


## JOB DESCRIPTION

Job title:	Quality Assurance (QA) Officer
Pay Band	Band 6
Department:	Quality
Reporting Structure:	 <pre> graph TD     HQ[Head of Quality] --&gt; QAO[Quality Assurance Officer]             </pre>
Staff reporting to postholder:	None
Main purpose of job:	<p>QA monitoring of studies, on and off-site facilities and (where relevant) suppliers and subcontractor service providers to ensure compliance with the International Regulatory Standards of GLP/GMP and VICH GCP and the Moredun Scientific Quality Management System (QMS).</p> <p>Act as Deputy Document Controller: provide support to document controller in accordance with QA requirement.</p>

Main duties  
of  
postholder:

Scheduling and conduct of audits (supplier, subcontractor, facility, process, critical phase, protocol, data and reports): GLP studies (Biosafety in-vivo, animal health and aquaculture), GMP In-vitro mycoplasma & sterility, animal health & aquaculture efficacy studies (including VICH GCP) in accordance with the Moredun Scientific QMS and regulatory requirements.

Review and provide QA approval of Standard Operating Procedures, Study Plans, protocols equipment calibration validation records and supporting documentation.

Maintain Master Schedule

Provide assistance and support in training of Moredun staff, including Study Directors and Scientists working in regulatory compliant areas.

To provide advice and guidance for any department within Moredun where appropriate, that works to or aims to work to regulatory standards.

Participate in regulatory and client visits/inspections of Moredun areas.

Participate in the ongoing improvement of the QMS.

Assist with the inspection and approval of incoming goods. Maintain the equipment register database, compile and circulate the monthly maintenance lists. Full support, development and implementation of the Quality Management System i.e. Change controls, Deviations, CAPAS, Out of Specifications, Supplier Vendor approval, Material specifications, Equipment Calibration & Validation.

QA initiatives as required.

To act as deputy Document Controller for all Moredun Scientific controlled documents (e.g. update of SOPs, Org charts, Study Plans, forms, etc). Responsible for ensuring documents are issued for review at appropriate intervals and controlled copies issued.

## PERSON SPECIFICATION

	Essential	Desirable
Attainments:	Degree	
Experience:	Experience in a similar role	
	Biological expertise across scientific disciplines (e.g. bacteriology, virology etc).	
	Sound knowledge of GLP/GCP VICH and GMP regulations and current trends.	

**Skills:**

Good knowledge of pharmacopoeia and related guidelines for tests and studies undertaken by the company.	
Working knowledge of spreadsheets, databases or other project management systems.	Working knowledge of Q-Pulse Quality Management System software.
<b>Communication</b> - excellent interpersonal and communication skills when dealing with a wide range of managers and staff  Ability to contribute to discussion at meetings plus taking minutes and writing up.  Ability to write reports or briefs.	
<b>Managing relationships</b> – ability to deal with a wide range of people with tact and diplomacy  Able to build and maintain effective working relationships with a range of people.	
<b>Team working</b> - ability to work flexibly and effectively as part of the team.  Able to build and maintain effective working relationships with a range of people.	
<b>Resilience</b> - strong ability to work with ambiguity and constantly changing set of circumstances and issues.	
<b>Planning and organisation</b> - able to prioritise and plan activities taking into account deadlines and resources.	
<b>Decision making</b> – able to take independent action where necessary in line with policies and procedures  Ability to quickly assimilate complex information and take effective decisions when required	
<b>Flexibility</b> – ability to adapt and work effectively with a variety of situations, individuals or groups.  Able to understand and appreciate different and opposing perspectives on	

	an issue and to adapt an approach as the situation changes	
<b>Other skills</b> please specify		
<b>Other requirements</b> please specify	A degree of lifting and transporting goods is required.	