Facility Validation Engineer 2 – Job Description

Role Purpose:

To contribute to the delivery and realisation of project work through preparation, development, research, design, testing and analysis work in line with team and technology team requirements. The Facility Validation Engineer 2 will work using their own initiative and with some technical supervision from their manager and senior colleagues, assisting with development and improvement activities.

Key Responsibilities:

- To maintain consistent and document compliance with all relevant Safety, Health and Environmental (SHE), Good Manufacturing Practice (GMP), Data Integrity (DI), quality and best practice requirements.
- To build and maintain a network of relevant internal stakeholders, to represent self and the wider team as a credible professional in networks and groups.
- To keep self up to date with developments in areas relevant to role, and/or legislative and SHE related changes, ensuring understanding of these and any associated new best practice, methods, or techniques.
- To support in Business Development and Bid Proposal activities, to contribute to proposal / project development and direct customer engagement.
- To present and formally report experimental conclusions and supporting data for internal peer review and submission to clients, to agreed timescales and standards.
- To actively engage in hazard studies / SRA studies and discussions, as appropriate to role level.
- To set up, plan and execute experimental / pilot scale runs and analyse, interpret, and report the results of these within agreed timescales and standards and in accordance with project requirements.
- To be responsible for providing clearly documented records of technical data, decisions, methodologies, calculations, and software use in an agreed format.
- To take ownership in agreeing weekly workplans with line manager, project manager(s) and other relevant stakeholders, and delivering plan to agreed schedule.
- To be responsible for the maintenance and calibration of equipment to ensure it operates in a safe and efficient manner and is available to meet customer needs.

Responsibilities specific to role:

- Lead/Maintain the validation of Facility/Utilities/equipment as per Site Validation Master Plans for CPI Biologics Facility cGMP sites (specifically CPI Biologics Darlington 1 Union Square and RNA Centre of Excellence sites)
- Plan and carry out Facility validation activities to documented plan.
- Collect and analyse data to make improvements to Facility Validation activities and planning.
- Investigate and resolve problems relating to validation of CPI GMP Facilities/Utilities/equipment.
- Conduct & take part in risk assessments to ensure safety and regulatory requirements, including for cGMP validation.

- Manage and optimise costs associated with validation of CPI GMP Facilities.
- Take part in Validation authoring, review and approvals of Biologics Operations Validation documentation, including validation phases for the design, installation, testing, operation, performance, and ongoing validated status maintenance for Biologics GMP manufacturing operations.
- Manage changes and deviations and support internal and external audits and regulatory inspections (i.e. MHRA) as a subject matter expert
- Collaborate cross-functionally with Quality, Facility management and Operations to ensure seamless project delivery

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: Up to 5 direct reports

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Person specification

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in an engineering related discipline plus significant industrial experience. Or Educated to Degree level (or equivalent) in an engineering related discipline, plus relevant industrial experience.	Educated to Masters level (or equivalent) in an engineering related discipline plus relevant industrial experience. Chartered (or working toward) 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.	• 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.

• 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.	• 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 value for the business	• 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.

Knowledge and Experience:

Essential:	Desirable:
Will possess technical knowledge and good underpinning knowledge in facility validation engineering, as well as evidence of technical problem solving. Will exhibit professional mastery of principles and practices in facility validation engineering, gained in academic or industrial environments. Can demonstrate evidence of knowledge sharing and network building practice across teams or groups. Has ability to apply theoretical and practical Facility Validation methods to contribute to ongoing business activities. Can provide examples of actively utilising cross-team collaboration to achieve desired results.	Is a member of a relevant professional body. Understanding of Biologics Vaccine manufacturing facilities. Hands on experience also desirable for validation of gas supply systems, water for injection and autoclaves for a GMP Manufacturing Facility. Hands on experience of revalidation and temperature mapping for GMP equipment such as freezers, autoclaves and washers is desirable.

Has confidence to use own judgement and initiative within standard facility validation practices and planning, as well as an understanding of when to seek advice from colleagues. Direct experience working within Grade D & C clean room environment for Facility/utilities/equipment Validation, and experience including Facility HVAC, compressed air, freezer and Environmental Monitoring Systems Validation.	

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