Director of Biologics & RNA Centre of Excellence – Job Description

Role Purpose:

The Director of Biologics for the National Biologics Manufacturing Centre (NBMC), as the holder of a Manufacturing Authorisation, must manufacture medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the Marketing Authorisation or Clinical Trial Authorisation, as appropriate and do not place patients at risk due to inadequate safety, quality or efficacy.

The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by its distributors.

To achieve this quality objective reliably there is a comprehensively designed and correctly implemented Pharmaceutical Quality System incorporating Good Manufacturing Practice and Quality Risk Management. It is fully documented and its effectiveness monitored via monthly Quality Council meetings. All parts of the Pharmaceutical Quality System are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

- To develop the National Biologics Manufacturing Centre (NBMC) the as an open-access innovation centre for advanced Biopharmaceutical product design and manufacture within CPI.
- To develop the sustainable capability of Biologics to deliver CPI Business plans by achieving target KPIs on revenue (private, CRD and Catapult) vs cost profile, Engagements (SME, Academic) and Thought Leadership in Biologics spaces.
- To establish and lead the UK National Biologics Manufacturing Centre within CPI and develop effective networks with partners to serve the innovation needs of the biopharmaceutical community spanning academia, SMEs and large corporates.
- Develop UK National BMC to create and deliver a UK clinical supply chain service in support of nucleic acid

Key Responsibilities:

Leadership

- To champion and ensure compliance with agreed SHE, GMP and quality standards.
- Develop supply chain capability
- To identify and implement continuous improvement to SHE and quality standards.
- To champion the CPI brand and promote it both externally and internally.
- To collaborate with other CPI business units in order to develop added value and increased opportunity for the company in its chosen markets.
- To create the energy and drive required to recruit and motivate talented people to deliver the overall objectives consistent with broader CPI objectives.
- To provide strategic leadership to Biologics teams.
- To undertake horizon scanning to maintain current up to date knowledge of developments within biopharmaceutical technologies and continuously improve the Centre's technical capability leadership.
- To create an integrated team, sharing knowledge effectively in order to predict, understand and interpret customer needs.
- To develop and maintain an effective communications framework which ensures that there is open dialogue across the Centre and that colleagues have a clear understanding about the performance of each project and the part they play in its success.
- To apply sound commercial and technology judgment aligned with best professional practice.

- To provide professional guidance to colleagues and contribute to own and team's continuous professional development.

Capability Development

- To lead capability development to accelerate the design and optimisation of new biopharmaceutical products throughout the innovation supply chain from R&D to production and market.
- To develop technology capability that can be implemented in a production environment to provide better products, improved quality and significant economic or environmental benefit.
- To lead development of integrated product and process design that delivers positive techno/economic the impact to the UK bio-pharmaceutical sector.
- To ensure that technical capability development is undertaken to optimise safety, financial performance and positive environmental impact.
- To be lead the translation of ideas and concepts into commercial value offerings.
- To work collaboratively with Commercial and Technology teams to identify areas where innovation can add value to customer projects and increase the CPI's value offering.
- To lead development of professional guidance to colleagues and contribute to own and team's continuous professional development to build and expand capability.
- To strategically plan project asset and resource requirements effectively to deliver projects to time and budget.
- To understand and apply effective business discipline and ensure that time is allocated to relevant project codes within agreed budgets, alerting relevant stakeholders to any slippage or potential over runs communicating clearly across CPI via C&R format.
- Actively develop a culture of continuous capability development within teams in alignment with CPI strategy and project deliverables.

