Scientist 2 – Analytical – 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 individual team and the wider technology team's requirements. The Scientist 2 will work using their own initiative and with some technical supervision from their manager and senior colleagues, assisting with development and improvement activities.

To characterise in-process and final product biopharmaceuticals such as proteins, viral vectors, and nucleic-acid based products expressed in mammalian, bacterial, insect, yeast cells and/or cell-free systems.

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.

Role Specific responsibilities:

- To design, verify and utilise analytical methods for characterisation of in process and final

product biopharmaceuticals.
- To support process technology development through timely completion of analytical techniques.
- To perform analytical characterisation of biopharmaceuticals with in-house platform methodology.
- To 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.
- Maintaining 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.

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

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience	Chartered status with a relevant professional institution

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 (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 taking ownership of their actions and how they present them. • Is able to influence others by preparing a reasoned argument to adopt a specific tactics 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.

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Collaboration (Enabling)	**Delivery (Enabling)**
• Understands the value of establishing effective and supportive relationships, and collaborative working. • 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.	• Prioritises activities based on their impact and strategic importance. • 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.

Knowledge and Experience:

Essential:	Desirable:
Will possess technical expertise through theory and a good underpinning knowledge, of Biologics characterisation, as well as evidence of technical problem solving **in some of the following analytical techniques:** UPLC/HPLC, sub-particle analysis, ELISA, qPCR, SDS-PAGE, cIEF, capillary electrophoresis, biolayer interferometry, dynamic light scattering, differential scanning calorimetry, circular dichroism. Will exhibit professional mastery of principles and practices in analytics, gained in academic or industrial environments. Can demonstrate evidence of knowledge sharing and network building practice across teams or groups. Has ability to apply theoretical and practical scientific methods to contribute to business activities.	Is a member of a relevant professional body. Familiarity with high-throughput screening using automated liquid handling systems. Experience mentoring or training others. Familiarity with statistical analysis, QbD/DoE, and scientific software tools

Can provide examples of actively utilising cross-team collaboration to achieve desired results. Has confidence to use own judgement and initiative within standard scientific practices, as well as an understanding of when to seek advice from colleagues.	

Signature of Job Holder	
Printed name **Signature** **Date**	