Process Support Technician – Job Description

Role Purpose:

To provide operational support within the Medicines Manufacturing Innovation Centre (MMIC) building in line with team and business unit requirements. This work will typically include warehouse activities, dispensary operations, plant and equipment cleaning and operation of some utilities equipment (e.g. waste water treatment), and other duties to ensure the smooth running of the facility, in a GMP environment. The Technician will work under some supervision of line manager and senior colleagues, supporting a range of activities to meet business unit objectives, contributing to the realisation of project work.

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 ensure that as tasks are completed the relevant documentation is fully completed, and that any issues, deviations, or improvement opportunities identified are highlighted appropriately.
- To be a point of contact for technical project staff to address support requests and issues within the Technicians area of responsibility (e.g., a request for some dispensed material).
- To maintain the cleanliness and housekeeping within the operations envelope of the facility are critical in preventing any possible product contamination and maintaining the GMP standard of the facility - the Operations Support Technicians are responsible for this being maintained (with the support of Technical, Engineering and Quality staff as appropriate).
- To carry out all tasks to ensure material is available for production, including booking in, sampling, movement, dispensary activities and waste/final product handling.
- To perform day to day operational tasks in support of any project where it is deemed you are appropriately qualified and trained; for the avoidance of doubt this could be on any project or piece of equipment at any scale, subject to the prerequisite training and safety inductions.
- To actively engage in safety, and quality improvement activities as appropriate to role level.
- To troubleshoot issues to identify root cause of problems, rectifying or escalating as appropriate.

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.

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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

Person specification

Education / Qualifications:

Essential:	Desirable:
Educated to standard grade in Maths and English (or equivalent) in a scientific/engineering discipline plus relevant industrial experience. OR Significant quantity of operational experience in an GMP Operational Role.	

Competencies and behaviours	
Leadership (Core)	**Decision Making (Core)**
• Respects and values our diverse people and the differing talents, skills, and backgrounds that they bring to projects and day-to-day work.	• Within area of expertise recognises, identifies, and defines problems. • Generates and evaluates alternatives, draws conclusion, and analyses risk.

• 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.	• Takes timely and correct action using established methods to ensure effective solutions are implemented by working as a team and with and focused outcomes to be delivered.
Communication (Core)	**Developing self and others (Core)**
• Communicates in a clear and concise manner, covering all relevant points in a timely manner. • Uses the appropriate route and format to communicate. • Confirms understanding of others communication. • Asks questions to understand other people's viewpoints, keeping an open mind and embracing new ideas.	• Knows own career aspirations and clearly communicates them to relevant colleagues whilst actively working to achieve goals. • Sets personal development goals and deploys strengths to achieve them. • Takes responsibility for one's own performance and actions and invites and incorporates feedback from a variety of sources. • Regularly reflects on own capabilities to identify development priorities.
Collaboration (Core)	**Delivery (Core)**
• Establishes effective working relationships with other colleagues. • Builds and maintains a network of internal and external contacts. • Actively seeks, values, and incorporates different views and ideas to broaden their prospective, embracing differing perspectives and unconventional ideas.	• Plans, prioritises, and leads own area of work to deliver specified and agreed outcomes (time and standard). • Accurately scopes out length and difficulty of tasks, and repeatedly estimates correct amount of time needed for tasks. • Refers to lessons learnt from other projects/ tasks with related scope. • Acts with minimal supervision or direction by being purposely empowered to make decisions when needed. • Pays attention to detail and delivers accurate and high-quality outputs.

Knowledge and Experience:

Essential:	Desirable:
Will possess fundamental practical knowledge of plant operations, including ancillaries and warehouse.	Worked in a clean-room environment.

Relevant experience in a GMP environment, and able to describe the main requirements of GMP principles. Relevant experience in an environment with similar hazards to the MMIC and is able to describe some of these. Is able to demonstrate conformance with SHE and Quality standards. Has confidence to use own judgement and initiative within routine activities, as well as an understanding of when to seek advice from manager or colleagues.	NEBoSH training or worked on a COMAH site. Proven experience in root cause or continuous improvement techniques.

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