Team Leader – Formulation & Fill Finish – Job Description

Role Purpose:

Supervises and coordinates a technical group to provide expertise and input in order to contribute to the delivery of projects. Acts as technical lead in small/ medium scale projects, and projects of some complexity. Draws upon a broad range of technical know-how to provide carefully thought-through advice and expertise to a range of stakeholders. The Team Leader offers innovative solutions at business-unit level for area of discipline, contributing extensively to development and improvement activities, identifying training and development opportunities within team to maximise performance.

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 undertake line manager activities to ensure the smooth running of the group. This will include:
    - Short term (daily / weekly / monthly) planning of activities and objectives
    - Assisting the area Manager in setting team and individual objectives to meet departmental, business unit, and company objectives
    - Supporting the area Manager with performance management activities, and leading on these where appropriate
    - Providing training and coaching to team members to enable delivery of objectives
    - Act as a point of contact for team members' queries and escalations
    - Conduct regular meetings and one to one sessions with team members to ensure good communication across team
- To work with and provide advice to the area Manager(s) to ensure the relevant portfolio of project work is delivered on time and in accordance with SHE practice and policy.
- 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 team and 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 agree weekly workplans with team members, project manager(s) and other relevant stakeholders, and ensuring delivery to agreed schedule.
- 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.
- 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 within the team.

- 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 solution directions and issue advice, 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.

Role Specific Responsibilities:

To design and execute formulation and fill finish studies for biological products encompassing proteins, viral vectors, and nucleic-acid based products expressed in mammalian, bacterial, insect, yeast and/or cell-free systems. Supporting this will be experience and expertise in team supervision and individual development. Your knowledge/expertise should be both practical and theoretical in areas to support activities such as:

- To supervise a team, ensuring delivery of departmental goals, through appropriate delegation and providing feedback and motivation to team members. This includes providing first line-management support, allocation of resource to ensure project delivery and short-term planning of deliverables.
- To design and deliver formulation screens to identify optimal excipients for biologic product stability and activity.
- Completion of lyophilisation and freezing studies on biologic molecules to identify conditions for long term product storage and stability.
- To perform analytical characterisation of biopharmaceuticals with in-house platform methodology to confirm performance.
- To use and application of computer systems and software for data acquisition and analysis.
- Document writing, presentation and statistical analysis.
- To hold knowledge of bioprocessing industry and cGMP concepts.
- To apply your broad scientific knowledge to projects and client programs.
- To provide training, mentoring and supervision to other members of the team.
- To 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.

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

Person specification

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 Educated to Master Degree level (or equivalent) plus significant industrial experience Or	Supervisory or Management qualification or completed formalised management training / managerial development programme. Chartered status with a relevant professional institution

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 (Influencing)**
• 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.	• Assesses the skills and competence of others within the organisation, and recommends development activities. • 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 (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:
In-depth and comprehensive experience and understanding of biologics formulation and fill finish activities including screening of formulation components and lyophilisation conditions. Experience of analytical techniques for biologics characterisation including and not limited to UPLC/HPLC, sub-particle analysis, ELISA, qPCR, SDS-PAGE, cIEF, capillary electrophoresis. Will exhibit professional mastery of principles and practices in analytical development, gained in academic or industrial environments. 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 knowledge sharing and network building practice across teams or groups. Has ability to apply theoretical and practical scientific/engineering methods to contribute to business activities. Can provide examples of actively utilising cross-team collaboration to achieve desired results. Actively demonstrates in-depth technical and theoretical knowledge in at least one area and is viewed as a specialist in this area by peers.	Is an active member of a professional body, engaging with peers beyond CPI. Experience of supervising a small group or team within an operational environment. Experience with using appropriate computational tools to develop process models (mechanistic and/or statistical) to optimise processes. Will possess significant, technical expertise in purification and downstream processing. Familiarity with QbD and DoE and application to experimental design. Experience with high-throughput screening using automated liquid handling systems.

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.	

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