

Equipment Technician – Job Description

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.

Key Responsibilities:

- 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.
- 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.

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

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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	
<p>Leadership (Core)</p> <ul style="list-style-type: none"> 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. <p>Aligns own behaviours and actions to CPI's values, vision and goals.</p>	<p>Decision Making (Core)</p> <ul style="list-style-type: none"> Takes timely and correct action using established methods to ensure effective solutions are implemented. Generates and evaluates alternatives, draws conclusion and analyses risk.
<p>Communication (Core)</p> <ul style="list-style-type: none"> 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. 	<p>Developing self and others (Core)</p> <ul style="list-style-type: none"> Regularly reflects on own capabilities to identify development priorities. Knows/ Is willing to develop own career aspirations and clearly communicates them to relevant colleagues whilst actively working to achieve goals.
<p>Collaboration (Core)</p> <ul style="list-style-type: none"> Establishes effective working relationships with other colleagues. Builds and maintains a network of internal and external contacts. 	<p>Delivery (Core)</p> <ul style="list-style-type: none"> Acts with minimal supervision or direction. Pays attention to detail and delivers accurate and high quality outputs.

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Knowledge and Experience:

Essential:	Desirable:
<ul style="list-style-type: none"> • Hands-on craft skills with the ability to use hand and power tools in the pursuit of maintenance activities • The ability to interpret engineering diagrams, schematics and PID's • Good problem solving skills with the ability to logically trace faults to their root cause and identify steps to repair the problem. • The ability to communicate effectively using a full range of skills (speaking; listening; writing; body language; presentation). Being able to discuss their work across a number of functional areas to ensure the end users are aware of the maintenance/repair work being completed and thus infer the impact on their operations 	

Signature of Job Holder	
<p>Printed name</p> <p>Signature</p> <p>Date</p>	<p>DocuSigned by:</p> <p><i>Declan Boyle</i></p> <p> Signer Name: Declan Boyle Signing Reason: I have reviewed this document Signing Time: 15-Jun-2021 13:04 BST 68BF4F9F7B0643FE9DE08E4E8FF4D67D</p>