JOB DEFINITION

Job Title:	Regulatory Affairs Officer
Department:	Quality & Regulatory
Reports to:	Quality & Regulatory Manager
Location:	Hybrid, Burton upon Trent
Date:	Feb 2024

1. Job Purpose

This role shall be responsible for ensuring regulatory compliance across the organisation, including managing product registrations, defining, and implementing regulatory strategies for new products and reviewing regulatory requirements to ensure the BDS QMS covers all requirements where applicable.

The role requires professional experience in interpreting regulatory requirements into business actionable items.

2. Principal Accountabilities

1.	Regulatory Communications and submissions • Primary Contact for Regulatory Authorities, Authorised Representatives and Customers for regulatory matters, including registrations. • Management of Regulatory Authority, Authorised Representative, Customer and BDS team needs in the Regulatory field. • Fulfil the role of "Person Responsible for Regulatory Compliance (PRRC)" for BDS in line with European Regulation IVDR 2017/746.
2.	Post Market Surveillance • Manage all field safety notifications, ensuring BDS compliance with local authority needs. • Keep Authorised Representatives informed with any changes to BDS or their products to ensure compliance is retained. • Produce and maintain surveillance reports externally and internally, for example external and, internal CAPA reports.
3.	Regulations & Standards • Monitor the markets for updates to Regulations & Standards across the Business. • Review the Regulations & Standards for applicability to BDS, defining path forward and justification for non-applicable items. • Advise the team on how changes will affect BDS Products and steps that maybe needed to remain compliant.
4.	Regulatory Documentation • Define and implement a Regulatory Strategy across projects, that will deliver the needs of the product in planned submission markets. • Generate all necessary regulatory technical documentation for BDS, including but not limited to Product Technical Files and Declarations of conformity. • Support our OEM partners with Regulatory Documentation as and when needed.

5.	Supporting BDS Quality Management System • Working with the Quality & Regulatory Manager to ensure the Quality Management System meets the needs of required regulatory standards. • Carry out tasks to support the working of the QMS including but not limited to Internal Audits, Non-Conformance. • Participating in Customer Audits, Certification Audits and any Regulatory Audits as needed.

3. Dimensions

Finance	• Work with the Quality & Regulatory Manager to provide any financial costs or updates to the Finance Team
People	• Working closely with all teams within BDS • Manage relationships with Customers, Regulatory Authorities
Travel	• Occasional travel may be 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
Experience Profile:	• 4 years of professional experience in Regulatory Affairs relating to in vitro diagnostic medical devices with a proven track record in regulatory submissions and supporting ISO certifications. • In-depth software quality management in a professional environment. • Experience in regulatory submissions • Audit experienced/trained • Prior experience within the medical sector would be advantageous • Experience in managing own workload, and capable of prioritising
Behavioural Competencies:	• Result Oriented • Committed • Customer focused • Team player