Quality Validation Manager – 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 Quality Validation Manager is responsible for leading, development and implementation of the CPI validation philosophy and CPI standard approach to Validation. The focus of the role is to ensure the CPI framework and methodology across all qualification and validation activities (facility, equipment, process, utilities, analytical methods, cleaning and computerised systems), are in compliance with regulations and standards, and with cGMP, specifically to the requirements of Annexes 11 & 15 of EudraLex Volume 4 and taking into account ICH Q9 and ISPE Codes/Guides.

The QVM is responsible for developing the Validation Policy, validation framework and holistic VMP across CPI and will lead on all validation compliance activities and initiatives. The QVM is the subject master expert on validation and compliance with the GMP guidelines on validation; and will represent and present validation at CPI in meetings and audits with the regulatory agency, customers and partners.

The role will additionally provide wide ranging support to the quality function, promoting and integrating quality into every aspect of our business.

Key Responsibilities:

- To maintain consistent and documented compliance with all relevant Safety, Health and Environmental (SHE), Quality and best practice requirements.
- To develop and implement CPI's validation philosophy and approach.
- To develop and implement the Validation Policy, validation framework and holistic Validation Master Plan (VMP) across CPI
- To develop and implement CPI's validation standards and standard operating procedures.
- To generate and maintain the CPI VMP to ensure all facility, equipment, process, utilities, analytical methods, cleaning and computerised systems are qualified in compliance with regulations and standards, and specifically with GMP.
- To provide technical expertise and guidance in validation approach and documentation as relating to Business Units (BUs) and Grand Challenge (GC) team.
- To work with the Business Units (BUs), Grand Challenge (GC) teams and Quality Validation Specialists, adopting a risk management approach, to define the overall validation strategy for each of the BUs / GCs.
- To support and guide the BU validation managers and GCs with validation and qualification activities associated with any new facility design & build, including utility systems, the establishment of the process equipment, and with ongoing operations.

- To liaise with external stakeholders, including the MHRA, to ensure the validation philosophy and strategy towards innovative concepts, GCs and new facility projects are viable within cGMP regulations and guidelines.
- To provide the framework and appropriate templates to support generation of the URS, DQ, IQ, OQ and PQ documentation.
- To work with the BU / GC teams to determine the overall Validation strategy for the implementation of the Development Work Packages and new project work packages so that the required compliance to GMP is planned and enabled during GC / project definition and equipment/facility specification and then carried forwards through procurement, installation, commissioning and into operations.
- To provide technical liaison and arbitration between partners / clients validation resources and CPI grand challenges / projects. Resolve issues / differences of opinion and style.
- To comply with CPI procedures, including all safety and ISO9000 requirements.
- To keep up to date with external developments in validation, and/or legislative, quality and SHE related changes, ensuring application of new best practice and/or knowledge.

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

Quality Validation Manager – Job Description

Education / Qualifications:

Essential:	Desirable:
Educated to Degree level (or equivalent) in a science/engineering subject plus significant industrial experience within a GMP manufacturing environment.	A Validation or Quality related qualification and / or membership of a Validation or Quality group or committee

Competencies and behaviours	
Leadership (Influencing)	**Decision Making (Guiding)**
Promotes commitment to CPI's strategy, vision, values, and direction. Motivates, inspires and build resilience in others by making the vision shareable by everyone. Rewards and celebrates success with colleagues and teams. Future proofs work practices. Trusts others' judgment and demonstrates a willingness to try new things, even at the risk of failure.	Leads and facilitates a group to a decision from complex, inconclusive or contradictory data, prioritising the needs of CPI. Evaluates options by considering short term consequences and long-term gains. Uses correct communication method to present a case so that it has greatest persuasive impact. Is regularly sought out by colleagues for advice and solutions.
Communication (Guiding)	**Developing self and others (Influencing)**
Personally takes the lead in creating an environment that encourages open and honest communication at all levels in the organisation. Motivates and influences others via their communications. Adapts communication style and format recognising individuals' different needs/ motivations. Communicates corporate message with conviction and enthusiasm and thereby promotes commitment and belief in others.	Confidently draws reliable conclusions from diverse and sometimes incomplete data. Proactively sources and refers to how others have tackled similar problems previously. Considers risks, and consequences, and takes accountability for, the impact the decision has on the business including costs/benefits.
Collaboration (Guiding)	**Delivery (Guiding)**
Displays a collaborative style in day-to-day working whilst motivating others to achieve optimal performance and results. Develops relationships which facilitate the resolution of complex tasks and can apply different techniques to effectively mitigate any conflict. Can negotiate skilfully in tough situations with all stakeholders.	Demonstrates the ability to prepare, gain approval of, refine and update business cases that justify the initiation of a project. Displays the ability to manage stakeholders, taking account of their levels of influence and particular interests. Ensures actions and decisions within the team are aligned with CPI's priorities. Anticipates how team objectives must adapt and stretch to respond to change.

Quality Validation Manager – Job Description

Knowledge and Experience:

Essential:	Desirable:
In-depth experience of operating at an expert level. Will possess significant quality validation expertise and experience of operating within a senior operational role within a GMP environment, developing and implementing validation programmes. Can demonstrate evidence of building cross-industry and organisational knowledge sharing and network building. Expert knowledge of GAMP, GMP Guidelines EU GMP Annex 11 and Annex 15, 21 CFR Part 11. Experience of providing support for internal and external audits. Practical knowledge and experience of cGxP requirements for Pharma manufacturing plants. All aspects of facility, equipment, computer systems and laboratory validation. On time delivery of technical and operational objectives Managing and exceeding customer expectations Experience of providing support for internal and external audits	Experience managing collaborative R&D / Development technical transfers. Is an active member of IPSE.