

GMP Document Administrator – Job Description

Role Purpose:

Quality is a key foundation of our business and through effective quality management, CPI will continue to add value to the company and help achieve its business goals.

The focus of this role is to establish and maintain document management processes including issue and reconciliation of GMP documentation. The GMP Document Controller will perform a variety of tasks in support of Document Control Systems' and 'Writing, Reviewing, Version Control, Issuing & Archiving of BMR's and Logbooks to ensure compliance to the CPI Biologics quality management system to meet GMP requirements.

Key Responsibilities:

- To maintain consistent and documented compliance with all relevant Safety, Health and Environment (SHE), Good Manufacturing Practice (GMP), Data Integrity (DI), quality and best practice requirements.
- Document controller activities for all GMP controlled documentation including policies, SOPs and protocols.
- Control, issue, reconciliation, and archive of GMP manufacturing documentation including batch manufacturing records and logbooks.
- Printing, issuing and reconciliation of labels.
- Supporting the Quality team with any other requirements as required.

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.

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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:
A minimum of 5 GCSEs grade A*-C (9-4), including English Language, and Mathematics.	

Competencies and behaviours	
Leadership (Core)	Decision Making (Core)
<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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)
<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. 	<ul style="list-style-type: none"> 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.

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<ul style="list-style-type: none"> Asks questions to understand other people's viewpoints, keeping an open mind and embracing new ideas. 	<ul style="list-style-type: none"> 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 (Enabling)
<ul style="list-style-type: none"> 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 perspective, embracing differing perspectives and unconventional ideas. 	<ul style="list-style-type: none"> 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.

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Knowledge and Experience:

Essential:	Desirable:
<p>Strong attention to detail with a thorough approach.</p> <p>The ability to prioritise, be extremely organised and methodical.</p> <p>Excellent interpersonal and communication skills to establish good relationships across all functions and at all levels within the organisation in order to promote the use of established tools and systems for documentation.</p> <p>Ability to work in fast paced environment, flexibility to adjust with moving priorities and ensuring attention to detail remains first class.</p> <p>Demonstrates examples of collaborative working within and between multi-disciplinary teams.</p> <p>Has confidence to use own judgement and initiative within standard quality practices, as well as an understanding of when to seek advice from colleagues.</p>	<p>Experience using various paper and electronic document management systems.</p> <p>Document management expertise and experience of operating within a quality management system.</p> <p>Experience in the use and implementation of Electronic Document Management systems and QMS.</p>

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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