Production Scientist 2 – Job Description

Role Purpose:

The role holder will be responsible for maintaining the facilities to regulatory status, ensuring cleaning, environmental monitoring and maintenance schedules are up to date and maintained to GMP standards. Generating the relevant SOP's and reviewing validation documentation for new and existing manufacturing processes.

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 ensure Batch Records, logbook and GMP documentation are completed to a high compliant standard.
- To execute GMP manufactures working the required shift pattern to ensure the process is completed start to finish.
- To work closely with GMP Operations, QA, and cross functional teams to support the transfer of new processes into CPIs GMP manufacturing facilities.
- To oversee Occupational Hygiene Studies ensuring they are executed correctly from start to finish.
- To review Validation Documentation and participate in the execution of IQ's, OQs & PQ's, Conducting Data integrity (DI) Light assessments as required.
- To work with the Technical team to generate the New Product Introduction (NPI) transfer pack : Including, Safety Risk Assessments (SRA), Item/component, Technical Specifications, Training Matrix requirements, Standard Operating Procedures (SOPS) Batch Manufacturing Records (BMRs), Bill of Materials (BOMs) in process testing (IPC) , Waste removal protocols and any other documentation required,
- To complete GMP Manufactures ensuring the batch is executed compliantly, providing guidance to junior members of staff.
- To ensure the Clean room environment is maintained conducting line clearances and area cleans as required, participating in area spot checks & patrols.
- To ensure their own training Matrix is up to date and compliant to conduct GMP manufactures.
- To assist with training packages, uploaded to (QMS) Quality Management System.
- To provide specialist technical training to members of the team as required.
- To use technical knowledge to contribute and generate process deviation investigations, impact assessments and reports.
- To raise Quality Change Controls, Change & Modification following all actions to completion.

- To support GMP Operations and Bioengineering with fit assessments/gap analyses of equipment, facilities, and processes.
- To provide technical input where required to other functions including QA, QC, R&D, Bioengineering and procurement.
- To take ownership in agreeing weekly work plans with line manager, project manager and other relevant stakeholders.

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 participate in customer and regulatory bodies Audits & inspections.
- To write and/or review GMP material assessments and bill of materials for use in manufacturing. Generating the Technical Specifications.
- To contribute technical expertise to investigations and root cause analyses of process deviations and failures.
- To use knowledge and experience of bioprocessing to contribute to troubleshooting of process deviations and failures.
- To provide technical contribution to deviation impact assessments.
- To operate Line Clearance / Area / Facility Cleaning as Required.
- To assist with equipment validation activities, executing protocols.
- To identify technical process risks and suggest mitigations and solutions.
- To be familiar with set up and operation of equipment used in bioprocess manufacturing including shakeflask cultures, bioreactors, column chromatography and TFF systems.
- To be able to explain the theory behind common bioprocess techniques, including microbial/mammalian cell culture, protein separation by chromatography and purification by TFF.
- To assist in R&D process development as required by the business needs

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: No direct reports

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience at a senior level. Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience. Or Educated to Master Degree level (or equivalent) in a Scientific/Engineering discipline plus significant relevant industrial experience. Or Educated to PhD level (or equivalent) in a Scientific/Engineering discipline.	Experience of biologics or pharmaceutical manufacturing/development. or GMP tech transfer background.

Competencies and behaviours	
Leadership (Core)	**Decision Making (Enabling)**
• Respects and values the diversity of talents, skills and backgrounds that others bring to joint projects / work. • Has a positive influence on those in contact with. • Gains the respect and confidence of colleagues and supports them in achieving their goals and targets. • Aligns owns behaviours and actions to CPI's 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. • Is able to influence others by preparing a reasoned argument to adopt a specific tactics or plan, in line with strategy, and persuade other of the merit.	• 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 (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 value for the business	• 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:
Experience of running GMP manufacture. Will exhibit knowledge of principles and practices of upstream and/or downstream science gained in academic or industrial environments. Experience working with GMP documentation and Quality Management Systems. Capable of generating, reviewing, and approving GMP documentation such as Standard Operating Procedures, Batch records and technical input on Quality Management System documents. Can demonstrate evidence of building knowledge sharing and network building practice across teams and organisations to achieve desired results. Can take responsibility for diverse or complex technical activities where it is necessary to use own initiative and judgement, implementing innovative solutions in business-critical situations. An ability to work between teams and convey technical details to audiences with varying degrees of technical knowledge.	Experience of working with mRNA. Experience of running Occupational Hygiene studies . Experience of generating Safety Risk Assessments (SRA's).

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**	