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 business unit 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 documented compliance with all relevant Safety, Health and Environmental (SHE), 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:

- Maintain Site Validation Master Plans required for CPI Biologics Facility cGMP sites (specifically CPI Biologics Darlington 1 Union Square and RNA Centre of Excellence sites) ongoing GMP compliance.
- 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.
- 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 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.

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Direct reports: No direct reports

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a discipline related to Facility Validation Engineering plus significant industrial experience Or Educated to Degree level (or equivalent) in a discipline related to Facility Validation Engineering, plus relevant industrial experience	Educated to Masters level (or equivalent) in a discipline related to Facility Validation Engineering, 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. • 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 (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.	• 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.

Cultivates and maintains partnerships across departments to deliver value for the business	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. 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. Have minimum of 3-5years direct experience working within Grade D & C clean room environment for Facility Validation, and experience with Facility HVAC Validation and Environmental Monitoring Systems Validation.	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 for a GMP Manufacturing Facility. Hands on experience of revalidation and temperature mapping for GMP equipment such as freezers, autoclaves and washers is desirable.