

## Computer Software Validation Engineer

### Role Purpose:

Review pharmaceutical machines against MHRA, FDA and GAMP compliance regulations and code of practice.

**Salary:** Dependent on experience

**Location:** Hybrid working – home and client site (Hertfordshire)

### Role Responsibilities:

#### 1) Key Deliverables

- Validation of software and automation hardware for intended use and user needs. This includes testing R&D pilot plant machines under actual or simulated use conditions.
- Validation of computer system integrity to ensure accurate, reliable, consistent, secure deliverables of computer records and signatures against intended performance.
- Thorough understanding of CSV-V model and its application in machine testing within the Pharma industry.

#### 2) Client Management

- Attend regular site reviews via Teams or in person at the clients or manufacturers site.
- Validate process and documentation supplied against requirements and give expert feedback.
- Ensure relevant stakeholders are kept up to date with progress.
- Present monthly client update at JPH business meetings.
- Project management of technical deliverables against project plan.

#### 3) Relationship management

- Develop collaborative relationships that are effective for both the client and for JPH.
- Understand client's values and motivations, ways of working and ordering processes; tailoring your approach to suit their requirements.
- Encourage and manage performance feedback from the client.
- Build a rapport with the JPH team, providing effective line management; and provide support and mentorship to new team members as needed.

**Person specification:**

<b>Qualifications</b>	Essential	Desirable
BSc qualified in Controls, Automation Process Engineering or similar	√	
GAMP or equivalent		√
18 <sup>th</sup> Edition or Plc training		√
<b>Experience</b>		
Siemens and/or Rockwell Plc and Scada knowledge	√	
Delta V knowledge		√
Manufacturing or Pharma background (3 years+)	√	
Knowledge of Process Manufacturing Equipment (2 years+)		√
System or equipment validation		√
<b>Skills</b>		
Automation Design and Commissioning	√	
Ethernet protocols & data comms e.g. OPC comms		√
Software backup and recovery		√
Functional Safety and Machine Safety		√
Design Risk Assessment and CE marking		√
Hands-on, practical bias, can do attitude	√	
Customer focus and delivery of results	√	
Project management		√

**About JP Hildreth Ltd**

**An inclusive environment:**

At JP Hildreth we are committed to fostering an inclusive and diverse workplace where everyone feels valued and respected. We believe that a diverse team brings a wealth of perspectives and ideas, driving innovation and success. We welcome applications from individuals of all backgrounds, experiences and identities. Our hiring practices ensure fairness and equality, and we strive to create an environment where everyone can thrive and contribute to our mission of delivering manufacturing excellence.

**Company values:**

Our company is built on the principles of integrity, simplicity, and clarity. These core values shape our decisions, actions, and interactions with both our clients and each other.

- **Integrity:** We honour our commitments to ourselves and our clients whilst being ethical, transparent and trustworthy.
- **Simplicity:** We deliver simple, effective solutions that prioritise efficiency and accessibility for ourselves and our clients.
- **Clarity:** We use clear communication and actions which lead ourselves and our clients to visible success.

**Employee owned:**

JP Hildreth is an Employee Ownership Trust (EOT) which means that the business is owned by an independent trust tasked to act in the best interest of the employees.

<https://employeeownership.co.uk> provides further information about the EOT philosophy and its practical impacts.

Exceptional benefits of this type of structure for both our employees and our clients include (subject to contract conditions):

- The long-term future and independence of JPH is secure.



- The structure demands an active employee representation and involvement through to the operating board.
- All employees are beneficiaries of the trust and business profits are re-invested and/or shared equitably among the employees (part of profit share payments are made free from income tax).

Ultimately, all of us employed here at JP Hildreth have an equitable stake in the future and success of the business. If this sounds like something you would love to be a part of then we would like to hear from you!