Scientist 1 – Microbial Upstream – Job Description

Role Purpose:

To contribute to the delivery and realisation of project work through preparation, development, research, design, testing and analysis work in line with technology team requirements. The Scientist 1 will work under technical supervision of line manager and senior colleagues, supporting with a range of activities to meet technology team objectives.

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 keep self up to date with developments in areas relevant to role, and/or legislative and SHE related changes as communicated by senior colleagues, ensuring understanding of these and any associated new best practice, methods, or techniques.
- 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 quality standards, and in accordance with project / client 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.
- To take responsibility for general housekeeping of technical areas, to contribute to a safe and healthy workplace.

Responsibilities and expertise specific to role:

To develop and apply knowledge/expertise relevant to upstream processing of biopharmaceuticals such as proteins, viral vectors, and nucleic-acid based products expressed in bacterial, yeast cells and/or cell-free systems. Responsibilities and expertise include:

- Theoretical and practical knowledge of Molecular Biology, Biologics expression, Bioreactor scale up, high-throughput screening and relevant analytical techniques.

- Support delivery of experimentation around the production of therapeutic biologics focussed on the design, development and scale-down/scale-up of upstream processes
- Expertise and practical understanding of microbial strain construction, selection, and characterisation
- Use and application of computer systems and software for data acquisition and analysis
- Document writing, data interpretation, presentation, and statistical analysis
- To assist the scale up of upstream processes (up to pilot scale) to provide proof of successful process development/optimisation.
- Develop and maintain knowledge of new practices and procedures from relevant literature and other sources.
- Knowledge of bioprocessing industry and cGMP concepts

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 relevant industrial experience. Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline.	

Knowledge and Experience:

Essential:	Desirable:
Will possess foundation of technical knowledge and some underpinning knowledge in upstream microbial processing, as well as evidence of technical problem solving gained in academic or industrial environments. Practical experience in one or more of the following areas: • Microbial culture • Bioreactor/fermenter operation • Microbiology and/or aseptic techniques • Molecular biology Experience of planning and delivering technical work. Experience of data analysis & reporting findings (documentation and/or presentations). Can demonstrate evidence of knowledge sharing and network building practice across teams or groups.	Understanding of GMP & the requirements for the production of biopharmaceuticals. Experience with relevant analytical techniques including qPCR, SDS-PAGE, HPLC and/or ELISAs. Familiar with use of support equipment such as autoclaves, incubators, centrifuges, bioanalysers and other analytical equipment. Familiarity with the use of design of experiment methodologies to inform experimental design. Practical cloning experience from strain construction, selection, and characterisation.

Has ability to apply learnt theoretical and practical scientific methods to contribute to business activities. Will be learning to apply own judgement and initiative within standard engineering or scientific practices, as well as an understanding of when to seek advice from colleagues.	

Competencies and behaviours	
Leadership (Core)	**Decision Making (Enabling)**
• Respects and values our diverse people and the differing talents, skills, and backgrounds that they bring to projects and day-to-day work. • Has a positive influence on those they are in contact with. • Gains the respect and confidence of colleagues and supports them in achieving their goals and targets. • Aligns their behaviours and actions to our PRIDE values, vision, and goals.	• Pro-actively identifies and prioritises the key issues involved to facilitate the decision-making process. • Seeks input from the relevant stakeholders when appropriate, considers risks, and takes accountability for the impact a decision may have on others. • Makes decisions in a timely manner. • Identifies the key factors in a complex problem.
Communication (Core)	**Developing self and others (Enabling)**
• Communicates in a clear and concise manner, covering all relevant points in a timely manner. • Uses the appropriate route and format to communicate. • Confirms understanding of others communication. • Asks questions to understand other people's viewpoints, keeping an open mind and embracing new ideas.	• 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 (Enabling)	**Delivery (Enabling)**
• Understands the value of establishing effective and supportive relationships, and collaborative working.	• Prioritises activities based on their impact and strategic importance.

• Actively listens, questions, and observes body language so as to understand communication from others. • Cultivates and maintains partnerships across departments to deliver impactful innovations for the business as a whole.	• Takes responsibility and monitors own performance. • Can articulate how their work feeds into projects. • Creates and exploits useful metrics. • Displays commitment and engagement to own work. • Pursues everything with energy, drive, and a need to finish, even when faced with setbacks or resistance.

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**	