MSAT Lead – Job Description

Role Purpose:

To provide high-level technical expertise and leadership of transfer of development processes into GMP manufacture within CPI's RNA Centre of Excellence. Working with process teams internally and/ or externally, alongside GMP operations, bioengineering, QA, QC, procurement and other departments to progress transfer. Utilising scientific, process and necessary regulatory expertise to quickly understand complex concepts, taking a leading position in resolving technical problems in GMP biopharmaceutical production.

Key Responsibilities:

- To maintain consistent and document compliance with all relevant Safety, Health and Environmental (SHE), Good Manufacturing Practice (GMP), Data Integrity (DI), quality and best practice requirements.
- To be the technical point of contact for customers for technology transfer into GMP manufacture.
- To work closely with other departments including GMP Operations, bioengineering, QA, QC, and procurement as tech transfer lead to support the transfer of new processes and products into CPI's GMP manufacturing facilities.
- Ensures that all tech transfers into operations are controlled and implemented within GMP regulatory guidelines.
- Develops and implement large/ complex multidisciplinary programs, delivering first time, on time and on budget.
- Ensures the availability of appropriate SOPs and documentation are provided to enable right first time and on time delivery of customer tech transfer projects.
- Participates in strategic resource and capacity planning for the site.
- To liaise with the R&D team (or Customer for direct transfer of external processes) to ensure processes for GMP manufacture are robust, scalable, and suitable for the GMP specific equipment.
- To supervise and coach junior team members to deliver high quality technical input for transferring production processes to GMP manufacturing.
- To provide specialist technical training to members of the GMP Operations team where appropriate.
- To keep up to date with regulatory guidelines to ensure suitability of processes for GMP.
- To use technical knowledge to lead to process deviation investigations, impact assessments and reports.
- To support GMP Operations and Bioengineering with fit assessments/gap analyses of equipment, facilities and processes.

Responsibilities specific to role:

- To contribute to writing and reviewing process descriptions, equipment SOPs, process change controls, process risk assessments, batch manufacturing records and other documentation relevant to GMP manufacturing.
- To have a strong technical understanding across USP, DSP and Analytical testing.
- To review GMP material assessments and bill of materials for use in manufacturing.
- To be the technical author of deviation impact assessments which feed into the Quality Management System.
- To actively engage in safety risk assessments and process risk assessments to identify mitigations and solutions to problems which may adversely impact the process.
- To build, influence and exploit a network of relevant (inter)national external stakeholders, customers, partners, research organisations and authorities, to represent CPI as the technical expert in networks and discuss and lobby for projects and future developments.
- To be familiar with set up and operation of equipment used in bioprocess manufacturing including bioreactors, column chromatography and TFF systems.
- To have an ability to work between teams and convey technical details to audiences with varying degrees of technical knowledge.
- To work collaboratively with Business Development and other technical colleagues, providing support relating to proposal / project development and direct customer engagement. Seek out and engage in business development opportunities where appropriate.
- To act as a credible partner to Bid Development teams, actively involved in defining and advising on the technical elements of a bid, in order to develop a programme of works.
- To assist in R&D process development as required by business needs.
- As required, to undertake all management activities to ensure the smooth running of a group. This will include:
    - Medium to long term forecasting and planning of activities and objectives.
    - Setting team and individual objectives to meet departmental, business unit, and company objectives, contributing to the wider strategy.
    - Identifying and conducting performance management activities to ensure behaviours and performance of team meet required expectations, providing training and/or relevant support where needed.
    - Act as a point of contact for team members' queries and escalations with regards to more complex matters.
    - Conduct regular meetings, one-to-one sessions, and performance development conversations with team members to ensure high levels of communication, feedback and performance across team.

MSAT Lead – Job Description

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 relevant scientific/engineering discipline plus significant industrial experience. Or Educated to Degree level (or equivalent) in a relevant scientific/engineering discipline plus industrial experience.	People Management Qualification.

Or Educated to Masters Degree level (or equivalent) in a scientific/engineering discipline plus relevant industrial experience. Or Educated to PhD level (or equivalent) in a Scientific/Engineering discipline plus industrial experience in a relevant field.	

Competencies and behaviours	
Leadership (Guiding)	**Decision Making (Guiding)**
• Leads people with confidence and is empathetic. • Displays flexibility in leadership styles in order to tell/sell/involve and delegate. • Empowers others to constantly achieve and strive to exceed personal and company objectives. • Talks beyond today, about future possibilities optimistically, showing others how they can benefit and contribute to the business.	• Confidently takes decisions that require political/organisational interpretation and that could cause controversy but moves CPI forward. • Reliably and boldly takes decisions involving the charting of a way forward into a new territory where no precedent exists and analysis of all available data provides no clear single conclusion. • Models drive and resilience in ensuring the solutions are adopted.
Communication (Guiding)	**Developing self and others (Guiding)**
• Personally takes the lead in creating an environment that encourages open and honest communication at all levels in the organisation. • Motivates and influences others via their communications. • Adapts communication style and format recognising individuals' different needs/ motivations.	• Intervenes to address sources of lagging performance. • Provides challenging and stretching tasks and assignments to develop others. • Highly effective at supporting high performers and addressing underperformance through effective, constructive and open dialogue. • Collects information on performance and evidence of behaviours and uses it effectively to improve individual and team performance.
Collaboration (Guiding)	**Delivery (Guiding)**
• 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	• Demonstrates the ability to prepare, gain approval of, refine and update business cases that justify the initiation of a project. • Displays the ability to manage stakeholders, taking account of their

different techniques to effectively mitigate any conflict. • Can negotiate skilfully in tough situations with all stakeholders.	levels of influence and particular interests. • Ensures actions and decisions within the team are aligned with CPI's priorities. • Anticipates how team objectives must adapt and stretch to respond to change.

Knowledge and Experience:

Essential:	Desirable:
Significant and practical experience of good manufacturing practices (GMP) and quality systems concepts. Understanding of cGMP, FDA and EMA guidance, ICH guidelines, and CMC content of regulatory submissions. Strong authorship skills, able to critically review protocols, investigations, deviations, reports, interpret results, and generate technical conclusions consistent with fundamental scientific knowledge, GMP and Good Documentation Practices (GDocP). Track record of technology transfer of processes for the production of biologic products. Ability to prioritize and manage multiple tasks simultaneously, integrate cross-functional issues and balance competing priorities effectively. Will possess significant, technical expertise in biologics & bioprocessing as well as compelling evidence of complex technical problem solving. Is a recognised industry expert in their area of expertise, as well as having broader technical knowledge and capability, and ability to apply in a variety of contexts. Is comfortable using own judgement and initiative within standard engineering / scientific practices,	Supervision/management of other team members. Is an active member of a professional body, engaging with peers beyond CPI. Experience with mRNA-based products in either R&D or GMP context. Project management experience.

as well as an understanding of when to seek advice from colleagues. Will exhibit professional mastery of principles and practices in area of expertise gained through career to date in area of specialism. 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. Can provide examples of actively building cross-team and business unit collaboration to achieve desired results.	