GMP Operator – Job Description

Role Purpose:

Supporting the cGMP Grade D & C clean room manufacturing suites. Participate in the end-of-campaign batch cleaning, routine daily, weekly, and monthly cleaning and any out of hours ad-hoc cleaning activities of the classified cleanrooms. Ensuring cleaning activities are carried out to a high-level completing line clearance, component preparation tasks and stock replenishment activities in accordance with cGMP Standard Operating Procedures (SOPs). Working to the GMP Operations and Manufacturing teams schedules and requirements.

The GMP Operator will ensure cGMP cleaning, component preparation and manufacturing support activities, are carried out to a high standard. This role is essential to maintaining the cleanliness of GMP facility and ensuring the manufacturing schedules are achieved. Good documentation practice is essential ensuring Batch Records, logbook and GMP documentation is completed to a high compliant standard.

Contribute to development and improvement, identifying any future improvements to assist the GMP Operations team. Ensuring the required quality and safety standards are followed and maintained with respect to cGMP operating procedures, all cGMP batch manufacturing documentation, area housekeeping in cGMP suites, SHE (Safety, Health & Environment), ensuring compliance with regulatory (MHRA Orange Guide etc) and legislative requirements.

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 be aware of COSHH & Risk Assessments required for cleaning activities.
- To perform a variety of cleaning and hygiene tasks as detailed within the cleaning procedures.
- To follow daily, weekly and monthly cleaning schedules, in conjunction with the GMP MSAT team, ensuring cleaning consumables and resource are available to maintain and clean the GMP suites pre, post and during manufactures.
- To ensure that correct equipment and materials are available to conduct cleaning activities at all times preventing any manufacturing delays.
- To ensure that waste material is correctly disposed of in accordance with CPI's procedures.
- To report to the GMP Operations Management team any issues that may impact upon the integrity of the clean.
- To ensure all training within health & safety, hygiene, and CPI's GMP policy's & procedures are up to date.

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Responsibilities specific to role:

- To participate in the management of the laundry service required for clean room garments, ensuring collection and replenishment activities are completed.
- To participate in the management of the cleaning consumables & replenishment activities.
- To ensure critical clean room consumable, gowning garment are replenished regularly ensuring no interruption to the manufacturing activities within the clean room suites.
- To ensure Consumable and Cleaning, Bill of Materials (BOMs) are completed for picking in a timely manner to meet the cleaning and manufacturing schedules.
- To follow GMP documentation and batch records to complete room set up, line clearance, item cleaning, component preparation and sterilisation.
- To support the GMP Operations and Manufacturing teams with the day-to-day cleanliness and stock replenishment of the GMP Facility and clean room suites.
- To follow and apply Good Manufacturing Practice, carry out quality and safety housekeeping patrols as required.
- To complete any other tasks deemed suitable to support the GMP Operations team.

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

Person specification

Education / Qualifications:

Essential:	Desirable:
Educated to GCSE level 9 – 4 (or equivalent) in English and Maths. Or Relevant experience in a GMP Manufacturing environment.	Educated to GCSE level 9 – 4 (or equivalent) in a science subject.

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. • 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.	• Within area of expertise recognises, identifies, and defines problems. • Generates and evaluates alternatives, draws conclusion, and analyses risk. • 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.	• 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

• Asks questions to understand other people's viewpoints, keeping an open mind and embracing new ideas.	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:
Experience working within a GMP, Clean room environment. Experience working autonomously. Experience of following and conducting cleaning procedures. A good understanding of cGMP requirement. Experience of good documentation completion, good verbal, and written communication skills.	Environmental monitoring experience. Experience in working Shift Patterns. Experience of packaging and inspection & storage of cGMP manufactured products. Clean room Grade D & C experience. Experience of working with pharmaceutical manufacturing. Experience of working in a food manufacturing environment. Familiar with COSHH & Risk Assessments.

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