Senior Scientist 1 – Synthetic & Mammalian Upstream
Job Description

Role Purpose:

To provide technical expertise and input in order to contribute to the delivery and realisation of projects, acting as technical lead in small and medium scale projects, and projects of some complexity. Draws upon a range of technical know-how to provide carefully thought-through advice and expertise to a range of stakeholders across the organisation. The Senior (1) is viewed as a specialist in their area of discipline, offering innovative solutions at technology team level, contributing to development and improvement activities.

Key Responsibilities:

- 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.
- To build and maintain a network of relevant internal stakeholders, to represent self and the wider team as a credible professional in networks and groups.
- To keep self up to date with developments in areas relevant to role, and/or legislative and SHE related changes, ensuring understanding of these and any associated new best practice, methods or techniques.
- To support in Business Development and Bid Proposal activities, to contribute to proposal / project development and direct customer engagement.
- To present and formally report experimental conclusions and supporting data for internal peer review and submission to clients, to agreed timescales and standards.
- 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 within agreed timescales and standards and in accordance with project requirements.
- To be responsible for providing clearly documented records of technical data, decisions, methodologies, calculations and software use in an agreed format.
- To take ownership in agreeing weekly workplans with line manager, project manager(s) and other relevant stakeholders, and delivering plan to agreed schedule.
- To be responsible for the maintenance and calibration of equipment to ensure it operates in a safe and efficient manner and is available to meet customer needs.

Responsibilities and expertise specific to role:

To have and continuously develop a good knowledge/expertise focused on the development, validation and scale up/ scale down of synthetic and mammalian expression systems and processes for the production of biologics including recombinant proteins, mRNA, viral vectored products and

other modalities. Your knowledge/expertise should be both practical and theoretical in areas such as:

- Practical knowledge in Molecular Biology, Cell biology and engineering, Biologics expression in mammalian, synthetic and/or cell-free systems, high throughput screening, Bioreactor scale up and relevant analytical techniques.
- Lead and deliver experimentation around the development and validation of synthetic and cell based-expression systems suitable for the production of protein and gene-therapy based biologics including mRNA, viral vectored products and other novel systems.
- Lead and deliver experimentation around the production of therapeutic biologics focussed on the design, development and scale-down/scale-up of upstream processes
- Knowledge and use of reusable or single use bioreactor systems such as Sartorius's Biostat range or similar
- Knowledge and practical experience of mammalian perfusion culture and process intensification for production of biologics
- Application of techniques for the analysis of proteins, DNA, RNA and other biologics including cell-based assays.
- Application of experimental design and statistical concepts to experimental planning
- Use and application of computer systems and software for data acquisition and analysis
- Document writing, data interpretation, presentation and statistical analysis
- Knowledge of bioprocessing industry and cGMP concepts
- Application of your broad scientific knowledge to projects and client programs
- Providing training, mentoring and supervision to other members of the team
- To assist the scale up of synthetic and mammalian processes (up to pilot scale) to provide proof of successful process development/optimisation.
- Maintain knowledge of new practices and procedures from relevant literature and other sources.

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.

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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.

Direct reports: No direct reports

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience at a senior level Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience Or Educated to master's degree level (or equivalent) in a Scientific/Engineering discipline plus significant relevant industrial experience Or Educated to PhD level (or equivalent) in a Scientific/Engineering discipline	

Competencies and behaviours

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Leadership (Enabling)	Decision Making (Influencing)
• Builds and leads groups, communicates a compelling and inspired vision and sense of core purpose to deliver the incredible by arriving at an agreed schedule of work for a project, including agreed success criteria. • Demonstrates commitment to common goals, integrity and trust in all dealings with colleagues and customers.	• Confidently draws reliable conclusions from diverse and sometimes incomplete data. • Proactively sources and refers to how others have tackled similar problems previously. • Considers risks, and consequences, and takes accountability for, the impact the decision has on the business including costs/ benefits. • Thinks ahead, ensuring that the potential of teams and projects are unlocked and making future focused decisions.
Communication (Enabling)	**Developing self and others (Enabling)**
• Presents complex issues/ data with a high level of clarity and impact, using the appropriate format and driving action. • Is able to write clearly and succinctly recommendations and messages that have the desired effect. • Is aware of the impact of their communications and pro-actively seeks feedback for improvement, learning from their experiences and takes ownership of their actions and how they present them. • Is able to influence others by preparing a reasoned argument to adopt a specific tactic or plan, in line with strategy, and persuade others of the merit.	• Supports others in their development. • Is personally committed to, and actively seeks, opportunities to improve continuously. • Is comfortable learning from the experiences of others and recognises the differing strengths of team members. • Provides honest helpful feedback to others on their performance. • Insightful about self, strengths and limitations, and how to maximise contribution.
Collaboration (Influencing)	**Delivery (Influencing)**
• Blends people into teams, leveraging the use of talents available from any part of the organisation that result in the most innovative solution. • Fosters a sense of energy, ownership, and personal commitment to collaborative work, ensuring that diverse people are able to collaborate openly and honestly as one team even with differing views and perspectives. • Understands the priorities and deeper needs of different stakeholder groups, being sensitive to different experiences. • Supports and enables people to work together to meet objectives.	• Prepares and maintain schedules for activities and events for projects. • Delegates responsibilities for tasks and decisions to the appropriate staff; sets SMART objectives and monitors progress, fostering an atmosphere of purposeful empowerment in order to allow teams to function efficiently. • Researches capabilities and constraints, in advance of a project, which could affect its approach and outcomes. • Holds people accountable for achieving results.

Knowledge and Experience:

Essential:	Desirable:
Will exhibit professional mastery of principles and practices of molecular, cellular and vector	Understanding of GMP & the requirements for the production of biopharmaceuticals

biology, gained in academic or industrial environments OR Will exhibit professional mastery of principles and practices of upstream processing, gained in academic or industrial environments Significant practical experience using and/or developing different expression systems for protein and nucleic acid based biological products including both cell and/or cell-free, stable and or/ transient systems Experience with complex technical problem solving Significant practical cloning experience including vector design, restriction, ligation and transformation Practical mammalian cell culture experience Experience with development and utilisation of relevant analytical techniques including qPCR, SDS-PAGE, ELISAs and cell-based reporter assays Experience of leading technical development projects Is comfortable using own judgement and initiative within standard engineering / scientific practices, as well as an understanding of when to seek advice from colleagues Can demonstrate evidence of building knowledge sharing and network building practice across teams Actively demonstrates in-depth technical and theoretical knowledge in at least one area and is viewed as a specialist in this area by peers	Familiarity with the use of design of experiment methodologies to inform experimental design Supervision/management of other team members Use of high throughput bioreactor platforms Knowledge and practical experience of perfusion culture and process intensification

Can provide examples of actively building cross-team and wider technology team collaboration to achieve desired results Actively participates in diverse or complex technical activities where it is necessary to use own initiative and judgement	

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**	