



# JOB OPPORTUNITY

## VALIDATION PROCESS ENGINEER

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### OVERALL PURPOSE OF JOB

Accountable for all supporting activities for the procurement, installation, validation, operation, maintenance and repair of equipment and processes used directly and indirectly for product realisation.

### RESPONSABILITIES AND AUTHORITIES:

- Responsible for continuous improvement activities within the business relating to Production and Manufacturing Processes and equipment and Validation, and ensuring these are completed through change control activities.
- Responsible for creating User Requirement Specifications; sourcing, installing, and validating capital expenditure equipment to meet business objectives.
- Responsible for maintaining the validation life cycle within the business, to include periodic reviews and Computer Software Validation.
- Responsible for ensuring safe system of works are created, trained and implemented with new processes and equipment.
- Authority to stop any hazardous or dangerous activities during the development of new processes and equipment, or when observed during equipment/tool/jig use.
- Responsible for defining and creating process routes and BOMs on the Mi3 ERP system.

### JOB REQUIREMENTS (ESSENTIAL)

- BSc (Hons) or equivalent in a Science or Engineering discipline.
- Minimum of 5 years' experience in a production or process engineering role within a manufacturing environment.
- Minimum of 3 years' experience performing equipment and process validation within the medical device industry.
- Knowledge of the processing and assembly of plastics from compounds to components to products.
- Demonstrable success of leading or managing projects.
- Has spec'd and commissioned capital equipment.
- Good skills in written and spoken English to enable communication with colleagues and to understand technical and QMS related documents and to write technical and general reports.
- Good numerical skills appropriate to managing and reviewing tool sampling and validation processes and summarising of data within technical reports.
- Moderate to advanced computer literacy in MS Office applications.
- Must be able to work alone and in a team, with good leadership ability.
- Must be able to self-manage workload, remain calm under pressure, and make reasoned judgements on behalf of the company.