working knowledge of GMP, and with deep knowledge of and management experience of sterile and ideally aseptic manufacturing environments. • Degree or equivalent in biological science, engineering or related area • Experience of introducing new processes and equipment into a GMP manufacturing facility. • Experience of leading the production team in EU and/or FDA GMP regulatory inspections. • Experience of manufacturing cell therapy products or biologicals, and/or demonstrate the capability of learning the relevant processes. • Significant experience of managing a team responsible for manufacturing in licensed GMP Grade A, B and C environments. • Good understanding of the Quality Management System and proactive approach to resolving deviations and CAPAs • Good understanding of lean manufacturing principles.	• Experience of establishing a new GMP manufacturing unit and identifying and documenting all relevant processes. • Green belt LSS
Skills and Competencies required	• Ability to take a pragmatic approach to solving problems, resolving conflict, and developing practical solutions.	

Author:	Date:
Revised:	Date: