**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 |
| **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 |

**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) |