Principal Scientist – Microbial Upstream – Job Description

Role Purpose:

To provide high-level technical expertise and leadership in order to deliver large scale / complex projects and develop technology team level knowledge and practice.

The Principal Scientist acts as a credible technical expert for the organisation, drawing upon a broad range of technical know-how to provide technical expertise and advice to a range of stakeholders, in order to inform technical strategy and direction.

Key Responsibilities:

- To embrace and role model the desired behaviours to exemplify our Company values, promoting an ethical, positive company culture.
- To maintain consistent and documented compliance with all relevant Safety, Health and Environmental (SHE), Good Manufacturing Practice (GMP), Data Integrity (DI), quality and best practice requirements.
- Application of your broad scientific knowledge to projects and client programs
- To assist the development and analytical characterisation of Biologics processes to provide proof of successful process development/optimisation.
- Maintain knowledge of new practices and procedures from relevant literature and other sources.
- To identify new technical developments and trends, translating these into building blocks for opportunities across and outside of CPI and initiate the creation of (new) technological innovations/applications.
- To utilise own expert knowledge to inform the technology strategy at technology team level, translating this into practice through the creation of deliverable plans to achieve technology team objectives.
- To build, influence and exploit a network of relevant (inter)national external stakeholders, customers, partners, research organisations and authorities, to represent CPI as the technical expert in networks and discuss and lobby for projects and future developments.
- To actively contribute to a culture of continuous capability development within teams, in alignment with company strategy and project deliverables. This will be achieved by coaching and developing colleagues, (both technically and behaviourally) to help them reach their potential and acting as a mentor to senior colleagues across the organisation, providing a strategic perspective.
- To keep self up to date with developments in technological innovations/applications and/or legislative and SHE related changes, ensuring implementation and application of new best practice and/or knowledge.
- To work collaboratively with Business Development and technical colleagues, providing support relating to proposal / project development and direct customer engagement. Seek out and engage in business development opportunities where appropriate.

- To act as a credible partner to Bid Development teams, actively involved in defining and advising on the technical elements of a bid, in order to develop a programme of works.
- To formulate and present solutions to a range of stakeholders, using deep technical knowledge to provide up to date views, opinions, and advice to managers, and is regularly sought out to do so.
- To actively engage in hazard studies / SRA studies and discussions, as appropriate to role level.
- To set up, plan and execute experimental / pilot scale runs and analyse, interpret, and report the results of these, translating obtained findings and knowledge.
- To be responsible for providing clearly documented records of technical data, decisions, methodologies, calculations, and software use in an agreed format.

Knowledge and Expertise specific to role:

To have and continuously develop a broad knowledge/expertise relevant to upstream and/or downstream processing and/or analytical characterisation of biopharmaceuticals such as proteins, viral vectors, and nucleic-acid based products expressed in mammalian, bacterial, insect, yeast cells and/or cell-free systems. Your knowledge/expertise should be both practical and theoretical in areas such as:

- Theoretical and practical knowledge and expertise in Cell Biology, Biologics expression, Bioreactor scale up and relevant analytical techniques (expert knowledge in field or understanding to support your area of expertise).
- Theoretical and practical knowledge and expertise in Biochemistry, Biologics Purification, Biochemical Engineering and relevant analytical techniques (expert knowledge in field or understanding to support your area of expertise).
- Theoretical and practical knowledge and expertise in the development, utilisation and verification of analytical methods for characterisation of in process and final product biopharmaceuticals (expert knowledge in field or understanding to support your area of expertise).
- Comprehensive experience and knowledge of leading and delivering experimentation around the production and/or analysis of therapeutic biologics focussed on the design, development and scale-down/scale-up of processes or the development and/or adoption of new technologies.
- Knowledge, application and use of CIP or reusable or single use systems in Biologics.
- Application of techniques for the analysis of proteins and other biologics.
- Application of experimental design and statistical concepts to experimental planning.
- Use and application of computer systems and software for data acquisition and analysis.
- Extensive experience and high levels skills in document writing, data interpretation, presentation and statistical analysis.

- Knowledge of bioprocessing industry and cGMP concepts.
- Comprehensive experience and knowledge in the development and analytical characterisation of Biologics processes to provide proof of successful process development/optimisation.
- Comprehensive experience of being the primary technical contact for clients, using customer management skills to build excellent working relationships.
- Experienced technical leader/manager of collaborative research and development and/or commercial projects, co-ordinating the activities of the assigned team.
- Support/supervision of other scientists and the evaluation of data integrity.
- To evaluate and develop new technologies for use in the upstream and/or downstream processing and/or analytical characterisation of biopharmaceutical products.

