JOB DESCRIPTION

Quality & Validation Engineer

Department: Quality

Reports to: Quality Manager

RESPONSIBILITIES:

- Cycle development of aseptic isolators for the pharmaceutical industry
- Cycle validation of aseptic isolators at client sites
- Preparation of validation documents (FAT/IQ&OQ protocols)
- Project team member in delivering projects and involved in customer design meetings/URS reviews
- Design Qualification(Traceability Matrix) of projects
- Draft and revise testing SOPs and quality documentation

ROLE REQUIREMENTS:

- Quality focused with knowledge and understanding of scientific rationale and cGMP quality systems
- Proven problem solving skills
- Team player
- Excellent interpersonal skills and the ability to communicate well, both verbally and written
- Excellent organizational and detail-oriented skills

EDUCATION:

- Technical/Science or Engineering qualification or with equivalent experience in a pharmaceutical or medial device industry

KEY INTERACTIONS & STAKEHOLDERS

Internal

- Mechanical Design Department
- Automation Department
- Document Control
- Procurement
- Finance
- Senior Leadership
- Production and Planning
- Warehouse and Shipping

External

- End User Clients
- Engineering Consultancies

- Suppliers (including approval process of new suppliers)
- Automation Department

JOB LOCATION

This role is primarily located at the ProSys Group offices in Carrigtwohill, Co. Cork. International travel to client sites for validation activities approx. 30%.