**JOB SPECIFICATION**

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| **EMPLOYEE NAME** |  |
| **JOB TITLE** | Senior Regulatory Affairs Specialist |
| **GRADE** | R3 |
| **DEPARTMENT** | Regulatory Affairs |
| **LOCATION** | The Ridley Innovation Centre |
| **LINE MANAGER** | Head of Regulatory Affairs |
| **PURPOSE OF ROLE** | The purpose of this role is to provide and maintain regulatory support, supply regulatory input and data and ensure compliance with standards and medical device regulations worldwide. |
| **KEY ACTIVITIES/****ACCOUNTABILITIES** | * Provide support for registration activity in your assigned geographic region(s) this includes (but is not limited to):
	+ Developing registration and launch plans with the regional sales managers to ensure that
	+ The preparation and submission of registration dossiers, and their submission and remediation.
	+ Establish and maintain regulatory information systems such as technical documentation, quality records, routine reports and regulatory agency communications
	+ Interpret existing and/or new regulatory requirements/guidelines and standards as they relate to company products and procedures
* Ensure compliance to global regulatory requirements and company policies
* Provide input to Company activities including the risk management process, process and procedure improvements, management review and support new product development activities
* Review document and product changes for regulatory submission impact
* Support equipment, system and process development in-house and with suppliers
* Interface and co-ordinate with regulatory agencies; provide regulatory input and appropriate follow-up support to inspections and audits (e.g. FDA, Notified Bodies etc)
* Participate on product development teams to ensure regulatory requirements are incorporated into the development process
* All such other tasks as may be reasonably required to support the activities of the Regulatory Affairs department and the Company
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| **COMPETENCIES**  | 1. ***Ambition:*** We have the drive to continuously improve
2. ***Integrity:*** We are accountable for what we do acting ethically and in the best interests of our customers, patients and stakeholders
3. ***Openness:*** We positively consider new ideas and challenges
4. ***Respect:*** We support each other and our customers to succeed
5. ***External Awareness:*** Understands and keeps up to date on local, national, and international policies and trends that affect the organization and shape stakeholders' views; is aware of the organisation's impact on the external environment.
6. ***Adaptability:*** Adjusts to changing environments whilst maintaining effectiveness
7. ***Communication:*** Communicates effectively, listens sensitively, adapts communication to audience and fosters effective communication with others
8. ***Decisiveness:*** Makes well-informed, effective, and timely decisions, even when data are limited, or solutions produce unpleasant consequences; perceives the impact and implications of decisions.
9. ***Teamwork:*** Contributes fully to the team effort and plays an integral part in the smooth running of teams without necessarily taking the lead
10. ***Organisational Awareness:*** Demonstrates an understanding of underlying organisational issues
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**PERSON SPECIFICATION**

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| **QUALIFICATIONS/ TRAINING/ EXPERIENCE** | **Essential*** 3-5 years’ experience in a Regulatory role in a medical devices company – including direct interaction with regulatory authorities (Notified Bodies, Competent Authorities, Government Agencies etc.)
* Either:
	+ A degree in a science, clinical or engineering subject
	+ Equivalent experience achieved through working in a medical device or a medical environment for 3-5 years
* Experienced in the requirements of Quality System concepts, practices and procedures (e.g. MDSAP, ISO 13485, CFR820)
* Experienced with the requirements of the Medical Device Directive/Medical Device Regulation

**Desirable*** Registration experience in one or more of the following:
	+ India
	+ China
	+ Russia
	+ Brazil
	+ USA
* Experience working across export markets and dealing with international distributors
* Familiar with databases and business management systems (ERP)
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