Job Description

Job Title	Department	Reports to:
Quality Assurance Specialist	Quality Assurance	QARA Manager

MAIN FUNCTION OF THE ROLE

1 Assist the QARA Manager with quality, regulatory and compliance matters as needed to ensure that the required standards continue to be met throughout all areas of the business.

2 Support the QARA Manager and all site activities to ensure site inspection readiness for both notified body audits and customer audits.

3 To liaise between SI and AHL in any matter as required to build and strengthen group synergies and understanding.

4 The job holder may be required to perform other duties assigned by either QARA Manager or management from time to time.

RESPONSIBLITIES

1 Work with all departments to ensure required changes to medical device regulations and quality matters are implemented in a timely manner and are aligned with implementation schedules.

2 Point of contact for Change Control process and compliance with relevant site requirements

3 Point of contact for Corrective and Preventative Actions (CAPA) process compliance with relevant requirements

4 Point of contact for external sourced documents process and compliance with relevant site requirements.

5 Point of contact for onboarding of Suppliers and continuous assessment of Suppliers and compliance with relevant site requirements.

6 Point of contact for onboarding of Customers and continuous assessment of Suppliers and compliance with relevant site requirements.

7 Perform internal audits and/or supplier audits on completion of training accreditation requirements'

Job Description

AUTHORITY

1- To ensure data completeness.

2- To drive timely completion of identified Quality Management Systems (QMS) actions

3- To ensure safekeeping of Quality Management Systems (QMS) records

4- To stop or prevent any operation, action or occurrence that would be a non-conformance, would compromise product quality or impact patient safety

5- To agree corrective actions and timescales for their implementation with the person(s) responsible for addressing any non-compliance(s) identified

PERSON SPECIFICATION

Essential

- Methodical and Accurate Approach.
- Excellent communication skills.
- Eye for detail.
- Office 365 knowledge
- 2 years' involvement in performing internal audits within medical devices or pharma sector.
- 2 years' involvement in discussions relating to Corrective and Preventative Actions (CAPA) within medical devices or pharma sector.

Desired Qualifications

1. B.Sc. or HND Degree educated or equivalent, in a life science or engineering discipline.
2. A minimum of 3 years' experience in a medical or pharma company working within either Quality Assurance or regulatory environment.
3. Strong Knowledge of the Medical Device Regulations (EU MDR) and or strong pharmaceuticals background.

Closing Date: Wednesday 09 September 2026

"Due to business growth envisaged with 2 to 3 years it is most likely changes to this job description will be proposed and discussed with job holder"