JOB DEFINITION

Job Title:	QA Manager
Department:	General & Administration
Reports to:	Managing Director
Location:	Office, Burton upon Trent and Home based.
Date:	July 2022

1. Job Purpose

Responsible for all aspects of BDS Quality Management System (QMS) and Information Security Management System (ISMS). This person shall ensure these systems are aligned to required ISO Standards, and that where applicable, the QMS is followed as part of BDS product development. This person will require four years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices, with a proven track record in regulatory submissions and ISO certifications. They will be responsible for leading a Quality team, and the organisation as it strives to deliver quality software within the In Vitro Diagnostic Industry.

2. Principal Accountabilities

1.	**Regulatory Knowledge** Ensure you are up to date and therefore the organisation is up to date with regulatory requirements, and potential updates to regulatory requirements. This will require working with Process Owners to discuss and determine changes and update to the QMS to ensure compliance.
2.	**Lead Audits** Ensure project adherence to the Quality Management System through internal audits and project check points. Including, but not limited to management of the Quality & Regulatory schedules. Audits are also carried out on BDS to ensure compliance from our customers and regulatory bodies, you will be responsible for ensuring the team involved in audits are sufficiently trained, planning and preparing for internal and customer audits, overseeing scheduling of the process, ensuring teams are prepared and relevant compliance in place.
3.	**Project Regulatory Strategy & Submissions** Responsible for working with the project and commercial team to define the product regulatory strategy and guide the team through regulatory assessments and classifications. Furthermore you will be responsible for bringing project documentation together along with other information required for a regulatory submission, particularly to FDA and IVDR.
4.	**Customer Relationships** Responsible for managing relationships with customer Quality and Regulatory teams. Ensuring requests are reasonably managed and supporting customers in making Quality & Regulatory decisions throughout project process, based on knowledge and experience.
5.	**Contract Reviews** Responsible for review and signoff to BDS Managing Director of Quality Agreements with customers and suppliers such as Authorised Representatives. This includes review of BDS and Customer responsibilities accordingly and in line with identified legal manufacturer.

6.	**Meeting Contributions** Participate in BDS Management meetings, sharing details of non-conformities, potential regulatory changes that could impact the organisation, audits and audit status and CAPA information. Taking the lead in Quality Review meetings for both BDS QMS & ISMS. Writing minutes and reviewing objectives with team identified.
7.	**Compliance** Work with BDS management team to ensure procedures & processes are in place to manage compliance including items mentioned within BDS Legislation Precis, including GDPR

3. Dimensions

Finance	• Define & manage Quality Budget working with MD and Finance
People	• Line Management of Quality Administrator • Working closely with all internal teams including Developers, Testers and relevant support functions. • Manage relationships with External customers.
Travel	• Occasional travel required to customer sites and or supplier sites.

4. Knowledge & Experience

Knowledge & Skills	• Knowledge of FDA and FDA requirements in relation to software • Knowledge of IVDR Regulation 2017/746 • Knowledge of UK Medical Device Regulation • Knowledge of ISO 13485, 14971, 27001 and standards IEC 62304 62375 • Ability to convert regulatory requirements into relevant quality management processes and work instructions • Strong stakeholder management • Strong attention to detail with the ability to prioritise • Excellent written and verbal communication skills • Ability to plan, organise and meet critical deadlines • Knowledge of MS applications
Experience Profile:	• 3 years' experience of in-depth software quality management in a professional environment. • Management of a Quality System to a recognized standard. • Experience in regulatory submissions • Experience in stakeholder management and team leadership • Audit experienced/trained • Formally educated to degree level in an IT based subject preferred but not essential. • Prior experience within the medical sector would be advantageous
Behavioural Competencies:	• Result Oriented • Committed • Entrepreneurial • Client focused • Team player