

Document Number: Job82	Revision: 02	Date: 03/07/2023	Page 1 of 4
			HR

## Change Control Administrator

### Job Description

Job Title	Document Control Administrator
Line Manager	Quality Assurance Manager
Department	Quality Assurance
Directly Reporting Responsibility	Not applicable
Indirectly Responsible for	Not applicable
Location	Washington Site; Sedling Road, Washington, NE38 9BZ
Contract Type	Permanent
Hours of Work	Shift Pattern: Monday to Thursday 9am to 5pm – Friday 9am to 4pm (inclusive of 30 min unpaid break) 36.5 hours.
<p>The job holder will be expected to work such hours as required to fulfil the needs of the role and the requirements of the business.</p> <p>Flexi-time – 2 days credit (15 hours) / 1 day deficit allowed (7.5 hours)</p>	

### JOB PURPOSE

Assist in the operation, maintenance, improvement of the Change Control System

### KEY RESPONSIBILITIES/ACCOUNTABILITIES

#### *Main Duties*

- Maintenance and operation of the Change Control System
- Deputise when required for Senior Document Control Coordinator
- To liaise with relevant departments with regards to ensuring the required changes are carried out in a timely manner.
- Assist in the review and update of documents in accordance with QMS Requirements.
- Assist in the introduction of new projects within Q-Pulse.
- Assist in the introduction of new software where required.
- Record, review and Control Batch History records.
- Ensure under GDPR, all data is effectively controlled, securely managed and stored as required within internal databases.
- Assist in the provision of reports on the status of the Change Control procedures for inclusion in the monthly Board Report and annual Management Review.
- Assist during External Audits by Notified Bodies and Regulatory Authorities as required.
- Assist in Internal Audits where required.
- Adhere to and assist in improving environmental, Health and Safety policies and procedures and maintain an appropriate environment for the occupational health of all employees.
- Ensure documentation is kept in a controlled way, disposing and re-issue of documents where necessary.
- Ensuring that relevant departments have access to controlled hard copy Standard Operating Procedures where required.
- Liaise with the quality department on all aspects of quality related documentation.

Document Number: Job82	Revision: 02	Date: 03/07/2023	Page 2 of 4
			HR

## Change Control Administrator

- Ensure under GDPR, all data is effectively controlled, securely managed and stored as required within internal databases.
- Any other such occasional tasks for which the jobholder is deemed to be qualified.

### People Responsibilities

N/A

### Quality Responsibilities

- To assist in the maintenance and improvement of all aspects of the QMS.
- Good understanding of GDPR

### Personal Attributes

- Self-reliance with the ability to work with the minimum of supervision, on his/her own initiative.
- The job entails interaction between departments within the Rocket organisation. It is essential that the jobholder have good interpersonal and communication skills via email/phone or in person.
- It is essential that the jobholder exhibit a very high degree of conscientiousness and accuracy in all tasks or duties.
- Must be a good organiser with a neat and methodical approach to the job.
- Must be pleasant and well presented.
- The job holder must maintain and uphold company values.

### Accountability

- Your performance will be measured against the Company Business plan and your Managers individual appraisal document.
- To be accountable for all actions as detailed within this document and product specifications, quality guidelines, company policies, general communications, rules, regulations and procedures as set out within the employee handbook.
- To adhere to existing working practices, methods and procedures and to undertake training and development as identified and to respond positively and to new and alternative practices or systems.
- To co-operate in compliance with Health and Safety legislation, safe systems of work, policies and procedures in the performance of the duties of the post.
- To maintain confidentiality and data protection as appropriate at all times.
- To undertake other duties and reasonable management instruction at all times.

Document Number: Job82	Revision: 02	Date: 03/07/2023	Page 3 of 4
			HR

## Change Control Administrator

Person Specification	Essential (E) or Desirable (D)	Application	Interview	Task/Test	Reference
<b>Qualification</b>					
Hold a Level 3 or Higher NVQ (or similar) in Business Administration or equivalent vocational experience	D				
Has a good general standard of education including Numeracy and Literacy.	E				
<b>Knowledge &amp; Experience</b>					
Previous specialist knowledge of the medical manufacturing industry.	D				
Practical experience in manufacturing technology and quality assurance	D				
Experience of Qpulse or similar system	D				
Knowledge of medical technology, ISO 13485, FDA requirements	D				
Knowledge of Health and Safety current regulations	D				
Knowledge of Kaizen or 5s continual improvement and lean manufacturing principals	D				
<b>Skills &amp; Competencies</b>					
Good to very good knowledge of common MS Office programs	E				
<b>Personal Qualities/Attributes</b>					
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	E				
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 adaptable to change to support the business objectives	E				
Desire to continuously improve technique and CPD					
Able to manage and take responsibility for work load commitments, planning and prioritising.	E				
Must be determined and a mind set to succeed	E				
<b>Other</b>					
Current UK Full Driving Licence	D				

Document Number: Job82	Revision: 02	Date: 03/07/2023	Page 4 of 4
			HR

<b>Change Control Administrator</b>
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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 outline 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	

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