Commercial

- To deliver agreed CPI private, CRD and public funding targets and budgets for the Biologics Business Unit.
- To agree and maintain a dynamic stakeholder map with Strategic Marketing and collaborate effectively to create sector capability and value.
- To create and develop a distinct biopharmaceutical community aligned with the UK High Value Manufacturing Catapult.
- To develop a strong customer focus culture within the biologics team.
- To build high quality, collaborative relationships with partners and customers, based upon openness and trust.
- To develop understanding of partner and customer need to identify opportunities to create value offerings based upon CPI capability and knowledge.
- To work with internal and external customers to identify and understand their needs and contribute to the design and delivery of agreed outcomes within agreed budgets and timescales.
- To provide biologics technology domain leadership to strategic project scoping and feasibility studies in pursuit of effective business generation.
- To develop and deliver a commercial budget for a clinical supply chain

Good Manufacturing Practice - GMP

CPI have a responsibility to manufacture medicinal products of the requisite quality, fit for their intended use and be in accordance with the relevant Manufacturing and Marketing Authorisations, Clinical Trial Authorisation, Product Specification, Drug Master File or CEP Dossier as appropriate and which do not place patients at risk due to inadequate safety, quality or efficacy. The Pharmaceutical Quality System, which incorporates Good Manufacturing Practice, is designed to deliver this quality objective, the attainment of which requires the participation and commitment of all staff across departments and at all levels within the company.

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Good Manufacturing Practice is the part of Quality Management which ensures that products are consistently produced to the correct quality standards. To comply with the principles of GMP, it is required that clearly defined procedures are adhered to when performing operations across CPI.

The GMP Responsibilities of the Director of Biologics are:

- To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality
- To approve the instructions relating to production operations and to ensure their strict implementation
- To ensure that the production records are evaluated and signed by an authorised person
- To ensure the qualification and maintenance of his department, premises and equipment
- To ensure that the appropriate validations are done
- To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need

This role has accountabilities for delegated levels of authority in line with our Contract Signatory Authorities policy, please refer to this separately

Direct reports: Up to 5 direct reports

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Person specification

Education / Qualifications:

Essential:	Desirable:
Educated to Degree level (or equivalent) in a scientific discipline (of relevance to role).	Educated to Masters Degree level (or above) in a scientific discipline (of relevance to role).

Competencies and behaviours	
Leadership (Shaping)	**Decision Making (Shaping)**
• Contributes to the strategic leadership of the business and has influence over organisational behaviour. • Manoeuvres through complex political issues effectively. • Uses the resources available effectively in the anticipation of future consequences and trends. • Sees beyond today's pressing priorities and pressures to provide a compelling vision of the future.	• Confidently takes decisions that require political/organisational interpretation and that could cause controversy but moves CPI forward. • Reliably and boldly takes decisions involving the charting of a way forward into a new territory where no precedent exists and analysis of all available data provides no clear single conclusion. • Models drive and resilience in ensuring the solutions are adopted.
Communication (Shaping)	**Developing self and others (Shaping)**
• Radiates experience and self confidence in all communication situations. • Is charismatic, enthusiastic and pro-actively shares knowledge, guidance and expertise across the organisation. • Develops and uses subtle strategies to influence or persuade CPI's strategic stakeholders, particularly in sensitive or high pressure situations.	• Creates an organisational climate that inspires development. • Develops successors to ensure availability of future talent. • Keeps fully up to date with developments outside immediate area of expertise. • Is highly intuitive about people and their development potential, and takes informal and creative risks. • Maximises the business benefits of having a well developed and motivated workforce.
Collaboration (Shaping)	**Delivery (Shaping)**
• Unites people around the business to deliver the strategy. • Represents CPI interests persuasively and builds an influential presence in the external business environment to raise profile with strategic stakeholder groups. • Can manoeuvre through complex political situations effectively and quietly.	• Maintains the clarity of reporting and decision making processes, the governance structures and the staffing, during the progress of projects. • Monitors progress against the benefits and plan, taking account of risks and changes in the environment and takes action to amend the project where appropriate to maximise achievement of the planned benefits/ outcomes. • Investigates externally to CPI, and brings in knowledge to improve CPI's performance.

Knowledge and Experience:

Essential:	Desirable:
Demonstrates a substantial track record of creating start-up organisations through building energy behind an opportunity and purpose. Demonstrate evidence of building cross-industry knowledge sharing networks to apply best practice. Demonstrates evidence based technology business management experience delivering high quality outcomes	Direct experience of chemical, biotechnology or Pharmaceutical process engineering in an applied research environment. Experience of developing a membership model organisation.