Quality Control Analyst – 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 provide wide ranging quality control support to the quality function, promoting and integrating quality into every aspect of our business. In this role, you will perform a variety of tasks in support of specific areas of the site quality control function mainly on focusing providing the technical support required to support the GMP manufacture of biological products.

Projects within CPI encompass a broad range of process technologies and novel measurement and analytical techniques, and this is reflected in the diversity of customers and their expertise. This role specifically requires an expertise in biological analysis techniques with the ability to provide support in the validation of methods for use in the QC laboratory as well as providing training for colleagues. Analysis techniques include plate assays, HPLC, UV Spectrophotometry, Gel Electrophoresis, qPCR, Dynamic Light Scattering, Raman Spectroscopy and other basic techniques.

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
- To perform laboratory work and data analysis in a timely manner and to a high standard.
- To perform all Quality Control duties and tasks in accordance with relevant GMP guidelines.
- To perform laboratory investigations and out of specification investigations to GMP standards.
- To calibrate and monitor analytical equipment.
- To perform method development and method validation activities.
- To perform equipment qualification and software validation activities.
- To perform the required release activities for raw materials and critical consumables
- Support in the training of Quality Control staff.
- To review and approve of risk assessments and validation documentation as required.
- To support the site Quality Management System including input into investigations and/or CAPAs.
- To write, review and approve SOPs, methods, and specifications.
- To support both internal and external audits including writing reports, agreeing CAPA and following these up as required.
- Conducting Product Quality Reviews as required.
- To support customer product quality complaints received at site.

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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

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Person specification

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience	Chartered status with a relevant professional institution

Competencies and behaviours	
Leadership (Core)	**Decision Making (Enabling)**
• 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. • Aligns owns behaviours and actions to CPI's values, vision and goals.	• Pro-actively identifies and prioritises the key issues involved to facilitate the decision-making process. • Seeks input from the relevant stakeholders when appropriate, considers risks, and takes accountability for the impact a decision may have on others. • Makes decisions in a timely manner. • Identifies the key factors in a complex problem.
Communication (Enabling)	**Developing self and others (Enabling)**
• Presents complex issues/ data with a high level of clarity and impact, using the appropriate format and driving action. • Is able to write clearly and succinctly recommendations and messages that have the desired effect. • Is aware of the impact of their communications and pro-actively seeks feedback for improvement, learning from their experiences and taking ownership of their actions and how they present them. • Is able to influence others by preparing a reasoned argument to adopt a specific tactics or plan, in line with strategy, and persuade other of the merit.	• Supports others in their development. • Is personally committed to, and actively seeks, opportunities to improve continuously. • Is comfortable learning from the experiences of others and recognises the differing strengths of team members. • Provides honest helpful feedback to others on their performance. • Insightful about self, strengths and limitations, and how to maximise contribution.
Collaboration (Enabling)	**Delivery (Enabling)**
• Understands the value of establishing effective and supportive relationships, and collaborative working. • Actively listens, questions and observes body language so as to understand communication from others. • Cultivates and maintains partnerships across departments to deliver impactful innovations for the business as a whole.	• 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:
Will possess significant quality control expertise and experience of operating within a GMP environment, developing and implementing system for quality control activities. Will exhibit professional mastery of principles and practices in GMP quality control systems, gained in industrial environments. Strong attention to detail with a thorough approach and good organisational skills. Ability to work in fast paced environment, flexibility to adjust with moving priorities and ensuring attention to detail remains first class. Can demonstrate evidence of knowledge sharing and network building practice across teams or groups. Has ability to apply theoretical and practical quality tools and techniques to contribute to business activities. Can provide examples of actively utilising cross-team collaboration to achieve desired results. Has confidence to use own judgement and initiative within standard quality practices, as well as an understanding of when to seek advice from colleagues. Knowledge of EU Pharmacopeia standards. Knowledge of EU GMP Guidelines inc Annexes 1, 2 & 15.	Is a member of a relevant professional body. Knowledge of ISO 9001 Quality Management System Standards Knowledge of EU GMP Guidelines Annexes 11 & 13. Knowledge of GLP requirements. Experience in Method Development and Validation. Experience in Raw Material testing and release. Knowledge and experience of Data Integrity principles. In-depth knowledge and practical experience in the development and application of analytical techniques and methodologies for the analysis of biological products including, but not limited to, plate assays, HPLC, UV Spectrophotometry, Gel Electrophoresis, qPCR, Dynamic Light Scattering, Raman Spectroscopy, Osmolality, pH, appearance, and other basic techniques.

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