

Role: Validation Engineer

Ref: 26-09-1

Location: Field Based with Dublin 12 or Cork base, regular travel across Ireland

Reports to: Service Manager/Automation Solutions Manager

Type: Full-time, permanent

Salary range: €50,000 to €60,000 depending on experience

The role

We are looking to recruit a Validation Engineer to lead the delivery of temperature equipment qualification for our clients and to deliver formal validation capability to our automation and factory application projects.

The primary focus is temperature mapping and thermal qualification of controlled temperature units, cold rooms, warehouses, ovens and process equipment for clients in the Life sciences industry.

Alongside that, you will support two other departments. Our Automation department designs, builds and commissions control systems including PLC/HMI applications, SCADA, DCS, MES and control panels, and needs validation documentation to compete for life sciences project work. Our Technical Solutions department supplies temperature monitoring systems that require qualification on installation.

Responsibilities - Temperature Mapping & Validation

This is the main body of the role.

- Complete Temperature Mapping Studies for clients including protocol, installation, monitoring, removal, report generation and handover.
- Author validation protocols and reports — Validation Master Plans, User Requirement Specifications, risk assessments, IQ, OQ and PQ protocols and summary reports
- Build and maintain traceability and calibration matrices linking study instrumentation to certified standards
- Manage study documentation to a standard that withstands client QA review and regulatory inspection
- Work with clients to agree protocols, tolerances and acceptance criteria before work begins
- Investigate and document deviations, hot and cold spots, and out-of-tolerance results, and advise clients on corrective action
- Develop and maintain our validation document templates and procedures within our ISO 9001 quality management system
- Manage our validation equipment inventory, including data logger fleet, calibration status and 21 CFR Part 11 compliance

Responsibilities — automation projects

Bonner is a system integrator for leading control and digital platforms. Life sciences clients require a validation methodology and a named validation resource before they will award control system work. You will provide that.

- Assist automation engineers to produce and maintain validation documentation for control system projects —

User Requirement Specifications, Functional and Design Specifications, and requirements traceability matrices

- Apply GAMP 5 categorisation and a risk-based approach to software and system validation
- Develop and execute FAT and SAT protocols alongside our automation engineers
- Deliver IQ and OQ for PLC, SCADA, DCS and MES systems
- Assess systems against 21 CFR Part 11 and EU GMP Annex 11, including audit trails, electronic signatures and data integrity (ALCOA+)
- Support tender and prequalification submissions with evidence of our validation approach
- Work with our engineers to build validation requirements into project scope and estimates from the outset, rather than at handover

Responsibilities — technical solutions

Our Technical Solutions department supplies factory application systems that clients need qualified before use.

- Deliver IQ and OQ for temperature and environmental monitoring systems
- Produce qualification documentation packages that clients can submit as part of their own quality systems
- Advise clients on the validation requirements of monitoring platforms during specification
- Support our sales team with the validation content of proposals and technical submissions

What we look for

We would expect the successful candidate to bring most of the following. If you are strong on thermal qualification and lighter on the automation side, we would still like to hear from you — training and development is available.

Essential

- Demonstrable experience authoring and executing IQ, OQ and PQ protocols in a regulated environment
- Practical experience of thermal mapping and qualification of controlled temperature units, cold rooms or warehouses
- Working knowledge of GMP requirements, and of the expectations of HPRA, FDA, BRC or equivalent
- Sound understanding of measurement, calibration and traceability, and how they underpin a valid study
- Excellent technical writing — clear, accurate documentation is the deliverable
- Full clean driving licence

Advantageous

- GAMP 5 and computerised system validation experience
- Knowledge of 21 CFR Part 11 and EU GMP Annex 11, and of data integrity principles
- Experience validating PLC, SCADA, DCS or MES systems
- Familiarity with validation data logger systems and analysis software
- Experience of commissioning and qualification (CQV) on capital projects
- NSAI Temperature Mapping of Enclosures training, or willingness to complete it
- Background in instrumentation, calibration or process control

Person

- Instrumentation, Automation, Control, Process or Life Sciences engineering background is required
- Methodical and precise, with genuine attention to detail
- Strong communication skills, with the ability to work alongside client QA, engineering and operations teams
- Comfortable working independently on client sites and liaising with managers for scheduling
- Organised
- Flexible / adaptable — some study work is scheduled outside normal hours or at weekends to suit client

production schedules

- Disciplined
- Self-motivated
- Honesty and integrity are essential

Education & Experience

- Degree or Diploma in Engineering, Science, Instrumentation, Automation or a related discipline; or a time-served apprenticeship in Instrumentation or Electrical & Instrumentation with relevant validation experience
- Three years or more in validation, qualification, CQV or a closely related role
- Candidates suitable for this role may have worked previously as: Validation Engineer, CQV Engineer, Qualification Engineer, Thermal Validation Engineer, Commissioning Engineer, Quality Engineer, or Instrumentation & Calibration Technician moving into validation

Benefits

- Strong Team Culture
- Competitive Salary
- Bonus
- Vehicle/Allowance
- Pension Contributions
- Sickness Benefits
- Daily Lunch Allowance
- Mobile Phone with unlimited data
- Laptop
- Permanent Health Insurance
- Death in Service Benefit
- Training & Education Assistance, including validation and metrology certification
- Support and opportunities in Community Involvement / Wellness and ESG activities

How to Apply

- Apply Online [HERE](#)

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