

## **Role Purpose:**

To define and perform the specific tasks required to calibrate, maintain, repair and install equipment, and to provide hands on support to maintain and improve the reliability of CPI equipment. Previous pharmaceutical experience would be a distinct advantage.

### 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 carry out routine maintenance tasks in line with agreed schedule, recording all results in the appropriate system and reporting back on any anomalies.
- Working within GMP areas and guidelines.
- To respond in a timely fashion to breakdown conditions and work in such a way as to minimise downtime.
- To provide maintenance cover throughout the working day and, at times, during out of hours working (extended days and weekends).
- To ensure that spare parts required for the maintenance activities are controlled and ordered in a timescale appropriate to maintaining the toolset uptime. Comply with the internal and external regulatory environment such as procurement, maintaining records, traceability, and confidentiality.
- To ensure all relevant personnel are kept informed of progress or proposed changes on their own maintenance operations so as to minimise the impact on the processes being operated on that particular tool.
- To be responsible for their own continuous professional development. Gradually put into practice skills and competencies learned both on and off the job and to share professional knowledge with colleagues.
- To identify and understand the requirements of internal and external customers and use creative thinking and problem solving to challenge assumptions, innovate, make new proposals, and build on existing ideas.
- To contribute to the development of specific technical projects and have a working knowledge of project management procedures; set up, planning and the execution.
- To report results within agreed timescales with the support of colleagues.
- To contribute to a culture of continuous performance improvement within the technical environment in alignment with company strategy and project deliverables.
- To work in a safe and efficient manner with due regard to the SHE rules and policies on the CPI site and be responsible for general housekeeping for the area they are working within.

## 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 HNC level (or equivalent) in a technical subject.	Educated to HND level (or equivalent) in a technical subject.

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



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• Has a positive influence on those they are in contact with.	Takes timely and correct action using established methods to ensure effective solutions are implemented.	
<ul> <li>Gains the respect and confidence of colleagues and supports them in achieving their goals and targets.</li> </ul>	effective solutions are implemented by working as a team and with and focused outcomes to be delivered.	
• Aligns their behaviours and actions to our PRIDE values, vision and goals.		
Communication (Core)	Developing self and others (Core)	
• Communicates in a clear and concise manner, covering all relevant points in a timely manner.	ear and concise • Knows own career aspirations and	
Uses the appropriate route and		
<ul><li>format to communicate.</li><li>Confirms understanding of others</li></ul>	• Sets personal development goals and deploys strengths to achieve them.	
communication.	Takes responsibility for one's own	
<ul> <li>Asks questions to understand other people's viewpoints, keeping an open mind and embracing new ideas.</li> </ul>	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)	
<ul> <li>Establishes effective working relationships with other colleagues.</li> <li>Builds and maintains a network of</li> </ul>	<ul> <li>Plans, prioritises and leads own area of work to deliver specified and agreed outcomes (time and standard).</li> </ul>	
internal and external contacts.		
<ul> <li>Actively seeks, values and incorporates different views and ideas to broaden their prospective, embracing differing perspectives and</li> </ul>	<ul> <li>Accurately scopes out length and difficulty of tasks, and repeatedly estimates correct amount of time needed for tasks.</li> </ul>	
unconventional ideas.	Refers to lessons learnt from other projects/ tasks with related scope.	
	<ul> <li>Acts with minimal supervision or direction by being purposely empowered to make decisions when needed.</li> </ul>	
	• Pays attention to detail and delivers accurate and high quality outputs.	



# Knowledge and Experience:

Desirable:

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By signing this you confirm you have read, understood, and agree to work in alignment with the above job description.		
Printed name		
Signature		
Date		