

Job Description

Job Title	Quality Assurance (QA) Associate
Job Holder	
Reports To	Senior Quality Assurance (QA) Associate
Location	Billingham
Date	Jan 20
Grade	31

Job Purpose

The Quality Assurance (QA) Associate ensure batch and manufacturing documentation are to the required standard at all times, that the facility and the operations within it are to cGMP standards.

Dimensions

Turnover	£100 million
Site Numbers	500
No of staff reporting to individual	None
Forward work plan	One to three months

Principal Accountabilities

Support the team in the delivery of manufacturing programmes in the required timelines

Review executed documentation and ensure cGMP standards are maintained at all times.

Ensure that all relevant documentation is made available for batch disposition including the requirements of the disposition pack.

To carry out inspections of the plant and escalate issues whilst following through to resolution.

Responsible for the review of data to support customer's regulatory submissions.

QA initial assessment of events and escalation where required.

Build and maintain good working relationships with Manufacturing and work with them to determine and implement better ways of working to improve cGMP standards.

Gain a good understanding of the facility and the standard approach to Mammalian Manufacture and Cell Banks.

Participate in projects, as required, on a range of Quality and Manufacturing deliverables.

Any other duties commensurate with the role.

Competencies:

Level: Core

Assessed: Customer focus, Analytical Thinking, Relationship Building, Achievement and Results Orientation, Change Management



Special Features

Minimum of one A level in a science based subjects or similar qualification or equivalent competence demonstrated by experience.

Must be able to work effectively and accurately when balancing conflicting priorities or handling large amounts of information, data or documentation.

Be able to identify when escalation to management is required with regard to conflicts in work or problems are identified.

Must have a flexible approach to work and be able to change priorities where needed.

Happy to spend time in the facility and learning the technical aspects of the process.

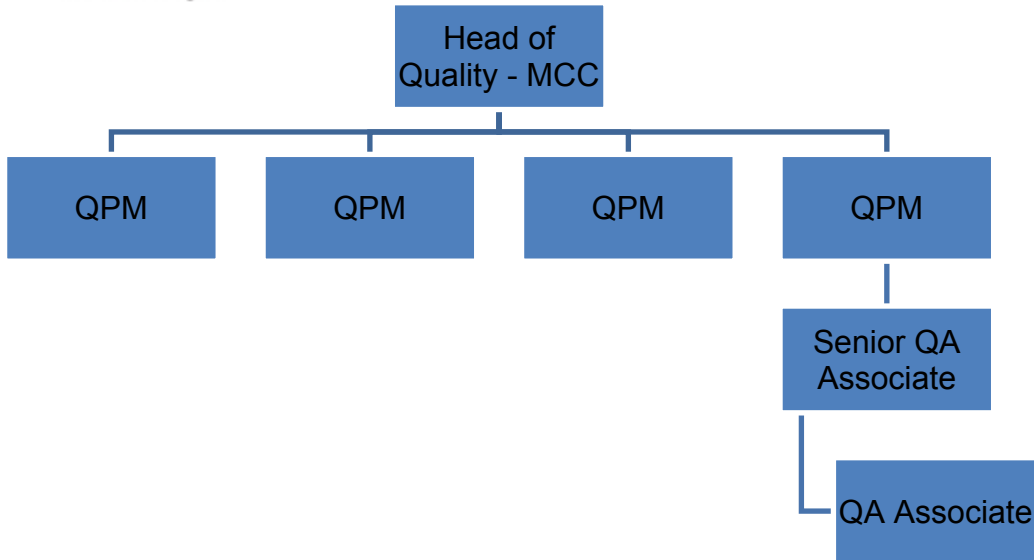
Excellent attention to detail.

Able to stand by own opinions when faced with disagreements.

Able to build and maintain effective and credible relationships with manufacturing personnel.

To be passionate towards continuously improving our systems and the way in which we work.

Organisation Chart



Signatures

Job Holder: Date:

Manager: Date:

Revision Table

Revision History	Date of Update	Authoriser
Revision 1	11 July 2018	D Chesworth
Revision 2	01 April 2019	A Dickson

Revision History – Amended due to revised Behavioural Competency Framework