Quality Specialist – 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 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 quality system mainly focusing on the implementation, sustainability and continued improvement of the CPI Biologics quality management system to meet GMP requirements.

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.

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.
- Support the site Quality Management System including routine review and approval of change controls, deviations, OOS, action plans and CAPA.
- Author, review and approval of documentation including policies, SOPs and protocols.
- Review, approval and issue of manufacturing documentation.
- Compile and review batch certification documents for compliance with EU GMP requirements.
- Assist in the resolution of manufacturing, testing and packaging issues to support the release of products.
- Participation in root cause analysis investigations arising from deviations, OOS and complaints.
- Support both internal and external audits including writing reports, agreeing CAPA and following these up as required.
- Participation in the supplier assessment program including audits, supplier evaluation and technical quality agreements.
- Review and approval of risk assessments and validation documentation as required.
- Conducting Product Quality Reviews as required.
- Coordinating of customer product quality complaints received at site.
- Assisting in the development, collating and reporting of trends and key quality metrics.

Quality Specialist – Job Description

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 or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience. Or	Chartered status with a relevant professional institution.

Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience.	

Competencies and behaviours	
Leadership (Core)	**Decision Making (Enabling)**
• 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.	• 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 others 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	• Prioritises activities based on their impact and strategic importance. • Takes responsibility and monitors own performance.

understand communication from others. • Cultivates and maintains partnerships across departments to deliver impactful innovations for the business as a whole.	• 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.

Knowledge and Experience:

Essential:	Desirable:
Will possess significant quality system expertise and experience of operating within a GMP environment, developing, implementing and monitoring quality systems. Will exhibit professional mastery of principles and practices in GMP quality 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	Is a member of a relevant professional body. Knowledge of ISO 9001 Quality Management System Standards Knowledge of EU GMP Guidelines inc Annexes 1, 2 & 15. Experience in the implementation of electronic/digital systems for operational activities.

well as an understanding of when to seek advice from colleagues. Knowledge of EU GMP Guidelines Annexes 11 & 13. Experience in the use and implementation of Electronic/Digital QMS.	

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**	