Job Description

Job Title	Validation Engineer
Line Manager	Quality Control Manager
Department	Quality Control
Directly Reporting Responsibility	Validation Technicians
Indirectly Responsible for	Not applicable
Location	Washington Site; Sedling Road, Washington, NE38 9BZ
Contract Type	Permanent
Hours of Work	Monday to Thursday inclusive 8.00am - 4.30pm Friday 8.00am – 3.30pm
The jobholder will be expected to work such hours as required to fulfil the needs of the role and the requirements of the business. Flexi-time – 2 days credit (16 hours) / 1-day deficit allowed (8 hours)	

JOB PURPOSE

The primary task of the role is to ensure that all site validation needs are met.
Rocket Medical PLC must validate all production, service provision, computer and software-based processes, the result of which cannot be verified by subsequent monitoring or measurement. Validation must demonstrate the ability of these processes to consistently achieve expected results.
The role includes re-validation of established processes as well as initial validation of amended or new processes, such as those introduced through new product development activities.

KEY RESPONSIBILITIES/ACCOUNTABILITIES

Main Duties

- Creating Validation Master Plans and associated protocols
- Create or amend standard operating procedures in accordance with the results of the validation"
- Creating validation and related working forms
- Supporting site cross-functional technical writing needs
- Maintenance of Sterilisation Validation for both Gamma and Ethylene Oxide processes.
- Assist in the implementation of the validation protocols and write the validation reports
- Support cross-functional risk management activities
- Support in the optimization of production processes
- Preparation of plans for maintenance, service, calibration, re-validation and cleaning of test and production equipment
- Policing and coordinating maintenance, service, calibration, re-validation and cleaning
- Advise the business on current best practice in validation and keep abreast of changes
- Contribute to continuous improvement projects

Accountability

- Must maintain confidentiality, in particular concerning internal company procedures and workflows

Person Specification	Essential (E) or Desirable (D)	Application	Interview	Task/Test	Reference
Qualification					
Hold a mechanical engineering or electrical engineering degree	E				
Has a good general standard of education including Numeracy and Literacy.	E				
Holds manufacturing or other relevant qualification	D				
Knowledge & Experience					
Previous experience of medical device or pharmaceutical manufacturing	E				
Practical experience in manufacturing technology and quality assurance	E				
GMP Experience	D				
Understanding of Quality Management Systems for medical devices (EN ISO 13485, 21 CFR 820)	E				
Experience in validation / qualification	E				
Knowledge of Health and Safety current regulations	D				
Knowledge of Kaizen or 5s continual improvement and lean manufacturing principles	D				
Knowledge of Gamma and Ethylene oxide sterilisation processes	D				
Knowledge of sterilisation validation for Gamma and Ethylene oxide sterilisation processes	D				
Skills & Competencies					
Experience in Project Work and/or Project Management	D				
Good to very good knowledge of common MS Office programs	E				
Personal Qualities/Attributes					
Able to adhere to and communicate the company values	E				
Must have strong communication skills able to communicate with all levels of organisation	E				
Able to mentor and develop skills in others	D				
A good team player who is able to adapt to working independently or with new or short-term teams	E				

Must have a fair-minded attitude	E				
Self-motivated and able to adapt to change to support the business objectives	E				
Desire to continuously improve technique and CPD	E				
Able to manage and take responsibility for workload commitments, planning and prioritising.	E				
Must be determined and a mind set to succeed	E				
Other					
Current UK Full Driving Licence	D				

This role description and specification document is not exhaustive and aims to define the fundamental purpose, responsibilities and accountabilities of the role and does not describe or define any individual role holder. In addition to the duties and responsibilities outlined herein, the role holder is expected to undertake all and any reasonable task allocated by their line manager.

This role description will be reviewed periodically and may be updated as appropriate.

Closing date for Applications	
Date of Issue	

Declaration:

I have read and understood this role description and person specification.

Job Holder Name	
Signature	
Date of Signing	
Agreed by Line Manager Name	
Signature	
Date of Signing	