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.

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.

Data Integrity - DI

Data Integrity is the degree to which data are complete, consistent, accurate, trustworthy, reliable and that these characteristics of the data are maintained throughout the data life cycle. The data should be collected and maintained in a secure manner, so that they are attributable, legible, contemporaneously recorded, original (or a true copy) and accurate. Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices.

CPI, as a GXP organisation, have developed a Pharmaceutical Quality System, which incorporates a DI Governance System – a series of arrangements to ensure that data, irrespective of the format in which they are generated, are recorded, processed, retained and used to ensure the record throughout the data lifecycle.

To comply with the principles of DI, it is required that clearly defined procedures are adhered to when performing operations across the site. All staff are actively encouraged/supported in the reporting of errors, omissions and undesirable results.

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Direct reports: No direct reports

Person Specification

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus significant and in-depth industrial experience at an expert level. Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience at an expert level. Or Educated to master's degree level (or equivalent) plus significant industrial experience at a very senior level. Or Educated to PhD level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience at a senior level.	Chartered status with a relevant professional institution.

Competencies and behaviours	
Leadership (Influencing)	**Decision Making (Guiding)**
• Promotes commitment to our PRIDE values, strategy, vision, and direction. • Motivates, inspires, and builds resilience in others by making the vision shareable by everyone, and ensuring that teams are purposefully empowered in order to work efficiently. • Rewards and celebrates success with colleagues and teams. • Future proofs work practices. • Trusts others' judgment and demonstrates radical thinking,	• Leads and facilitates a group to a decision from complex, inconclusive, or contradictory data, prioritising the needs of CPI. • Evaluates options by considering short term consequences and long-term gains. • Uses correct communication method to present a case so that it has greatest persuasive impact. • Is regularly sought out by colleagues for advice and solutions.

including a willingness to try new things, even at the risk of failure.	
Communication (Guiding)	**Developing self and others (Influencing)**
• Personally takes the lead in creating an environment that encourages open and honest communication at all levels in the organisation. • Motivates and influences others via their communications. • Adapts communication style and format recognising individuals' different needs/ motivations. • Communicates corporate message with conviction and enthusiasm, with knowledge and understanding of internal communications messages and branding, and thereby promotes commitment and belief in others.	• Assesses the skills and competence of others within the organisation and recommends development activities. • Brings diverse people together for collaboration, ensuring that employees are open to new ideas and effective collaboration. • Gives performance feedback in a timely manner on an informal basis regularly. • Actively shares expertise and learning across the organisation. • Takes personal accountability for success or failure of direct reports.
Collaboration (Guiding)	**Delivery (Guiding)**
• Displays a collaborative style in day-to-day working whilst motivating others to achieve optimal performance and results. • Fosters an inclusive atmosphere throughout their teams where ideas and creativity can thrive, and people feel empowered to be their whole selves. • Develops relationships which facilitate the resolution of complex tasks and can apply different techniques to effectively mitigate any conflict. • Can negotiate skilfully in tough situations with all stakeholders.	• Demonstrates the ability to prepare, gain approval of, refine and update business cases that justify the initiation of a project. • Displays the ability to manage stakeholders, taking account of their levels of influence and particular interests. • Ensures actions and decisions within the team are aligned with CPI's priorities. • Anticipates how team objectives must adapt and stretch to respond to change.

Knowledge and Experience:

Essential:	Desirable:
Experience of leading large cross-function technical development projects. Will possess significant, technical expertise in biologics & bioprocessing, upstream and/or downstream processing and/or analytical characterisation as well as compelling evidence of complex technical problem solving. Is a recognised industry expert in their area of expertise, as well as having broader technical knowledge and capability, and ability to apply in a variety of contexts. Significant practical experience of different expression systems and/or purification approaches and/or analytical characterisation for therapeutic biologics. This includes both cell and/or cell-free, stable, and or/ transient systems and associated analytics. Familiarity with the use of and design of experiment methodologies to inform experimental design. Is comfortable using own judgement and initiative within standard engineering / scientific practices, as well as an understanding of when to seek advice from colleagues. Will exhibit professional mastery of principles and practices in area of expertise gained through career to date in area of specialism. Can demonstrate evidence of building knowledge sharing and network building practice across teams.	Is an active member of a professional body, engaging with peers beyond CPI.

Actively demonstrates in-depth technical and theoretical knowledge in at least one area and is viewed as a specialist in this area by peers. Can provide examples of actively building cross-team and business area collaboration to achieve desired results.	

Signature of Job Holder By signing this you confirm you have read, understood, and agree to work in alignment with the above job description.	
Printed name **Signature** **Date**	