Quaity Validation Specialist

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 assist in the development and implementation of the validation strategy for the qualification of the CPI Biologics RNA Centre of Excellence, Grand Challenge projects and their equipment to a current GMP compliant standard; this includes process utilities, process equipment and computer systems. To deliver and maintain compliance to a GMP standard and specifically to the requirements of Annexes 11 & 15 of EudraLex Volume 4 and taking into account ICH Q9 and ISPE Codes/Guides.

Projects within CPI encompass a broad range of process technologies and novel measurement, and this is reflected in the diversity of customers and their expertise.

Key Responsibilities:

- To maintain consistent and documented compliance with all relevant Safety, Health and Environmental (SHE), quality and best practice requirements.
- To develop the RNA Centre of Excellence's validation philosophy and approach.
- To develop and implement validation policies, protocols and standard operating procedures.
- To work with the Biologics team, adopting a risk management approach with operations to define and implement the overall validation strategy for the RNA Centre of Excellence.
- To review and approve the validation and qualification activities associated with: the facility qualification and its utility systems; the establishment of the process equipment; and with ongoing operations.
- To work with the Grand Challenge Teams to determine the overall Validation strategy for the implementation of the Development Work Packages so that the required compliance to GMP is planned and enabled during GC definition and equipment/facility specification and then carried forwards through procurement, installation, commissioning and into operations.
- To work closely with the Biologics Team so that information, protocol and performance requirements are correctly specified and with contractors, engineers and vendors of facility, utility and equipment items so that these requirements are correctly delivered to enable initial and continued compliance.
- To work effectively and supportively with the Biologics project team members to deliver the development phase activities and the Facility in accordance with the programme, budgets and design intent.
- To coordinate with the Biologics Project Team on any future facility build projects to engage with external stakeholders (including the MHRA) to ensure that innovative Biologics concepts are viable within current GMP regulation.
- Support the site Pharmaceutical Quality System including input into investigations and/or CAPAs.

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- Support both internal and external audits including writing reports, agreeing CAPA and following these up as required.
- Review and approval of risk assessments and validation documentation as required.
- To keep self up to date with external developments in areas of specialism, 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

Education / Qualifications:

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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 industrial experience	Chartered status with a relevant professional institution

Competencies and behaviours	
Leadership (Enabling)	**Decision Making (Influencing)**
• 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. • 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. • Provides honest helpful feedback to others on their performance. • Insightful about self, strengths and limitations, and how to maximise contribution.
Collaboration (Influencing)	**Delivery (Influencing)**
• Understands the value of establishing effective and supportive relationships, and collaborative working.	• Prioritises activities based on their impact and strategic importance.

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Competencies and behaviours	
• Actively listens, questions and observes body language so as to understand communication from others. • Cultivates and maintains partnerships across departments to deliver value for the business	• 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..

Knowledge and Experience:

Essential:	Desirable:
Will possess significant quality system and validation expertise and experience of operating within a GMP environment, developing and implementing and monitoring quality systems and validation programmes. 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.	Is a member if 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 use of Electronic Document Management systems and QMS.

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Essential:	Desirable:
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 GAMP, EU GMP Guidelines Annexes 1, 2 & 15, 21 CFR Part 11. Experience of providing support for internal and external audits.	