

Entrust people are currently recruiting for a Validation Engineer to join a Dundee based business on a fixed term contract basis due to run 5 months but may extend. This role also offers the potential to continue the contract with another facility based in Wales upon completion of the fixed term contract should this be something the successful candidate would be open to.

The successful candidate would report directly to the Global Technical Operations Director and will be primarily be accountable for the validation and validation maintenance for Processes, Facilities, Equipment, Cleaning, CSV and IT projects.

### **RESPONSIBILITIES OF ROLE**

- Plan validation activities to ensure customer and business needs are met in alignment with the overall project plans and objectives. Prepare and issue Validation Master Plans, Summary Reports and other required documentation for a validation exercise. Organize and Lead Validation activities to provide an effective validation service.
- Provide validation leadership to ensure that all operations are carried out in compliance with regulatory and company requirements. Provide validation support and advice to other areas of the business as required.
- Ensure projects relating to processes, facilities, equipment, cleaning and CSV/IT Validation are validated in line with regulatory and company requirements.
- Provide specialist knowledge on process, facility, equipment, cleaning and automation/IT issues within the site.
- Promote effective working relationships and ensure they are maintained through the validation working party. Support a continuous improvement culture within the business.
- Provide leadership, guidance, and direction to staff
- Develop work plans, assign tasks, and supervise teams.
- Ensure staff has appropriate knowledge and training on department, site, and processes and procedures
- Addressing site validation gaps via generation and completion of Validation Master Plans
- Maintaining site validation status according to regulatory requirements
- Member of Project Team to close the Dundee, ensuring all appropriate validation aspects as governed by Quality are completed
- Identifying resource requirements and rate limiting steps within the Validation Master Plan

### **REQUIREMENTS**

- The job holder will ideally be degree qualified (or equivalent) with a minimum of 5 years' experience around validation within a science regulated industry.
- The job holder will be required to demonstrate previous experience in the areas of qualification, cleaning, analytical methods, lab equipment qualification, computer system validation, and requalification.
- Manufacturing process validation experience would preferably include the validation of new processes and changes to established processes using the lifecycle approach to validation.
- Cleaning validation experience should include validation of cleaning processes on a wide variety of commercial manufacturing equipment
- Natural influencer, adaptable, flexible as well as a pragmatically minded problem solver.
- Experienced in working on teams and demonstration of being "people-oriented".