Senior Biochemical Engineer 2 – Job Description

Role Purpose:

To provide technical expertise, capability and input in order to contribute to the delivery of projects, acting as technical lead in medium / large scale projects, and projects of increasing complexity. Draws upon a broad range of technical know-how to provide carefully thought-through advice and expertise to a range of stakeholders across the organisation. The Senior (2) is viewed as an authority in their area of discipline, offering innovative solutions at business-unit level, contributing extensively to development and improvement activities.

Key Responsibilities:

- 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 identify new technical developments and trends, translate these into building blocks for opportunities within the business unit, initiating the creation of (new) technological innovations/applications.
- To utilise own expert knowledge to assist in translating business unit strategy into practice through the delivery of plans to achieve business unit objectives.
- To build, maintain and exploit a network of relevant external stakeholders, customers, partners, research organisations and authorities, to represent the business unit and self as a credible expert, identifying opportunity for future projects and developments.
- To actively contribute to a culture of continuous capability development through coaching, mentoring and/or developing colleagues across the business unit and organisation, providing insights into areas of specialism. This may include coaching and developing colleagues (both technically and behaviourally) to help them reach their potential and acting as a mentor to colleagues across the organisation, providing an expert-level perspective.
- To keep self up to date with external developments in areas of specialism, and/or legislative and SHE related changes, ensuring application of new best practice and/or knowledge
- To work collaboratively with Business Development, Bid Proposal and technical colleagues to contribute to proposal / project development and direct customer engagement. Seek out and engage in business development opportunities where appropriate.
- To formulate and present possible solutions, providing advice upon request or at own initiative, building an internal reputation as a reliable and credible authority.
- 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.
- To take ownership in agreeing weekly workplans with line manager, project manager(s) and other relevant stakeholders, and delivering plan to agreed schedule.

Responsibilities specific to role:

- Design and test bioprocesses including the use of calculations, models, and simulations for optimisation.
- Collect and analyse data to make improvements to bioprocesses.
- Investigate and resolve problems relating to bioprocess, equipment or biologics products.

- Conduct risk assessments to ensure safety and regulatory requirements.
- Manage and optimise costs associated with bioprocesses and biologics products.
- Support and take a lead on Change & Modifications, including the design, installation, testing and validation of equipment and bioprocess.
- GMP requirements for assigned work, including validation.

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.

Direct reports: Up to 5 direct reports

Education / Qualifications:

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

Educated to Master Degree level (or equivalent) plus significant industrial experience Or Educated to PhD level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience	

Competencies and behaviours	
Leadership (Influencing)	**Decision Making (Influencing)**
• Promotes commitment to CPI's strategy, vision, values, and direction. • Motivates, inspires and build resilience in others by making the vision shareable by everyone. • Rewards and celebrates success with colleagues and teams. • Future proofs work practices. • Trusts others' judgment and demonstrates a willingness to try new things, even at the risk of failure.	• 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.
Communication (Influencing)	**Developing self and others (Enabling)**
• Employs comfortably a wide range of communication styles and approaches to suit different situations and audiences (external and internal stakeholders) in diverse situations. • Builds effective two-way communication channels within the business area and across departments whilst maintaining credibility and securing commitment.	• Supports others in their development. • Is personally committed to, and actively seeks, opportunities to improve continuously. • Provides honest helpful feedback to others on their performance. • Insightful about self, strengths and limitations, and how to maximise contribution.
Collaboration (Guiding)	**Delivery (Influencing)**
• Displays a collaborative style in day-to-day working whilst motivating others to achieve optimal performance and results. • 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.	• 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. • 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 possess significant technical expertise in Biochemical/Bioprocess as well as compelling evidence of complex technical problem solving.	Is an active member of a professional body, engaging with peers beyond CPI. Experience of biologics manufacture*, GMP regulatory considerations including validation,

Will exhibit professional mastery of principles and practices in Biochemical/Bioprocess gained through career to date in area of expertise. Can demonstrate evidence of building knowledge sharing and network building practice across teams and organisations to achieve desired results. Actively demonstrates in-depth technical and theoretical knowledge in Biochemical/Bioprocess and can participate at high level in more than one area. Is viewed as an authority in at least one area by peers and managers. Is able to take responsibility for diverse or complex technical activities where it is necessary to use own initiative and judgement, implementing innovative solutions in complex situations. Knowledge and experience of GMP and validation	and safety requirements including pressure systems, HAZOP** and contained processing aspects.